Better Height Restoration, Greater Kyphosis Correction, and Fewer Refractures of Cemented Vertebrae by Using an Intravertebral Reduction Device: a 1-Year Follow-up Study

Jiann-Her Lin¹-³, Sheng-Hao Wang¹, En-Yuan Lin¹, Yung-Hsiao Chiang¹-³

PURPOSE: This study compared the radiologic and clinical outcomes of kyphoplasty with intravertebral reduction device (IRD) and vertebroplasty (VP) in treating osteoporotic vertebral compression fractures (OVCFs).

MATERIALS AND METHODS: We enrolled 75 patients with OVCFs who were aged >60 years and treated them through VP or kyphoplasty with IRD. The radiologic outcomes, namely the anterior and middle body heights (ABH and MBH, respectively) and kyphotic angle (KA), were measured preoperatively and at postoperative 1 week, 3 months, 6 months, and 1 year. The refracture was identified on the basis of a decrease in ABH, MBH, or KA compared with those at postoperative 1 week. Visual analog scale (VAS) for pain and complications were recorded. The incidence of adjacent and nonadjacent fractures was also recorded.

RESULTS: We treated 36 patients with kyphoplasty with IRD (IRD group) and 39 through VP (VP group). The patient characteristics were comparable in both groups. The KA and its restoration were more favorable after IRD than after VP. Although ABHs were not different in either group, their restoration was more efficient after IRD than after VP. MBHs, their restoration, and their refracture rates were better after IRD than after VP. VAS pain scores and complication rates were not different between the groups. The incidences of adjacent or nonadjacent fractures were not different between the 2 groups.

CONCLUSION: Our findings reveal significantly more efficient height restoration and kyphosis correction and fewer refractures in the IRD group. IRD may not increase the risk of adjacent or nonadjacent fractures.

INTRODUCTION

Refractures of cemented vertebral bodies following vertebroplasty (VP) have recently gained attention because VP use has increased worldwide. VPs involving the percutaneous instillation of cement materials into a fractured vertebra are a widely accepted, minimally invasive procedure for treating painful and disabling osteoporotic vertebral compression fractures (OVCFs). Although its advantages over conservative treatments remain controversial,¹-⁵ VP effectively reduces pain and disability. However, height restoration and kyphosis correction of the spinal column following cement augmentation are not adequate.⁶,⁷ Refractures of cemented vertebral bodies occurred in 63% of OVCF cases.⁷ Some refractures result in severe pain, instability, and even neurologic deficits, requiring further interventions.⁸-¹¹ Refracture-related pain was reported in 18 patients and treated through repeated VP.¹¹ Instability in cemented vertebral bodies developed in 5 patients who presented with back pain or worsening neurologic status 8—17 months after VP and in 2 patients who presented with paraparesis.¹⁰ An intervertebral reduction device (IRD) (SpineJack) is designed to provide immediate robust fixation in situ and maintain the body height, as well as kyphotic angle for a longer term.¹²,¹³ For preventing refractures of cemented vertebral bodies, IRD appears to...
be an efficient treatment modality for OVCFs compared with other modalities. However, IRD requires cement augmentation, and subsequent refractures are a concern because of cement-induced osteonecrosis. Thus far, no study has compared the outcomes of IRD and VP. The present study compared the radiologic and clinical outcomes of IRD and VP in treating OVCFs.

MATERIALS AND METHODS
This retrospective comparative study was approved by an institutional review board at Taipei Medical University Hospital. Between August 2013 and February 2015, we included 75 patients with severe OVCFs treated through VP or kyphoplasty with IRD. Patients were included in the study if they were aged >60 years; experienced focal back pain without definite radicular signs and symptoms unresponsive to appropriate conservative treatment; experienced back pain related to the location of the OVCF, as observed on spinal radiographs; were diagnosed with an apparent bone edema in the fractured vertebra through magnetic resonance imaging (MRI) T2-weighted short tau inversion recovery sequences or with an enhanced area within the vertebral body on MRI-contrasted T1-weighted sequences; and revealed decreased bone mineral density (BMD, t scores, <−1). Patients were excluded if they exhibited spinal cord compression or stenosis of the vertebral canal, >30% of the local canal diameter; neurologic deficits; unmanageable bleeding disorders; systemic or local spine infections; or severe comorbidity in the heart, liver, kidney, or lung with intolerance to surgery.

The study population comprised 36 patients in the IRD group (mean age, 72.67 ± 7.52 years) and 39 patients in the VP group (mean age, 75.5 ± 6.62 years). All procedures were performed by 3 neurosurgeons (J. H. Lin, E. Y. Lin, and Y. H. Chiang). All patients underwent preoperative plain radiography, MRI, and dual-energy X-ray absorptiometry for determining the BMD. Changes in the narrow signal were assessed through MRI to determine the symptomatic levels of the fractures. All radiologic assessments were evaluated by a researcher (S. H. Wang) who was blinded to the clinical presentation and its outcome in the patients. The extent of vertebral body collapse was measured using the anterior and middle body heights (ABH and MBH, respectively) on lateral radiographs. The percentage of restoration, compared with the preoperative vertebral body height, was then calculated. The ABH and MBH were defined as the distance between the upper and lower end plates at the anterior vertebral body wall and in the center of the vertebral body, respectively. Furthermore, restoration in the vertebral BH was calculated using the formula (postoperative vertebral BH – preoperative vertebral BH)/preoperative vertebral BH × 100%. The kyphosis angle (KA) was assessed through lateral radiography by measuring the angle from the superior end plate of the vertebral body 1 level above the injury to the inferior end plate of the vertebral body 1 level below it. At postoperative 3, 6, and 12 months, refracture was defined at the ABH, MBH, and KA as >15%, >15%, and >8°, respectively, smaller than those at postoperative 1 week. The BMD, body mass index (BMI), and use of steroids and antosteoporosis medications were recorded by reviewing patient charts.

Outcome Assessment
Patient-reported outcomes were evaluated preoperatively and 12 months postoperatively. The visual analog scale (VAS) score was used to evaluate back pain. Any complications such as urinary tract infection, pneumonia, new neurologic deficit, blood transfusion, and stroke were recorded after the surgery. Cement leakage, defined as the presence of any extravertebral cement, was assessed independent of the treating physician by 2 investigators through an X-ray examination. Incidences of adjacent or nonadjacent fractures were recorded.

Statistical Analysis
Data were presented as the mean ± standard deviation. Statistical analysis for the calculations was performed using Prism 6 for Mac (GraphPad Software, Inc., La Jolla, California, USA). We used 2-way analysis of variance to compare radiologic outcomes at each time point between the 2 groups. Intergroup comparisons were conducted using the Student’s paired t-test or chi-square test.

RESULTS
Patient Characteristics
Table 1 shows the mean values for patient age, sex, BMI, BMD, steroid use, and presence of intravertebral cleft observed through MRI. These characteristics were not significantly different between the IRD and VP groups (see Table 1).

Clinical Outcomes
All 75 patients responded well to the operation. The follow-up rates of the IRD and VP groups were respectively 100% and

Table 1. Patient Characteristics

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<tr>
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<th>IRD</th>
<th>VP</th>
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<tr>
<td>Number</td>
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<td>39</td>
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<tr>
<td>Age</td>
<td>72.67 ± 7.5</td>
<td>75.73 ± 6.4</td>
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<td>Gender (female-to-male)</td>
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100% at 1 week, 91.67% and 94.87% at 3 months, 83.3% and 89.74% at 6 months, and 77.78% and 84.61% at 1 year. The VAS pain score significantly decreased in both groups: from a preoperative value of 6.83 ± 0.25 to a postoperative value of 2.75 ± 0.18 (P < 0.001) in the IRD group and from 6.795 ± 0.2469 to 2.818 ± 0.2152 (P < 0.001) in the VP group. Between the 2 groups, no significant difference was observed in the preoperative or postoperative value (0.91 and 0.81, respectively; Table 2). One patient in the IRD group and 2 in the VP group exhibited pneumonia. In addition, 6 patients in the IRD group and 8 in the VP group exhibited urinary tract infection. The complication rate in the IRD group was not different from that in the VP group. Moreover, in the IRD group, 4 patients exhibited adjacent fractures and no patient exhibited nonadjacent fractures; in the VP group, 6 patients exhibited adjacent fractures, and 1 patient presented with nonadjacent fractures. The incidence rates of adjacent or nonadjacent fractures were not significantly different between the groups (P = 0.74 and 1, respectively; see Table 2).

### Radiologic Outcomes

The KA and its restoration were more efficient after IRD than after VP, except for the mean KA at 1 week. The mean KAs after IRD and VP were respectively −10.07° ± 11.33° and −11.92° ± 11.38° preoperatively (P > 0.05), −0.01° ± 8.9° and −5.97° ± 11.22° at 1 week (P > 0.05), 1.9° ± 9.7° and 10.96° ± 11.08° at 3 months (P < 0.05), −3.83° ± 8.3° and −12.42° ± 11.23° at 6 months (P < 0.05), and −4.12° ± 8.07° and −13.79° ± 11.73° at 1 year (P < 0.05) (Figure 1, A). Furthermore, the mean KA restoration after IRD and VP was respectively 10.06° ± 6.71° and 5.99° ± 6.58° at 1 week (P < 0.05), 7.50° ± 6.85° and 1.52° ± 6.01° at 3 months (P < 0.05), 5.40° ± 6.85° and -0.32° ± 6.32° at 6 months (P < 0.05), and 4.88° ± 7.11° and −1.5° ± 5.76° at 1 year (P < 0.05) (Figure 1, B).

ABHs were not different in either group, but its restoration was more efficient after IRD than after VP. The mean ABH after IRD and VP was respectively 1.41 ± 0.63 and 1.56 ± 0.55 mm preoperatively (P > 0.05), 2.13 ± 0.49 and 2.03 ± 0.59 mm at 1 week (P > 0.05), 1.99 ± 0.44 and 1.73 ± 0.56 mm at 3 months (P > 0.05), 1.92 ± 0.45 and 1.64 ± 0.59 mm at 6 months (P > 0.05), and 1.89 ± 0.49 and 1.52 ± 0.55 mm at 1 year (P > 0.05) (Figure 2, A). The mean ABH restoration after IRD and VP was respectively 75.66% ± 71.54% and 35.53% ± 34.76% at 1 week (P < 0.05), 39.29% ± 71.66% and 13.82% ± 27.00% at 3 months (P < 0.05), 63.74% ± 107.3% and 7.34% ± 27.29% at 6 months (P < 0.05), and 50.52% ± 74.04% and 1.56% ± 23.95% at 1 year (P < 0.05) (Figure 2, B).

MBHs and their restoration were more favorable after IRD than after VP. The mean MBH after IRD and VP was respectively 1.26 ± 0.50 and 1.45 ± 0.46 mm preoperatively (P < 0.05), 2.16 ± 0.32 and 1.88 ± 0.51 mm at 1 week (P < 0.05), 2.06 ± 0.34 and 1.67 ± 0.45 mm at 3 months (P < 0.05), 1.90 ± 0.36 and 1.57 ± 0.44 mm at 6 months (P < 0.05), and 1.96 ± 0.38 and 1.47 ± 0.43 mm at 1

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### Table 2. Clinical Outcomes

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<tr>
<td>Preoperative VAS</td>
<td>6.83 ± 0.25</td>
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<td>0.9133</td>
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<tr>
<td>Postoperative VAS</td>
<td>2.75 ± 0.18*</td>
<td>2.82 ± 0.22*</td>
<td>0.8137</td>
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<tr>
<td>Adjacent fracture</td>
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<td>0.7381</td>
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<tr>
<td>Nonadjacent fracture</td>
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<tr>
<td>Complication</td>
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<td>9</td>
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<td>Pneumonia</td>
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<td>Urinary tract infection</td>
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<td>New neurologic deficit</td>
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<td>Blood transfusion</td>
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<td>Stroke</td>
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VAS, visual analog scale. *Post-VAS score was significantly lower than preoperative VAS score.
year ($P < 0.05$) (Figure 3, A). Moreover, the mean MBH restoration after IRD and VP was respectively $93.50\% \pm 67.58\%$ and $33.15\% \pm 29.59\%$ at 1 week ($P < 0.05$), $79.36\% \pm 62.86\%$ and $17.94\% \pm 29.58\%$ at 3 months ($P < 0.05$), $75.60\% \pm 78.37\%$ and $9.62\% \pm 29.57\%$ at 6 months ($P < 0.05$), $72.68\% \pm 67.92\%$ and $5.09\% \pm 26.41\%$ at 1 year ($P < 0.05$) (Figure 3, B).

The refracture rate of the MBH was significantly higher after IRD than after VP. Furthermore, the refracture rates of the KA in the IRD and VP groups were respectively $3.03\%$ and $16.22\%$ at 3 months ($P = 0.11$), $23.33\%$ and $25.71\%$ at 6 months ($P = 1.00$), and $35.71\%$ and $39.39\%$ at 1 year ($P = 0.79$). The refracture rates of the ABH in the IRD and VP groups were respectively $15.15\%$ and $40.54\%$ at 3 months ($P = 0.1662$), $20\%$ and $51.43\%$ at 6 months ($P = 0.1293$), and $32.14\%$ and $51.43\%$ at 1 year ($P = 0.0341$). Furthermore, the refracture rates of the MBH in the IRD and VP groups were respectively $9.09\%$ and $27.03\%$ at 3 months ($P = 0.0691$), $20\%$ and $57.14\%$ at 6 months ($P = 0.0027$), and $21.43\%$ and $66.67\%$ at 1 year ($P = 0.0007$) (Table 3).

**DISCUSSION**

The KA and its restoration were more favorable after IRD than after VP. Although ABHs were not different in either group, their restoration was more efficient after IRD than after VP. MBHs, their restoration, and their refracture rates were better after IRD than after VP. Moreover, the VAS pain scores and complication rates were not different between the groups. The rates of adjacent or nonadjacent fractures after IRD were not different from those after VP. Our results echoed with the results of the previous studies. Similar results were reported using another device based on the same principle to cut down the incidence of leakage of poly-methyl-methacrylate into epidural space in about 10% of cases.

IRD significantly reduced the incidence of refractures compared with VP in terms of MBH. Refractures were common in cemented vertebral bodies after VP. Refractures of cemented vertebrae after VP were observed in 63% of patients with osteoporosis. In our study, the incidences of refractures in the ABH, MBH, or KA at 1 year after IRD were $21.4\%$, $32.1\%$, and $35.7\%$, respectively. In
addition, our results revealed recollapse happened earlier than 3 months and that the vertebral BHs at postoperative 3 months had decreased to preoperative levels in VP group. By contrast, the incidence of refractures of the MBH was significantly lower after IRD (see Table 3).

The causes of refracture in cemented vertebral bodies remain unknown and may be multifactorial. A higher ABH correction after VP and gas-containing vertebrae are associated with an increased risk of refracture in cemented vertebral bodies. Osteonecrosis may be another cause of refracture in cemented vertebral bodies. The competency of the bone—cement interface is reasonable in most cases; however, a polymethylmethacrylate (PMMA) injection in rabbit lumbar vertebral bodies produced early focal bone necrosis in 50% of cases. In primate vertebral bodies, small zones of osteonecrosis were observed histologically at the bone—cement interface in a few cases. In human vertebral bodies, the bone immediately surrounded by the cement did not show extensive necrosis; however, a few spicules of a necrotic bone and foreign body giant cells and macrophages were identified in the fibrous membrane around the PMMA in all segments. Osteonecrosis at the bone—cement interface is uncommon in healthy vertebral bodies; however, this observation may be different in osteoporotic cemented vertebral bodies. Preoperative osteonecrosis is a predisposing factor for refracture in patients with OVCFs. The peri-cement halo phenomenon was associated with refractures of cemented vertebral bodies, and osteonecrosis in cemented vertebral bodies was radiologically observed in 4 patients with recurring back pain. Furthermore, an antosteoporotic treatment revealed borderline significance between refractured and nonrefractured vertebrae. Our results demonstrated that IRD reduced refractures of cemented vertebral bodies by providing additional anterior mechanical support. We suggest that insufficient anterior mechanical support after VP is a cause of refractures in cemented vertebral bodies.

Osteoporosis, excessive KA correction, previous cemented augmentation, and spinopelvic imbalance were reportedly associated with subsequent VCFs. The severity of osteoporosis (BMD; t score, <-3.0) was associated with new VCFs after VP. A 5-year follow-up study reported that excessive angular correction was associated with an adjacent fracture after VP. A previous VP is considered a risk factor for a new VCF because a strengthened cemented vertebral level may exert excessive mechanical load on the adjacent vertebral levels. However, a systemic review revealed no adequate evidence supporting that VP contributes to an increased risk of subsequent vertebral fracture, neither adjacent nor total vertebral fractures. Patients who had undergone VP or percutaneous kyphoplasty were not associated with an increased risk of VCFs. Moreover, a spinopelvic imbalance in the fractured level, such as segmental KA, sacral slope, and lumbar lordosis, was significantly associated with a risk of adjacent-level fractures. In our study, the incidence of adjacent or nonadjacent fractures in the IRD group was not different from that in the VP group for at least 1 year. This observation suggests that IRD did not increase the risk of adjacent-level fractures, although the intravertebral titanium device IRD strengthened the cement vertebral body more and facilitated more angle correction than did VP. We consider that KA correction by IRD enables a decrease in the incidence of adjacent level VCFs and that the strengthening by IRD did not increase the risk of adjacent-level VCFs.

CONCLUSION

Our findings reveal significantly more efficient height restoration and kyphosis correction in the IRD group. The refracture rate was lower for at least 1 year in treating OVCFs in elderly patients. IRD may not increase the risk of adjacent or nonadjacent fractures.

REFERENCES


Conflict of interest statement: The authors declare that the article content was composed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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