Research Article

Short-term outcomes of percutaneous pedicle screw fixation combined with vertebroplasty: A minimally invasive treatment for Kümmell’s disease with intravertebral instability

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ABSTRACT

Objective: The aim of this study was to present early clinical and radiological outcomes of percutaneous pedicle screw fixation (PPSF) combined with vertebroplasty (VP) in the treatment of Kümmell’s disease with intravertebral instability.

Methods: In this study, 21 consecutive patients (4 male and 17 female; mean age = 75.6 years; age range=65-86 years) who suffered from stage II and III Kümmell’s disease with intravertebral instability were prospectively recruited from 2012 to 2016 and treated with PPSF combined with VP. The Cobb angle (CA) or wedge angle (WA) in both flexion and extension positions was measured using lateral radiographs, computed tomography, or magnetic resonance imaging. In addition to these radiological parameters, clinical outcome measures, including the visual analog scale (VAS) and the Oswestry Disability Index (ODI) were collected preoperatively; 1 week and 1, 3, 6, and 12 months postoperatively; and then annually. Complications were also recorded.

Results: The mean follow-up was 19.3 (range=12-36) months. The mean operating time was 135.4 (range, 110-175) min, and the mean estimated blood loss was 106.9 (range, 50-165) mL. The mean VAS score and ODI significantly decreased from 7.7±1.1 and 65.3%±7.7% preoperatively to 3.4±0.6 and 30.0%±7.6% postoperatively, respectively (p<0.05). At the final follow-up, the mean VAS score and ODI were 2.5±0.8 and 21.5%±8.8%, respectively (p>0.05). CA and WA significantly decreased from 26.9°±9.7° and 21.3°±6.0° preoperatively to 12.7°±7.2° to 8.6°±4.5° postoperatively, respectively (p<0.05). At the final follow-up, CA was 4.2°±2.0°, and WA was 4.7°±1.8° (p<0.05). No major complications were encountered during the follow-up period.

Conclusion: PPSF combined with VP seems to be an effective surgical option for the treatment of Kümmell’s disease with intravertebral instability.

Level of Evidence: Level IV, Therapeutic study

Introduction

Kümmell’s disease, which is a form of delayed post-traumatic collapse of vertebral body, was first described in 1895 by Hermann Kümmell (1). Recently, multiple synonymous terms have been used to describe Kümmell’s disease, such as intravertebral cleft, intravertebral pseudarthrosis, intravertebral vacuum phenomenon, delayed post-traumatic osteonecrosis, and intraosseous vacuum phenomenon (2, 3). With the development of imaging technology, including computed tomography (CT) and magnetic resonance (MR) imaging, the numbers of the reported cases of Kümmell’s disease have gradually started to increase in recent decades. The prevalence of Kümmell’s disease after osteoporotic vertebral compression fractures (OVCFs) in elderly patients ranges from 7% to 37% (2). Due to its sequelae of disabilities and mortality, Kümmell’s disease has become a serious health problem in elderly patients.

Currently, surgical intervention is most commonly used for Kümmell’s disease treatment. However, the ideal treatment for Kümmell’s disease with intravertebral instability remains controversial. In stage I and II Kümmell’s disease (4), percutaneous vertebroplasty (VP) and balloon kyphoplasty (KP) achieved good results in some studies (5, 6), but some investigations revealed that cement displacement and refracture at the same level often occurred in these patients (7-9). Moreover, in patients with kyphosis and intravertebral instability secondary to stage II and III Kümmell’s disease, VP and KP are unsuitable. In the past, although operations by posterior decompression with pedicle subtraction osteotomy, anterior decompression and reconstruction, or a combined anterior and posterior approach were used to treat these cases and achieved good results. They are inappropriate to elderly patients with serious comorbidities because of their time-consuming procedures and the ability to cause severe traumas, hemorrhage, and other complications (10-12).

Recently, short-segment pedicle screw fixation with VP was found to be more effective in the treatment of Kümmell’s disease with neurological deficits (2, 13), but no report exists prospectively investigating the effect and outcomes of percutaneous pedicle screw fixation (PPSF) combined with VP for Kümmell’s disease with intravertebral instability. Therefore, we...
hypothesized that PPSF combined with VP can be an effective and safe procedure for Kümmell’s disease with intravertebral instability. In this study, 21 patients with kyphosis and intravertebral instability secondary to stage II and III Kümmell’s disease were treated by PPSF (pedicle screw above or below the index fractured vertebra) combined with VP. Here, we report the details of the treatment process, the outcomes of the clinical and radiological follow-up, and the related complications.

Materials and Methods

We conducted this prospective study in our hospital from January 2012 to August 2016, which was approved by our institutional review board and the Biomedical Research Ethics Committee of our hospital. Written informed consent for the participation in this study was obtained from all patients. The following inclusion criteria were used: (1) stage II and III Kümmell’s disease where single-level vertebral body delayed osteonecrosis with an intravertebral vacuum cleft and spine kyphosis deformity; (2) instability and sclerosis at the fracture edge but no obvious paravertebral callus formation were confirmed with radiographs or CT scans; (3) the Cobb angle (CA) or wedge angle (WA) changes more than 10° by comparing supine cross-table extension films as a 10-cm-high towel was placed beneath the back just caudal to the fractured (index) vertebra for 1 h with standing flexion lateral radiographs as reported previously (14, 15); and (4) less than one-third spinal canal stenosis and no neurological deficits. Patients with previous spine surgery, infection, tumor, or rigid kyphosis, defined as uncorrectable kyphosis after postural reduction, were excluded.

Twenty-one patients (4 males and 17 females) met the inclusion criteria and were enrolled in the study. Their details are presented in Table 1. The mean age of the patients was 75.6±5.4 years (range, 65-86 years). Of these 21 patients, 7 had hypertension, 5 had diabetes mellitus type II, 1 had hepatitis B virus-related hepatic cirrhosis, and 1 had chronic bronchitis. The thoracolumbar junction was the most affected segment (T11-L2; 17 patients, 81.0%) (Table 1). Lumbar spine bone mineral density (BMD) was assessed over L1-L4 using dual-energy X-ray absorptiometry. All patients had no surgical contraindications for minimally invasive surgery in their preoperative assessment and no neurological deficits on admission to our hospital.

At the time of the enrollment, the patients were examined by modified flexion-extension lateral films using radiographs, CT scans, or MR images (Figure 1). CA or WA in extension position was measured by lateral radiographs, CT scans, or MR images while the patients were lying for 1 h on a towel with a length, width, and height of 50, 20, and 10 cm, respectively, placed beneath their back just caudal to the fractured (index) vertebra. CA or WA in flexion position was measured using lateral radiographs, CT scan, or MR image when the patient was on standing position. (b) CA or WA in extension position was measured using a lateral radiograph, CT scan, or MR image when the patient lied with a 10-cm-high towel (long 50 cm wide 20 cm high 10 cm) placed beneath the back just caudal to the fractured (index) vertebra for 1 h. Intravertebral instability defined as more than 10° CA or WA was changed preoperatively by comparing supine cross-table extension lateral radiographs, CT scans, or MR images with standing flexion lateral radiographs.

All surgical procedures were performed by an experienced spinal surgeon. The PPSF protocol applied is described in detail in our previous study (16). Subsequently, VP was performed. Avoiding the longitudinal connecting rods, a 5-mm-diameter trocar was inserted into the injured vertebral body on the side of the pedicle with a larger E-angle. Once the needle was at the optimal position, the high-viscosity bone cement was slowly injected into the vertebral body, which was visualized using a fluoroscopic monitor. The cement injection was ceased if any leak was detected. No cross-links were routinely used.

The minimally invasive internal fixation stabilization system was supplied by Zhejiang Kehui Company of China; the VP system was supplied by Shandong Guanlong Company of China and polymethylmethacrylate bone cement was supplied by Heraeus Medical GmbH Company of Germany.

All patients were encouraged to stand and walk on the first day after operation without braces. Bisphosphonates, vitamin D, and calcium supplementation were routinely administered to each patient to treat osteoporosis. Any perioperative medical or surgical complications that might need specific intervention or treatment were noted. All patients were examined preoperatively; 1 week and 1, 3, 6, and 12 months postoperatively; and then annually. The level of pain was assessed using a visual analog scale (VAS) of 0 to 10, with 10 indicating the most severe pain. The level of disability was evaluated using the Oswestry Disability Index (ODI) of 100 scores, with a higher score indicating more severe pain and disability.

Preoperative imaging was performed using standing anteroposterior and lateral radiographs, supine cross-table extension lateral radiographs, CT scans, and MR images through a 10-cm towel placed for 1 h beneath the back just caudal to the fractured (index) vertebra. After

Figure 1. a, b. Intravertebral instability secondary to Kümmell’s disease was identified using a modified flexion-extension lateral radiograph, CT scan, or MR image. (a) CA or WA in flexion position was measured using lateral radiographs when the patient was on standing position. (b) CA or WA in extension position was measured using a lateral radiograph, CT scan, or MR image when the patient lied with a 10-cm-high towel (long 50 cm wide 20 cm high 10 cm) placed beneath the back just caudal to the fractured (index) vertebra for 1 h. Intravertebral instability defined as more than 10° CA or WA was changed preoperatively by comparing supine cross-table extension lateral radiographs, CT scans, or MR images with standing flexion lateral radiographs.

**Highlights**

- Intravertebral instability in Kümmell’s disease mostly happened in the location of the cleft, the intravertebral space.
- Kümmell’s disease with intravertebral instability could be defined by comparing the supine cross-table extension lateral radiographs, CT scans, or MR images with standing flexion lateral radiographs.
- PPSF combined with VP seems to be an effective surgical option for the treatment of Kümmell’s disease with intravertebral instability.
surgery, standing anteroposterior and lateral radiographs were taken for all patients, as well as lateral flexion-extension radiographs and CT scans, to assess the displacement of the bone cement, the loosening of the internal fixation, and the stability of the spine. CA was determined using the Cobb’s method of measurements between the superior endplate of the vertebra directly above and the lower endplate of the vertebra directly below on a standard lateral radiograph. WA was measured as the angle between the upper and lower endplates of the fractured vertebral body.

The angle between the superior and inferior endplate of the intra-vertebral instability vertebral body was defined as WA. CA and WA were measured simultaneously (Figure 2). The reductions in WA and CA were calculated and recorded at each follow-up and compared with the data at the preoperative period. The loss of correction was calculated using the difference between the postoperative and final follow-up. All imaging measurements were obtained with a picture archiving and communication system v3.0 (Infinitt, Shanghai, China) and evaluated by two independent observers.

Statistical analysis
Statistical analysis was conducted using the Statistical Package for Social Sciences version 20.0 (IBM SPSS Corp.; Armonk, NY, USA). The data were expressed as the mean±standard deviation. The Student’s t-test was used to evaluate the changes in VAS, ODI, CA, and WA on the basis of the data obtained preoperatively, postoperatively, and at the final follow-up. The level of statistical significance was set to p<0.05.

Results
In all 21 patients, the fractured vertebra was re-expanded using a 10-cm towel placed for 1 h beneath the supine patient. Specifically, 14 patients underwent short-segment fixation (the instrumentation extended from one level above to one level below) with VP (Figure 3), and seven patients were subjected to long-segment fixation (the instrumentation extended from two levels above to two levels below) with VP because of severe osteoporosis (the T-value of BMD was <−3.5).

Figure 3. a-f. Case 1, male, 72 years, L1 Kümmell’s disease with kyphosis and intravertebral instability. (a, c) Intravertebral instability was identified by a modified flexion-extension lateral radiograph and MR image. (d, e) The patient underwent short-segment percutaneous pedicle screw fixation combined with VP. (f) Radiograph showing at 15 months after surgery, no screws loosened.
Figure 4. a-e. Case 2, female, 85 years, T11 Kümmell’s disease with kyphosis and intravertebral instability. (a, b) Intravertebral instability was identified by a modified flexion-extension lateral MR image and CT scan. (c, e) The patient underwent long-segment percutaneous pedicle screw fixation combined with VP. (d) Radiograph showed at 27 months after surgery that no screws loosened, and CA and WA were maintained well.

Figure 5. Clinical function perioperatively and at follow-up

The mean operation time was 135.4±21.3 (range, 110-175) min. The mean estimated blood loss was 106.9±34.3 (range, 50-165) mL. Bone cement was injected into the vertebra through one pedicle of the fractured vertebra. The mean volume of cement injected was 4.7±0.9 (range, 2.5-6.0) mL. The mean hospital stay was 9.4±2.2 (range, 7-14) days, and the mean follow-up duration was 19.3±4.2 (range, 12-36) months (Table 1).

The mean VAS score and ODI significantly decreased from 7.7±1.1 and 65.3±7.7% preoperatively to 3.4±0.6 and 30.0±7.6% postoperatively, respectively (p<0.05). At the final follow-up, the mean VAS score and ODI were 2.5±0.8 and 21.5±8.8%, respectively, which were maintained well at the time of the final follow-up (p>0.05) (Figure 5). In addition, two patients (14%) required oral nonsteroidal anti-inflammatory drugs for pain control at the final follow-up.
There was a significant correction of CA and WA from 26.9°±9.7° and 21.3°±6.0° preoperatively to 12.7°±7.2° and 8.6°±4.5° postoperatively, respectively (p<0.05). There was no significant loss in the local CA and WA at the time of the final follow-up (CA was 4.2°±2.0° and WA was 4.7°±1.8°) (p>0.05) (Figure 6).

In general, all the 21 patients had a favorable outcome, and no patient experienced severe perioperative complications such as massive bleeding, hemorrhagic shock, pulmonary embolism, cardiac arrest, or neurological deficits. Six of the patients had perivertebral cement leakage in their baseline postoperative CT scans, whereas no symptoms were present at the follow-up. One patient with hepatitis B virus-related hepatic cirrhosis developed wound dehiscence that was healed after 2 weeks of dressing. Implant-related complications of slight screw loosening were encountered in six patients. However, no obvious dislocations of the internal fixation were found at the follow-up. Two patients required oral nonsteroidal anti-inflammatory drugs for pain control at the final follow-up. In addition, one patient developed subsequent vertebral compression fracture because of a ground-level fall at 6 months postoperatively and was cured by repeated VP.

Discussion

The intravertebral cleft sign and intraosseous vacuum phenomenon were detected in both the CT scan and MR image, which is the reason why Kümmell’s disease is also called delayed post-traumatic nonunion (3, 17). VP and KP have been demonstrated to stabilize the vertebral body, relieve back pain, and restore the vertebral body height and correct kyphosis in patients with Kümmell’s disease (5, 6). However, in Kümmell’s disease with intravertebral instability, cement was injected into a cyst-like cavity created by the intravertebral cleft, which contributed to the formation of lump cement. It usually causes no or rare spiculation of cement into the trabecular bone, which may intercept the mechanical interlock by surrounding the trabecular bone (18). Another factor that might have influenced the outcome is that the cement in this situation served only as space-filling material in the cleft without any mechanical interlock or biocompatibility exerted. Therefore, an extrusion or displacement of the cement bolus might have happened leading to further kyphotic deformity (19). Heo et al. reported that the incidence of recollapse after VP was significantly higher in patients with osteonecrosis (28.6%) than in those in the nonosteonecrosis group (1.2%) (20). The authors suggested that OVCF with osteonecrosis or pseudarthrosis may be a relative contraindication for VP, especially for Kümmell’s disease patients with intravertebral instability.

In this study, one of the key points was to judge the intravertebral instability in patients with Kümmell’s disease. Different from tradi-

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**Table 1. Summary of data obtained from 21 patients with Kümmell’s disease**

| Case no. | Age/Sex | BMI  | BMD  | Trauma history | Disease duration (days) | Disease level | Follow-up (months) | Fixed level | Operation time (min) | Cement volume (mL) | Intraoperative blood loss (mL) | Length of stay (days) |
|----------|---------|------|------|---------------|------------------------|--------------|-------------------|------------|---------------------|----------------|--------------------------|-----------------|
| 1        | 77/F    | 16.5 | -3.7 | No            | Lumbar strain          | 30           | T10               | 19         | T8,9,11,12          | 165            | 2.5                      | 150             |
| 2        | 77/F    | 24.9 | -3.2 | Lumbar strain | Flat falling           | 26           | L1                | 12         | T12,2               | 130            | 4.5                      | 60              |
| 3        | 74/F    | 23.2 | -3.4 | Flat falling  | Flat falling           | 210          | T10               | 28         | T9,11               | 145            | 5.1                      | 95              |
| 4        | 85/F    | 20.4 | -5.3 | Weight loading| Flat falling           | 60           | T11               | 13         | T9,10,12,L1         | 170            | 4.8                      | 100             |
| 5        | 71/F    | 20.5 | -4.3 | No            | No                     | 150          | T11               | 19         | T9,10,12,L1         | 160            | 4.8                      | 165             |
| 6        | 78/F    | 27.4 | -2.3 | No            | T10,11,L1,2            | 120          | T12               | 14         | T11,L1              | 115            | 4.1                      | 50              |
| 7        | 74/F    | 22.3 | -4.3 | Flat falling  | Flat falling           | 120          | T12               | 24         | T10,11,L1,L1,2      | 135            | 5.6                      | 125             |
| 8        | 72/M    | 21.2 | -2.9 | Flat falling  | Flat falling           | 150          | L1                | 19         | T12,2               | 110            | 5.5                      | 85              |
| 9        | 74/F    | 26.7 | -3.1 | Lumbar strain | Flat falling           | 21           | L2                | 21         | L1,3                | 115            | 5                       | 95              |
| 10       | 81/M    | 18.9 | -3.3 | No            | No                     | 90           | L2                | 23         | L1,3                | 130            | 6                       | 100             |
| 11       | 65/F    | 22.6 | -2.9 | Flat falling  | No                     | 30           | T7                | 13         | T6,8                | 135            | 3.3                      | 115             |
| 12       | 78/F    | 17.1 | -4.2 | No            | No                     | 21           | L1                | 15         | T11,12,L2,3         | 175            | 3.5                      | 160             |
| 13       | 80/F    | 29.2 | -4.7 | No            | No                     | 30           | L1                | 17         | T11,12,L2,3         | 160            | 4.8                      | 156             |
| 14       | 68/F    | 17.6 | -2.8 | Flat falling  | Flat falling           | 27           | L1                | 16         | T12,2               | 118            | 5.6                      | 118             |
| 15       | 79/M    | 23.7 | -3.4 | Weight loading| Flat falling           | 45           | T12               | 18         | T11,L1              | 120            | 4.5                      | 70              |
| 16       | 73/F    | 24.2 | -3.2 | No            | No                     | 80           | T12               | 12         | T11,L1              | 130            | 4.8                      | 100             |
| 17       | 81/F    | 20.8 | -1.3 | No            | No                     | 105          | T10               | 16         | T9,11               | 110            | 4.0                      | 90              |
| 18       | 86/F    | 23.0 | -4.8 | L1,3          | No                     | 140          | L1                | 20         | T11,12,L2,3         | 160            | 5.5                      | 160             |
| 19       | 69/F    | 17.7 | -2.7 | Flat falling  | Flat falling           | 130          | L1                | 14         | T12,2               | 115            | 6.0                      | 90              |
| 20       | 71/M    | 26.1 | -3.1 | Flat falling  | Flat falling           | 60           | L2                | 16         | L1,3                | 125            | 5.0                      | 80              |
| 21       | 73/F    | 25.7 | -3.0 | No            | No                     | 90           | T11               | 15         | T10,12              | 120            | 4.0                      | 80              |
tional degenerative spinal instability, which usually occurs in the intervertebral (21), the intravertebral instability in Kümmell’s disease mostly happened in the location of the cleft, the intravertebral space. An interesting phenomenon in this study, consistent with that in the report of Kim et al., was that the axial distraction forces caused by intravertebral instability and kyphosis may lead to the development of a posterior element fracture such as a widened space of the spinous process and even an avulsion fracture of the spinous process (Figures 3b and 4b) (22). Here, the intravertebral instability in patients with Kümmell’s disease was assessed using flexion-extension radiographs, CT scans, or MR images based on the methods for diagnosis of lumbar intervertebral instability, which was defined as CA or WA change more than 10° (23, 24). Because a high proportion of elderly patients with Kümmell’s disease suffered from severe back pain during their visit to our institute, it was not always possible to perform flexion-extension lateral radiographs in a standing position. We thus applied the method reported by McKiernan et al., in which the patients were placed in an extension position for 1 h with a 10-cm-high towel placed beneath their back just caudal to the fractured (index) vertebra to simulate standing extension position (14, 15). This study defined that the intravertebral instability secondary to Kümmell’s disease was a change in CA or WA of more than 10° from the preoperative values, established by comparing supine cross-table extension lateral radiographs, CT scans, or MR images with standing flexion lateral radiographs. This examination can also be used as a basis for preoperative planning to determine the postural reduction of the kyphosis and the height of the vertebra during surgery.

Based on the results of our previous study (16) and the understanding of Kümmell’s disease (25), in this study, we introduced PPSF combined with VP to treat intravertebral instability secondary to Kümmell’s disease. We found that this minimally invasive procedure can effectively restore the spinal stability, correct kyphosis, reconstruct the spinal alignment, and rapidly relieve back pain. Although the correction of CA and WA regressed slightly during the follow-up period, there was no significant difference as compared with the outcomes of traditional anterior and posterior techniques (12). All patients had good clinical and radiological outcomes at the time of the final follow-up. Our study evidenced that PPSF combined with VP can safely provide good outcomes in patients with intravertebral instability secondary to Kümmell’s disease. Moreover, we found that indirect neural decompression can be achieved by postural reduction for the treatment of stage III Kümmell’s disease with retropulsed bony fragment into the spinal canal (Figure 4). The notion of indirect decompression was also adopted by Kashii et al. (26).

Loosening of the pedicle screws is a relatively common implant-related complication in OVCF treatment. Wu et al. reported that the long construct had higher stiffness in extension and lateral bending than the short construct and was thus suggested for application in patients with severe osteoporotic thoracolumbar burst fractures (27). In this study, 7 patients underwent long-segment fixation with VP because of severe osteoporosis (the T-value of BMD was <-3.5). During the follow-up period of over 1 year, no obvious screw loosening or shifting of internal fixation device occurred. Only slight screw loosening appeared in six patients, and oral nonsteroidal anti-inflammatory drugs for pain control were required in two patients. Loosening of an internal fixation may occur after longer follow-up periods in individual patients, in whom the internal fixator could be removed (16). Additionally, compared with the results reported for other procedures, posterior fixation combined with VP did not considerably increase the incidence of adjacent compression fractures or surgical complications (2). In this study, one case developed subsequent vertebral compression fracture in distal because of a ground-level fall at 6 months postoperatively, which was cured by repeated VP. Although the incidence of adjacent vertebral fractures is low, more attention has to be paid, and further studies need to focus on the issue of internal fixation in elderly patients, especially in those with long internal fixation.

The limitation of this study is the lack of comparison groups of patients treated by either conservative treatment or VP alone as well as its relatively small sample size because of the rarity of Kümmell’s disease. Furthermore, the precise circumstances around the long-term complications were not clear because of the relatively short-term follow-up. Therefore, more prospective studies are needed to further elucidate this issue.

In conclusion, PPSF combined with VP seems to be an effective surgical option for the treatment of Kümmell’s disease with intravertebral instability to restore the spinal stability, reconstruct the spinal alignment, and rapidly relieve pain, especially for elderly patients with poor general condition.

Ethics Committee Approval: Ethics committee approval was received for this study from the Biomedical Research Ethics Committee of Lishui Hospital of Zhejiang University (file number: 04; file year: 2011).

Informed Consent: Written informed consent for the participation in this study was obtained from all patients.

Author Contributions: Concept - C.L.; Design - C.L., D.H.; Supervision - C.L.; Materials - C.L., W.Y., D.H.; Data Collection and/or Processing – Z.C., J.G.; Analysis and/or Interpretation - Z.C., J.G.; Literature Search - C.L., F.L., D.H.; Writing Manuscript - C.L., W.Y.; Critical Review - F.L., D.H.

Conflict of Interest: The authors have no conflicts of interest to declare.

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