Kyphoplasty with an intravertebral reduction device for osteoporotic vertebral compression fractures with spinal canal encroachment

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INTRODUCTION

Osteoporotic vertebral compression fractures (OVCFs) are the most common sequelae of osteoporosis, comprising approximately 700,000 of a total 1.5 million osteoporotic fractures annually in the United States.¹ In Taiwan, 10,785 patients in 10 years were hospitalized because of painful OVCFs.² Some OVCFs may be asymptomatic or
may only result in the loss of height or a stooped posture.\[3] However, others may cause acute back pain with or without neurological deficits resulting from the fracture itself. Moreover, because of low bone mineral density owing to a fragile bone microarchitecture, even with low-energy impact on the thoracolumbar vertebrae, an unstable compression fracture involving the posterior column may occur with significant spinal canal encroachment (SCE) and angulation of the thoracolumbar junction.\[4]

According to the American College of Radiology guidelines, significant spinal canal (SC) compromise or compression is a relative contraindication for vertebroplasty (VP).\[9] However, many studies have reported that VP is typically safe and efficient in treating spinal fractures with SCE.\[6-11] VP ameliorated 23.3\% of SCE and significantly improved the kyphotic angle (KA), wedge angle, and vertebral body height in patients with osteoporotic burst fractures.\[7] Furthermore, VP yielded immediate pain relief in patients with OCVFs and SCE.\[10] Li et al. compared the clinical and radiological outcomes between osteoporotic burst fractures and OCVFs treated through VP and reported no significant differences in postoperative visual analog scale (VAS), Oswestry Disability Index (ODI), KA, or body height observations.

Two major concerns of VP in treating OCVF-associated SCE are cement leakage into the SC during the procedure and decrease of posterior body height (PBH). Both of them may result in new neurological deficits postoperatively because of the damaged posterior body wall (PBW). First, cement leakage during the procedure, particularly into the SC, is likely to cause nerve root injury and cord damage.\[12,13]\ A systematic review of meta-analysis comparing VP and balloon kyphoplasty (KP) for treating single-level OCVFs revealed that the incidence rates of cement leakage were 41\% and 20\% during VP and balloon KP.\[14,15]\ In OCVF-associated SCE, the PBW is not intact, resulting in a higher risk of cement leakage into the SC through the fractured PBW during the procedure.\[10]\ Second, decrease of the height of cemented vertebral bodies is frequent after VP.\[12]\ It results in the retropulsion of the PBW and SCE, compressing the cord or nerve roots and consequently causing severe pain, instability, and even neurological deficits.\[17,21\]

KP with an intravertebral reduction device (IRD) can restore and maintain vertebral body heights and has been widely used in cases of high- or low-energy vertebrae fractures, including traumatic VCFs and OCVFs.\[22,23\] Our previous study revealed that KP with an IRD was more efficient than VP in the restoration and maintenance of anterior body height (ABH), middle body height (MBH), and correction of KA for OCVFs with significantly lower refraction rates and that the incidence rate of cement leakage and functional outcomes in KP with an IRD were comparable to those in VP.\[22]\ However, for OVCF-associated SCE, whether KP with an IRD can restore and maintain PBH or whether the incidence of postoperative cement leakage is higher has yet to be comprehensively studied. Hence, the objective of this study was to compare the complications and radiological and functional outcomes after KP with an IRD and after VP for treating OVCF-associated SCE without neurological deficits.

**MATERIALS AND METHODS**

This study was approved by the Joint Institutional Review Board of Taipei Medical University (TMU-JIRB: N201705068). From January 2013 to December 2016, 660 consecutive patients with thoracolumbar OVCFs treated with VP or KP with an IRD were reviewed. The patient selection criteria were as follows: (1) being aged 65–85 years, (2) having no neurological deficits, and (3) having SCE. Patients were excluded if they exhibited neurological deficits; unmanageable bleeding disorders; systemic or local spinal infections; or severe comorbidities of the heart, liver, kidney, or lung with intolerance to surgery. Among the reviewed patients, 57 fulfilled all three criteria and were enrolled in this study [Figure 1]. Among these 57 patients, 41 underwent VP (VP group) and 16 underwent KP with an IRD (SpineJack\textsuperscript{TM}, IRD group). OCVFs were detected through magnetic resonance imaging (MRI), with bone edema in the fractured vertebra in T2-weighted short tau inversion recovery sequences or vertebral body enhancement on MRI-contrasted T1-weighted sequences. Peters \textit{et al.} and Jensen and Dion have defined SCE as canal narrowing exceeding 20\%,\[24,25\] SCE was present if the following criteria were fulfilled:

1. Posterior vertebral body height ratio,
   \[
   \text{PBHr} = \frac{B}{(A + C)/2} < 0.8 \quad [\text{Figure 2-1}]\]

2. Area ratio of SCE = \[
   \frac{B}{(A + C)/2} < 0.8 \quad [\text{Figure 2-2}]\]

3. Ratio of anteroposterior diameters
   \[
   = \frac{B}{(A + C)/2} < 0.8 \quad [\text{Figure 2-3}]\]

The PBHr was measured from plain X-ray images, whereas the area ratio of SCE and ratio of anteroposterior diameter (APD) were determined from T2-weighted magnetic resonance axial images or sagittal images. All factors were calculated by dividing the injured level by the average of the adjacent two levels.
Radiological outcomes
The ABH, MBH, PBH, and KA on lateral lumbar spine dynamic films were determined preoperatively and within 1 week, 3 and 6 months, and 1 year postoperatively [Figure 3]. Lateral lumbar spine dynamic films were routinely done for the patients before and after VP or KP with IRD in our hospital to detect if there was any instability in fractured vertebral body. The radiological measurements were done on both flexion and extension views, and the average of the measurements in these two views was defined as the final radiological outcome. The ABH, PBH, and MBH were defined as the distance between the upper and lower end plates at the anterior and posterior vertebral body wall and in the center of the vertebral body. The KA was assessed by measuring the angle from the inferior end plate of the vertebral body one level above the injury to the superior end plate of the vertebral body one level below it. Furthermore, the restoration and maintenance of the vertebral BH were calculated using the following formula:

\[
\text{Body height restoration ratio} = \frac{\text{postoperative BH} - \text{preoperative BH}}{\text{preoperative BH}} \times 100\% \tag{22}
\]

1. Body height restoration ratio

2. Body height maintenance ratio = \( \frac{\text{postoperative BH} \times 100\%}{\text{postoperative within 1 week BH}} \)

The restoration of the KA (RKA) was determined using the following formula:

\[
\text{RKA} = \text{postoperative KA} - \text{preoperative KA}
\]

Cement leakage into the SC was defined as positive if cement presented between the PBW and lamina on lateral lumbar spine X‑ray images and presented between bilateral pedicles on anteroposterior lumbar spine X‑ray images. The leakage was assessed by two neurosurgeons.

Clinical outcomes
Patient‑reported outcomes were evaluated preoperatively and postoperatively. The preoperative VAS, ODI, and EuroQol‑5D‑5 L (EQ‑5D‑5 L) were determined using charts, and the postoperative outcomes were obtained through phone interviews.

Any complications, including adjacent fractures, nonadjacent fractures, urinary tract infection, pneumonia, new neurological deficits, blood transfusion, and stroke, were reviewed using postoperative charts.

Statistical analysis
Data are presented as the mean ± standard deviation. Statistical analysis for the calculations was performed using Prism 7 for Windows (GraphPad Software, Inc., La Jolla, California, USA) and IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. (Armonk, NY: IBM Corp.). The Mann–Whitney U‑test was used for comparing the radiological outcomes of the two groups at each time point. Intergroup comparisons were performed using the Student paired t‑test, independent t‑test, or Chi‑squared test.
RESULTS

Patient characteristics
Among the 57 patients, 16 and 41 were enrolled in the IRD and VP groups, respectively. Table 1 shows the demographic data of all the patients. No significant differences were observed in age, sex, body mass index, bone mineral density, or injury level between the two groups.

Radiological outcomes
The follow-up rates of radiological outcomes in the IRD and VP groups were 100% versus 97.6% at 1 week, 68.8% versus 43.9% at 3 months, 37.5% versus 24.4% at 6 months, and 31.3% versus 20% at 1 year, respectively. ABHs were more favorable after KP with IRD than after VP. The mean ABHs in the IRD and VP groups were, respectively, 1.43 ± 0.42 versus 1.18 ± 0.43 cm preoperatively (P = 0.047), 2.09 ± 0.40 versus 1.85 ± 0.38 cm at 1 week (P = 0.029), 2.07 ± 0.41 versus 1.71 ± 0.35 cm at 3 months (P = 0.028), 1.98 ± 0.22 versus 1.44 ± 0.34 cm at 6 months (P = 0.013), and 2.06 ± 0.29 versus 1.35 ± 0.26 cm at 1 year (P = 0.003) [Table 2]. Significant differences were observed between the two groups preoperatively and postoperatively [Figure 4]. Furthermore, the restoration ratios (RRs) and maintenance ratios (MRs) of the ABH showed no significant differences between the two groups. The mean RRs of the ABH in the IRD and VP groups were 0.55 ± 0.09 versus 0.79 ± 0.13 at 1 week (P = 0.790), 0.71 ± 0.18 versus 0.75 ± 0.20 at 3 months (P = 0.722), 0.40 ± 0.13 versus 0.72 ± 0.24 at 6 months (P = 0.680), and 0.42 ± 0.17 versus 0.38 ± 0.24 at 1 year (P = 0.463), respectively [Table 2]. The mean MRs of the ABH in the IRD and VP groups were 1.00 ± 0.05 versus 0.90 ± 0.02 at 3 months (P = 0.070), 0.95 ± 0.04 versus 0.86 ± 0.03 at 6 months (P = 0.117), and 0.86 ± 0.05 versus 0.74 ± 0.05 at 1 year (P = 0.096), respectively [Table 2].

The observed MBHs were more favorable after KP with IRD than after VP. The mean MBHs in the IRD and VP groups were, respectively, 1.25 ± 0.42 versus 1.07 ± 0.38 cm preoperatively (P = 0.047), 2.09 ± 0.40 versus 1.85 ± 0.38 cm at 1 week (P = 0.029), 2.07 ± 0.41 versus 1.71 ± 0.35 cm at 3 months (P = 0.028), 1.98 ± 0.22 versus 1.44 ± 0.34 cm at 6 months (P = 0.013), and 2.06 ± 0.29 versus 1.35 ± 0.26 cm at 1 year (P = 0.003) [Table 2].

Table 1: Demographics of patient after kyphoplasty with intravertebral reduction device and after vertebroplasty

|               | KP with IRD (n=16) | VP (n=41) | P     |
|---------------|-------------------|-----------|-------|
| Age (years)   | 76.3±5.42         | 77.9±4.82 | 0.28  |
| Sex (female:male) | 8:8           | 31:10     | 0.06  |
| BMI (kg/m²)   | 24.9±3.29         | 24.0±3.81 | 0.42  |
| BMD (SD)      | -1.95±1.49        | -1.96±1.37| 0.98  |
| Level of injury |                   |           |       |
| T7            | 0                 | 2         | 0.07  |
| T8            | 0                 | 3         |       |
| T9            | 0                 | 0         |       |
| T10           | 0                 | 0         |       |
| T11           | 1                 | 7         |       |
| T12           | 2                 | 13        |       |
| L1            | 11                | 12        |       |
| L2            | 1                 | 4         |       |
| L3            | 1                 | 0         |       |
| L4            | 0                 | 0         |       |
| L5            | 0                 | 0         |       |

IRD: Intravertebral reduction device, KP: Kyphoplasty, VP: Vertebroplasty, BMI: Body mass index, SD: Standard deviation, BMD: Bone mineral density

Figure 3: Illustration of anterior body height, middle body height, posterior body height, and kyphotic angle measurement

Figure 4: Comparison of body heights. Anterior body height (a), middle body height (b), and posterior body height (c) were more favorable after kyphoplasty with an intravertebral reduction device than after vertebroplasty at postoperative 1 week, 3, 6, 12 months. (*P < 0.05)
Chi, et al.: Kyphoplasty with an IRD for OVCFs with spinal canal encroachment

The observed PBHs were more favorable after KP with IRD than after VP application. The mean PBHs in the IRD and VP groups were, respectively, 2.33 ± 0.41 versus 2.12 ± 0.33 cm preoperatively (*P = 0.106), 2.885 ± 0.32 versus 2.43 ± 0.39 cm at 1 week (*P < 0.05), 2.796 ± 0.43 versus 2.40 ± 0.26 cm at 3 months (*P = 0.003), 2.85 ± 0.30 versus 2.29 ± 0.30 cm at 6 months (*P = 0.004), and 2.908 ± 0.62 versus 2.11 ± 0.33 cm at 1 year (*P = 0.003; Figure 4) [Table 2]. The RRs of the PBH were not significantly different between the two groups. The mean RRs of the MBH in the IRD and VP groups were 0.94 ± 0.04 versus 0.91 ± 0.02 at 3 months (*P = 0.374), 0.91 ± 0.04 versus 0.90 ± 0.04 at 6 months (*P = 0.680), and 0.90 ± 0.05 versus 0.75 ± 0.05 at 1 year (*P = 0.096), respectively [Table 2].

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**Table 2: Comparison of radiologic results between kyphoplasty with intravertebral reduction device and vertebroplasty**

| Parameters | KP with IRD (n=16) | VP (n=41) | P  |
|------------|---------------------|-----------|----|
| ABH        |                     |           |    |
| Preoperative | 1.43±0.42           | 1.88±0.43 | 0.07|
| 1 week     | 2.09±0.40           | 1.88±0.38 | 0.029|
| 3 months   | 2.07±0.41           | 1.71±0.35 | 0.028|
| 6 months   | 1.98±0.22           | 1.44±0.34 | 0.013|
| 12 months  | 2.06±0.29           | 1.35±0.26 | 0.003|
| ABHRR      |                     |           |    |
| 1 week     | 0.55±0.09           | 0.79±0.13 | 0.790|
| 3 months   | 0.71±0.18           | 0.75±0.20 | 0.722|
| 6 months   | 0.40±0.13           | 0.72±0.24 | 0.680|
| 12 months  | 0.42±0.17           | 0.38±0.24 | 0.463|
| ABHMRR     |                     |           |    |
| 3 months   | 1.00±0.05           | 0.90±0.02 | 0.070|
| 6 months   | 0.95±0.04           | 0.86±0.03 | 0.117|
| 12 months  | 0.86±0.05           | 0.74±0.05 | 0.096|
| MBH        |                     |           |    |
| Preoperative | 1.25±0.42           | 1.07±0.38 | 0.118|
| 1 week     | 2.19±0.38           | 1.69±0.40 | 0.000|
| 3 months   | 2.15±0.37           | 1.61±0.36 | 0.001|
| 6 months   | 2.11±0.14           | 1.46±0.36 | 0.003|
| 12 months  | 2.21±0.51           | 1.21±0.31 | 0.003|
| MBHMRR     |                     |           |    |
| 3 months   | 0.95±0.04           | 0.91±0.02 | 0.374|
| 6 months   | 0.91±0.04           | 0.90±0.04 | 0.680|
| 12 months  | 0.90±0.05           | 0.75±0.05 | 0.096|
| PBH        |                     |           |    |
| Preoperative | 2.33±0.41           | 2.12±0.33 | 0.106|
| 1 week     | 2.885±0.32          | 2.43±0.39 | 0.000|
| 3 months   | 2.796±0.43          | 2.40±0.26 | 0.003|
| 6 months   | 2.85±0.30           | 2.29±0.30 | 0.004|
| 12 months  | 2.908±0.62          | 2.11±0.33 | 0.003|
| PBHRR      |                     |           |    |
| 1 week     | 0.26±0.04           | 0.16±0.02 | 0.013|
| 3 months   | 0.20±0.05           | 0.15±0.03 | 0.320|
| 6 months   | 0.23±0.05           | 0.11±0.04 | 0.117|
| 12 months  | 0.23±0.06           | 0.10±0.05 | 0.205|
| PBHMRR     |                     |           |    |
| 3 months   | 0.96±0.07           | 0.98±0.18 | 0.393|
| 6 months   | 0.94±0.08           | 0.95±0.05 | 0.914|
| 12 months  | 0.98±0.05           | 0.83±0.09 | 0.008|
| KA         |                     |           |    |
| Preoperative | −10.04±13.10        | −12.03±17.97 | 0.965|
| 1 week     | 0.29±9.15           | −4.48±8.89 | 0.104|
| 3 months   | −3.25±6.84          | −7.29±5.11 | 0.151|
| 6 months   | −1.05±8.26          | −7.58±8.89 | 0.193|
| 12 months  | −1.68±6.02          | −10.34±4.99 | 0.028|
| RKA        |                     |           |    |
| 1 week     | 10.33±5.95          | 7.42±7.36 | 0.128|
| 3 months   | 9.80±9.65           | 6.63±5.94 | 0.335|
| 6 months   | 8.47±8.37           | 8.17±7.47 | 0.745|
| 12 months  | 4.33±8.39           | 2.04±8.03 | 0.808|

ABH: Anterior body height, ABHRR: ABH restoration ratio, ABHM: ABH maintenance ratio, IRD: Intravertebral reduction device, KP: Kyphoplasty, MBH: Middle body height, MBHRR: MBH restoration ratio, MBHMRR: MBH maintenance ratio, PBH: Posterior body height, PBHRR: PBH restoration ratio, PBHMRR: PBH maintenance ratio, KA: Kyphotic angle, RKA: Restoration of the KA, VP: Vertebroplasty

**Figure 5: Comparison of posterior body height maintenance ratios.** Maintenance ratio of the posterior body height was more favorable after kyphoplasty with an intravertebral reduction device than after vertebroplasty at postoperative 12 months (*P < 0.05)
IRD and VP groups were 0.96 ± 0.07 versus 0.98 ± 0.18 at 3 months (P = 0.393), 0.94 ± 0.08 versus 0.95 ± 0.05 at 6 months (P = 0.914), and 0.98 ± 0.05 versus 0.83 ± 0.09 at 1 year (P = 0.008), respectively [Figure 5 and Table 2].

The KAs were not significantly different between the two groups except for 1-year follow-up. The mean KAs in the IRD and VP groups were, respectively, −10.04 ± 13.10 versus −12.03 ± 7.97 preoperatively (P = 0.965), 0.29 ± 9.15 versus −4.48 ± 6.89 at 1 week (P = 0.104), −3.25 ± 6.84 versus −7.29 ± 5.11 at 3 months (P = 0.151), −1.05 ± 8.26 versus −7.58 ± 8.89 at 6 months (P = 0.193), and −1.68 ± 6.02 versus −10.34 ± 4.99 cm at 1 year (P = 0.028) [Table 2]. The RKAs were not significantly different between the two groups. The mean RKAs in the IRD and VP groups were 10.33 ± 5.95 versus 7.42 ± 7.36 at 1 week (P = 0.128), 9.80 ± 9.65 versus 6.63 ± 5.94 at 3 months (P = 0.335), 8.47 ± 8.37 versus 8.17 ± 7.47 at 6 months (P = 0.745), and 4.33 ± 8.39 versus 2.04 ± 8.03 at 1 year (P = 0.808), respectively [Table 2].

Clinical outcomes
All 57 patients responded favorably to the surgery. The average follow-up period in the IRD group was 20.7 months and that in the VP group was 30.9 months, with follow-up rates of 93.75% and 75.61%, respectively. The pain VAS and ODI observations were significantly improved in both groups. In the IRD group, the pain VAS decreased from 4.80 ± 2.13 preoperatively to 1.50 ± 1.50 postoperatively (P < 0.001), and the ODI decreased from 65.07 ± 15.65 to 14.13 ± 22.10 (P < 0.001). In addition, in the VP group, the pain VAS decreased from 4.47 ± 2.03 to 1.60 ± 2.13 (P < 0.001), and the ODI decreased from 62.00 ± 18.55 to 19.10 ± 14.83 (P < 0.001). Five dimensions of EQ-5D-5L showed improvements in both groups [Figure 6]. The preoperative and postoperative values did not show significant differences between the two groups.

Subgroup analysis of L1 osteoporotic vertebral compression fractures
We subsequently compared the radiological and clinical outcomes of patients with L1°CVFs in both groups. A total of 11 and 12 patients were enrolled in the IRD and VP groups, respectively. No significant differences were observed in age, sex, body mass index, bone mineral density, and preoperative radiological or clinical parameters between the two groups. Significant differences were observed between the two groups in ABH, MBH at 12-month follow-up (P < 0.05), and PBH at 1 week and 6 months (P < 0.05). For the RR and MR, only MBHRR at 6 months and 12 months showed differences. For the postoperative clinical outcome, there was significant difference in ODI between two groups (P < 0.05) [Table 3].

Complications
No significant differences were observed between the two groups in postoperative complications [Table 4]. The incidence rates of cement leakage into the SC were 6.25% (1/16) and 9.77% (4/41) in the IRD and VP groups, respectively (P = 0.664). The incidence rates of adjacent fractures were 25% (4/16) and 21.95% (9/41) in the IRD and VP groups, respectively (P = 0.807). One case of nonadjacent fracture and one case of pneumonia were recorded. Overall, no patient experienced new neurological deficits.

DISCUSSION
This study demonstrated that compared with VP, KP with an IRD restored and maintained a more favorable PBH at least for 1 year postoperatively, with a comparable incidence rate of cement leakage into the SC and similar functional outcomes in OVCF-associated SCE. Remarkably, no new neurological deficits were observed postoperatively in both groups. Moreover, KP with an IRD yielded a more favorable ABH and MBH than did VP, although the RRs

Figure 6: Comparison of functional outcomes. Improvements in functional outcomes were similar between the two groups
Table 3: Comparison of subgroup L1 osteoporotic vertebral compression fractures between kyphoplasty with intra vertebral reduction device and vertebroplasty

|                | Spine jack | VP | P   |
|----------------|------------|----|-----|
| n              | 11         | 12 |     |
| Gender         |            |    |     |
| Female         | 6          | 9  | 0.4 |
| Male           | 5          | 3  |     |
| Age            | 75.6±4.92  | 78.5±1.35 | 0.23 |
| BMD            | 24.6±1.23  | 24.45±0.99 | 0.915 |
| Radiological outcome |    |    |     |
| ABH            |            |    |     |
| Preoperative   | 1.32±0.12  | 1.12±0.08 | 0.165 |
| 1 week         | 2.05±0.14  | 1.89±0.06 | 0.276 |
| 3 months       | 2.07±0.13  | 1.92±0.07 | 0.402 |
| 6 months       | 1.97±0.14  | 1.45±0.19 | 0.229 |
| 12 months      | 2.09±0.16  | 1.35±0.13 | 0.009** |
| MBH            |            |    |     |
| Preoperative   | 1.20±0.13  | 1.09±0.09 | 0.519 |
| 1 week         | 2.20±0.13  | 1.84±0.09 | 0.029* |
| 3 months       | 2.15±0.12  | 1.91±0.08 | 0.263 |
| 6 months       | 2.08±0.08  | 1.37±0.08 | 0.002** |
| 12 months      | 2.22±0.30  | 1.31±0.06 | 0.012* |
| PBH            |            |    |     |
| Preoperative   | 2.41±0.14  | 2.17±0.09 | 0.235 |
| 1 week         | 2.90±0.11  | 2.62±0.05 | 0.028* |
| 3 months       | 2.77±0.14  | 2.47±0.08 | 0.139 |
| 6 months       | 2.88±0.08  | 2.41±0.13 | 0.024* |
| 12 months      | 2.24±0.20  | 2.27±0.16 | 0.064 |
| Clinical outcome-preoperative |    |    |     |
| EQ VAS         | 33.3±5.58  | 43±5.78 | 0.28 |
| VAS            | 5.8±0.73   | 4±0.48 | 0.042 |
| ODI            | 59.1±6.75  | 58±7.12 | 0.907 |
| Clinical outcome-postoperative |    |    |     |
| EQ VAS         | 74.2±6.02  | 69±5.474 | 0.537 |

Table 3: Contd...

|                | Spine jack | VP | P   |
|----------------|------------|----|-----|
| VAS            | 1.29±0.52  | 2.25±0.7 | 0.48 |
| ODI            | 8.86±2.92  | 19.2±2.35 | 0.014* |

Table 4: Comparison of complications between kyphoplasty with intra vertebral reduction device and vertebroplasty

|                | KP with IRD (n=16), n (%) | VP (n=41), n (%) | P   |
|----------------|---------------------------|-----------------|-----|
| Cement leakage into spinal canal | 1 (6.25)  | 4 (9.77) | 0.664 |
| Adjacent fracture | 4 (25) | 9 (21.95) | 0.807 |
| Nonadjacent fracture | 0  | 1 (2.44) | 0.414 |
| New neurologic deficit | 0  | N/A | N/A |
| Pneumonia          | 0  | 1 (2.44) | 0.414 |
| Urinary tract infection | 0  | N/A | N/A |
| Blood transfusion   | 0  | N/A | N/A |
| Stroke             | 0  | N/A | N/A |

N/A: Not analyzed, IRD: Intravertebral reduction device, KP: Kyphoplasty, VP: Vertebroplasty

Radiological outcome

- ABH
  - Preoperative: 1.32±0.12, 1.12±0.08
  - 1 week: 2.05±0.14, 1.89±0.06
  - 3 months: 2.07±0.13, 1.92±0.07
  - 6 months: 1.97±0.14, 1.45±0.19
  - 12 months: 2.09±0.16, 1.35±0.13

- MBH
  - Preoperative: 1.20±0.13, 1.09±0.09
  - 1 week: 2.20±0.13, 1.84±0.09
  - 3 months: 2.15±0.12, 1.91±0.08
  - 6 months: 2.08±0.08, 1.37±0.08
  - 12 months: 2.22±0.30, 1.31±0.06

- PBH
  - Preoperative: 2.41±0.14, 2.17±0.09
  - 1 week: 2.90±0.11, 2.62±0.05
  - 3 months: 2.77±0.14, 2.47±0.08
  - 6 months: 2.88±0.08, 2.41±0.13
  - 12 months: 2.24±0.20, 2.27±0.16

- Clinical outcome
  - EQ VAS: 33.3±5.58, 43±5.78
  - VAS: 5.8±0.73, 4±0.48
  - ODI: 59.1±6.75, 58±7.12

The severity of SCE is a critical issue for the management of OVCF. Appel and Gilula developed a classification system for the severity of SCE.[13] This classification system categorized the severity of SCE by the patency of epidural space and the deformity of spinal cord with or without signal change. Category 1 is defined as loss of ventral epidural space with no spinal cord deformity; and MRs were not different in both groups. Finally, the incidence rates of adjacent or nonadjacent fractures in the IRD and VP groups, as well as the rate of cement leakage, were not different.

The definition of SCE varies in the literature. In our study, SCE was defined as a 20% loss of APD and the cross-sectional area and PBH compared with the most adjacent levels. The APD ratio is commonly used for SCE determination. Through the use of MRI or computed tomography (CT), the loss of APD can be calculated by comparing the APD of the encroached canal and the average APD of the most adjacent levels, with a 5%–20% encroachment rate.[20] The cross-sectional area ratio between the lesion and adjacent levels is another common indicator, with a 16.71% ± 16.49% encroachment rate.[27] Furthermore, studies have defined SCE as the distance from the line between the posterior margin of the adjacent vertebral bodies and the bony fragment on CT scans, with a mean repulsion of 4.2 mm.[8,16,20,26,27] Another study defined SCE as the loss of ventral epidural space and spinal cord deformity on MRI scans.[11]
category 2 as spinal cord deformity but no abnormal cord signal on T2-weighted images; and category 3 as cord deformity with increased signal within cord on T2-weighted images. According to this classification, the category 1 seems to be comparable to only bulking of the posterior wall or real cortical injury of posterior wall. In 16 patients underwent KP with IRD of our study, 4 patients were classified in category 1, 10 in category 2, and 2 in category 3; in 41 patients underwent VP, 12 patients were classified in category 1, 24 in category 2, and 5 in category 3 [Supplement Table 1]. The majority of the patients with OVCFs in our study were categorized as 1 or 2 (87.5% in IRD group and 87.5% in VP group). There was no significant difference in severity between patients underwent KP with IRD and VP.

For treating OVCF-associated SCE without neurological deficit, conservative treatment, VP, and KP have often been applied. Our study revealed that KP with an IRD was safe and efficient in treating OCVF-associated SCE, in addition to providing additional benefits in PBH maintenance. Conservative treatment strategies such as bed rest, physical therapy, braces, analgesics, or muscle relaxants are commonly accepted. Although VP has been considered a contraindication in patients with significant SC compromise, studies have reported that VP is typically accepted as a safe and efficient treatment. Moreover, KP significantly reduced pain in patients with incomplete osteoporotic burst fractures. In our study, both KP with an IRD and VP did not cause new neurological deficits postoperatively, and KP with an IRD was superior to VP in terms of PBH maintenance.

Cement leakage into the SC is a major concern during VP or KP for treating OCVF-associated SCE because it may worsen SCE and cause new neurological deficits. Cement leakage has been reported in 31%–96% and 7%–25% of VP and KP cases, respectively. The risk of cement leaking into the SC is higher when the PBW is damaged. A study reported that the cement leakage rates in compression fractures with and without the involvement of the PBW were 47.4% and 42.86%, respectively. The difference between cement extravasation in both groups was not significant, and all patients with cement leakage were clinically unremarkable. Another study on KP with an IRD revealed cement leakage in 43 of 108 (39.8%) treated vertebrae, but no clinical consequences were observed; additionally, symptomatic cement leakages were not observed in any patient. Although the cement leakage rate was 47.4%, all patients were clinically unremarkable.

Most cement leakage cases were asymptomatic, but in some cases, the leakage could cause severe neurological deficits when presented within the SC or as cement embolism to the lungs and other organ systems. A few studies have reported the incidence of cement leakage into the SC. A critical review of 15 articles revealed that 21 patients who received cement augmentations presented with severe neurological deficits following cement extravasation, and most of them even underwent surgery for cement removal. In our study, cement leakage into the SC occurred in 1 of 16 (6.25%) and 4 of 41 (9.77%) patients in the IRD and VP groups, respectively. No patients experienced new neurological deficits. This result is consistent with that of Krüger’s study, which recorded cement leakage into the SC after KP in 7 of 97 (7.2%) patients and reported no new neurological deficits.

This study has some limitations. Data in this retrospective study were obtained from a single medical hospital, and the study had a relatively small sample size along with a relatively short follow-up duration of 1 year. The selection criteria of surgical procedures varied among the surgeons in this study. Therefore, a long-term, prospective multicenter study enrolling a large sample size with a favorable follow-up rate is warranted.

**CONCLUSION**

KP with IRD was associated with better body heights and KA at least for 1 year for OVCF-associated SCE. KP with an IRD was not inferior to VP in terms of functional outcomes. The incidence rate of cement leakage into the SC after KP with an IRD was comparable to that after VP, and no new neurological deficits were reported postoperatively in both groups.

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**Conflicts of interest**

There are no conflicts of interest.

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### Supplement Table 1: Categories of spinal canal encroachment

| Category | KP with IRD (n=16) | Vertebroplasty (n=41) | P value |
|----------|--------------------|-----------------------|---------|
| 1        | 4                  | 12                    | 0.792   |
| 2        | 10                 | 24                    |         |
| 3        | 2                  | 5                     |         |

Category 1: Loss of ventral epidural space without spinal cord deformity. Category 2: Spinal cord deformity but no abnormal cord signal on T2-weighted images. Category 3: Spinal cord deformity with increased signal within cord on T2-weighted images.