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SCIENTIFIC ARTICLE

# Percutaneous vertebral augmentation using drill rotation for osteoporotic vertebral compression fractures with intravertebral vacuum cleft

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## Abstract

**Objective** To evaluate the efficacy of a new technique of percutaneous vertebral augmentation (PVA): drill rotation-cement injected under vacuum aspiration (DR-CIVAS) for vertebral compression fractures (OVCFs) with intravertebral vacuum cleft (IVC) sign.

**Materials and methods** A retrospective study was conducted in 46 consecutive patients with OVCFs and IVC signs, who underwent PVA using DR-CIVAS ($n = 22$, DR-CIVAS group) or traditional technique without DR-CIVAS ($n = 24$, control group). The pre- and postoperative vertebral height and wedge angle change and visual analog scale (VAS), the volume of cement injected, incidences of cement leakage, and subsequent new vertebral compression fractures were evaluated between the two groups.

**Results** No significant difference was found in cement leakage incidences, pre- and postoperative VAS scores, vertebral height, and wedge angle change between the two groups. The mean cement volume was significantly higher ($P < 0.001$) in DR-CIVAS group (4.87 mL) than in the control group (3.58 mL). Of the 22 patients in DR-CIVAS group, the subsequent fractures occurred in 2 cases (9.1%) located in the nonadjacent levels. In the control group, the subsequent fractures occurred in 6 cases (25.0%) located in the adjacent level ($n = 1$) and the augmented levels ($n = 5$). Although DR-CIVAS group did not demonstrate a statistical reduction of the incidence of subsequent fractures ($P = 0.25$), the subgroup analysis revealed that subsequent fractures frequently involved the augmented level in the control group ($P = 0.04$).

**Conclusions** PVA with DR-CIVAS technique is effective for OVCFs with IVC sign, with lower incidences of subsequent new vertebral compression fractures in the augmented vertebra.

**Keywords** Spine · Vertebroplasty · Fractures · Compression · Back pain · Bone cements

## Introduction

The presence of an intravertebral vacuum cleft (IVC) sign in osteoporotic vertebral compression fracture (OVCF) has been reported as an essential risk factor for severe vertebral collapse, progressive kyphosis, and intractable back pain [1–3]. Percutaneous vertebral augmentation (PVA) using vertebroplasty or kyphoplasty has been recommended to treat patients with painful OVCFs and IVC sign and achieved good outcomes at initial follow-up [4–6]. However, there has been a report [7–9] of a high incidence of the subsequent new vertebral compression fractures after routine PVA for the treatment of OVCFs with IVC sign during long-term follow-up. Trout et al. [9] deduced that the increased stiffness and rigidity of the injected cement, particularly as a focal mass within a cleft, may contribute to the subsequent fracture. Some authors speculated that the insufficient cement filled in an IVC [10] and the fibrocartilaginous membrane at the periphery of the IVC prevented cement being interdigitated with the surrounding cancellous bone and caused a recollapse of the augmented vertebrae [7, 8].

We propose that the ideal PVA method for OVCF lesions with IVC sign should include (i) the destruction of some

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fibrocartilaginous membrane to allow sufficient cement interdigitation with residual bone and (ii) the removal of IVC contents for sufficient cement filling. Based on this hypothesis, we adopted a novel method of PVA technique modified from that of Koike et al. [11]. In brief, the fibrocartilaginous membrane was partly broken by drill rotation (DR) with front and back movement and fan swing along puncture path. Then cement was injected under IVC decompression by vacuum aspiration using a three-way stopcock (CIVA); the technique was called as DR-CIVAS for short. Here we evaluate the efficacy of our DR-CIVAS technique versus conventional approach in PVA for OVCFs with IVC sign.

## Materials and methods

### Study population

This retrospective study was approved by our institutional review board, and all patients had previously consented to the use of their medical records for research purposes. DR-CIVAS technique was adopted in March 2016 to treat patients of OVCFs with IVC sign and persistent pain. IVC sign was identified with preprocedural medical imaging as a radiotranslucent band in the vertebral body on digital radiographs and computed tomography (CT), or fluid collection or gas containing signal on magnetic resonance imaging (MRI) [12, 13].

We reviewed the clinical and imaging data of consecutive patients of OVCFs with IVC sign who underwent DR-CIVAS between March 2016 and October 2017 as DR-CIVAS group; the patients treated by the conventional method between March 2015 and October 2016 served as the control group. To simplify the evaluation of post-procedure pain, patients who were treated at more than one level were excluded from the present study. Patients who only showed cement dense filling in the vertebral body without IVC sign on preprocedural medical imaging were also excluded from the present study [14].

### Methodology

The patients were routinely followed-up in the outpatient clinic at 1 week, 1 month, 3 months, and 6 months after PVA, or when there was recurrent back pain. If patients did not visit our hospitals for a follow-up appointment, a physician would interview them by telephone to determine whether there was recurrent pain. The missing data at follow-up were not taken into the analysis. Whenever subsequent fractures were suspected, an MRI examination was performed. The subsequent fractures were defined by marrow edema or fluids in the cemented vertebrae on MR imaging.

Based on the location, the subsequent vertebral fractures were divided into three categories: those on the adjacent levels, on the nonadjacent levels, and the augmented levels. Pain intensity was quantified on an 11-point numerical visual analog scale (VAS) with values from 0 to 10 (0 indicating no pain and 10 indicating the worst pain). Age, gender, baseline, and post-procedural VAS score, lumbar bone mineral density (BMD) with a T-score, history of bisphosphonate therapy, treated level, subsequent fractures, cement volume, cement leakage, and the changes of spinal geometry from pre- to post-procedure were recorded. The changes of spinal geometry—such as the height restoration rate and wedge angle correction in the compression vertebral body after the procedure—were measured using pre- and post-procedural radiographs, as described previously [6].

### Percutaneous vertebral augmentation technique

In typical circumstances, the procedures were performed under local anesthesia with minimal sedation by staff radiologists who used a modified form of the method described by Jensen et al. [15]. Patients were placed in a prone position and monitored by electrocardiography and oxygen saturation during the procedures. A 13-gauge needle was used to puncture the collapsed vertebral body via a unilateral transpedicular approach under C-arm fluoroscopic guidance.

For the control group, the needle tip was advanced into the IVC of the collapsed vertebral body. Cement was prepared by combining powder cement polymer and liquid monomer; the cement was loaded into a screw-type 10-mL syringe (LADI (T) 2002 No, 2040120, Guanlong, Jinan, China) and manually injected to a maximal possible amount in a paste with high viscosity phase under fluoroscopic guidance. For the DR-CIVAS group, the needle tip was advanced into the interface of the IVC and peripheral cancellous bone instead of being directly advanced into the IVC area. The stylet was removed, and a 1.7-mm-diameter drill was placed into the trocar to break some fibrocartilaginous membrane in the IVC through the back and forth rotation or slightly fan swing in any direction. According to the location of the drill and IVC, the drill should be pressed close to the cancellous bone to break some fibrocartilaginous membrane and communicate with IVC and the peripheral cancellous bone area (Figs. 1 and 2), and avoid injuring endplate. A 10-mL syringe was coupled with the trocar for back pumping; if blood was easily pumped into the syringe, the stylet was placed back into the trocar for a few minutes, until no blood or trace blood was pumped into the syringe. Then a 10-mL syringe for vacuum aspiration and a screw-type 10-mL syringe filled with bone cement for injection were prepared. After withdrawing the drill from the trocar, the syringes were connected to the proximal lumen of the trocar via a three-way stopcock (disposable combination stopcock; CHLMIC, Lihua, China) according to Koike' method

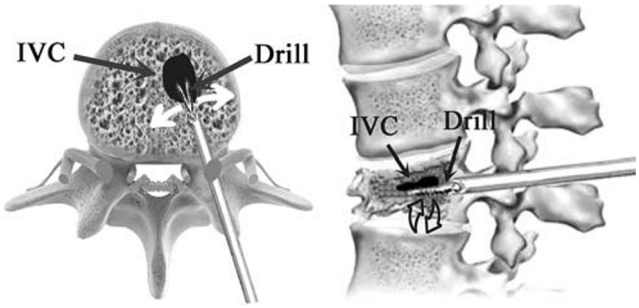


**Fig. 1** Diagrammatic representations demonstrate the drill on the interface of the cleft and peripheral cancellous bone to break some fibrocartilaginous membrane. The part of the shaded black represents the cleft, and the arrows represent the rotation of the drill

[11]. The IVC contents were manually vacuumed as thoroughly as possible. The stopcock was turned off without releasing the vacuum, and then cement was injected through another opening of the stopcock with the screw-type syringe (Fig. 3).

The cement was injected sluggishly to a maximal amount in a paste with a high viscosity phase. The procedure was under the fluoroscopic guidance in increments of 0.2 to 0.3 mL. Cement injection was stopped if it leaked into the perivertebral space or into the intervertebral disc space. The volume of injected cement was recorded. No unique postural maneuver to retain the vertebral alignment was used before or during the procedure.

## Statistical analysis

Data were analyzed using a commercially available statistical software package (SPSS for Windows, version 16.0; SPSS, Inc., Chicago, IL, USA). The changes pre- and post-procedure VAS pain scores were analyzed with the Kruskal-Wallis test. Age, bone density, the difference of the height restoration rate in the vertebral body and wedge angles, the changes in VAS pain scores, and the volume of injected cement between DR-CIVAS and control groups were analyzed with independent sample *t* test. Gender, the treated vertebral levels, history of bisphosphonate therapy, cement leakages, and the incidences of subsequent fractures between the two groups were

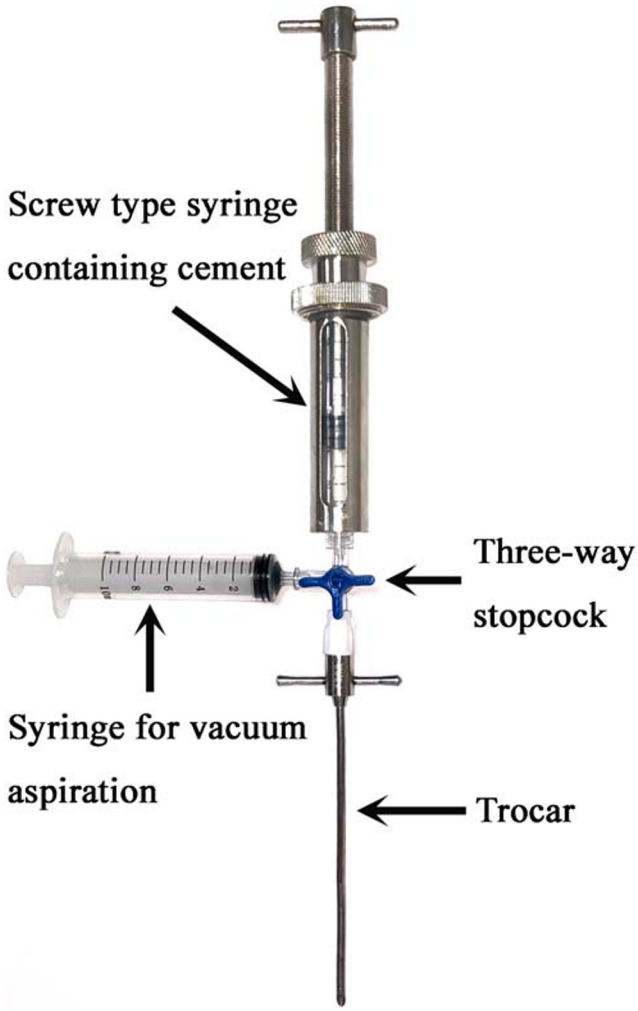


**Fig. 3** The setting of injection syringes: The IVC contents are manually vacuumed by a syringe for a vacuum aspiration. Then the stopcock is turned off without releasing the vacuum. Next, the cement is injected through another opening of the stopcock with the screw-type syringe

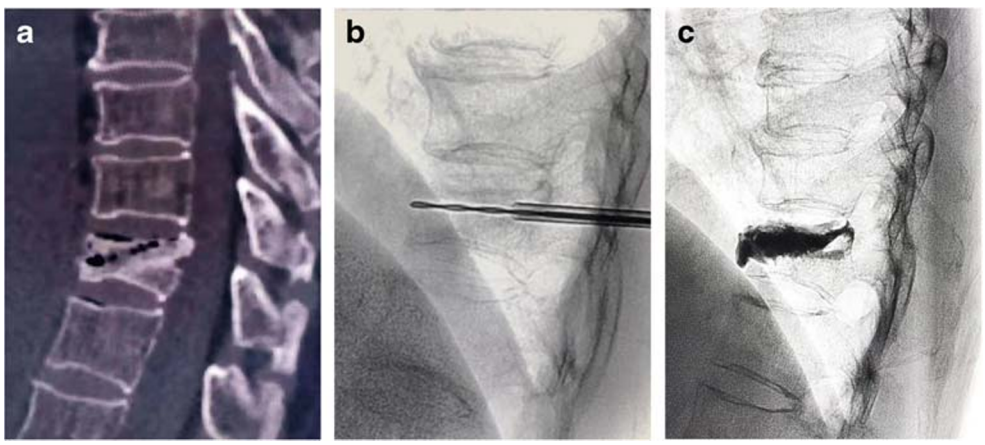


**Fig. 2** An 84-year-old woman with a T11 vertebral compression fracture with a cleft. **a** Preoperative MDCT with sagittal reformation shows a compression fracture at L1 with a cleft (arrow). **b** Radiograph obtained during vertebroplasty shows a drill introduced on the cleft and peripheral cancellous bone. **c** Post-operation radiograph indicates a mass of cement filled in the IVC, which spreads into the surrounding bone trabeculae

statistically analyzed by using chi-squared and Fisher's exact tests. For all statistical analyses, a *P* value of less than 0.05 was considered statistically significant.

## Results

### Patients

A total of 46 patients (20 males and 26 females) with a mean age of 79.07 ± 2.68 years (range 62–83) were included in this study. The period from incidence of back pain to PVA was 1.23 ± 3.21 months. Prior to and after PVA, 37 patients received bisphosphonates, calcium supplementation, and vitamin D for 4–6 months, and these patients maintained the same dose medication after the procedure. Out of the 37 patients, 9 could not use bisphosphonates due to gastrointestinal side effects. Twenty-two and 24 patients were classified into DR-CIVAS and control groups, respectively. The baseline characteristics of the patients are summarized in Table 1. There was no statistical significance between the two groups.

### Clinical evaluation

All procedures were technically successful and well-tolerated in all patients without any symptomatic complications. The clinical outcomes and the available data at follow-up are shown in Table 2. At 3 months follow-up, we could not interview 3 patients for the changed contact information in DR-CIVAS group. At the same time, we lost 6 patients at 3 months follow-up in the control group. Five patients changed their contact information and 1 patient died because of a heart attack.

The amount of cement injected was 5.48 ± 1.3 mL in the DR-CIVAS group, and 4.2 ± 1.3 mL in the control group, respectively. There was a statistically significant difference between the two groups ($P < 0.001$). Asymptomatic cement leakages occurred three cases in DR-CIVAS group with 5 locations (13.6%), leaking into the intervertebral disc space ($n = 2$), the puncture path ($n = 1$), and paravertebral space ($n = 2$), and five cases in control group with 7 locations (20.8%), with leaking into the intervertebral disc space ($n = 3$), puncture path ($n = 1$), and paravertebral space ($n = 3$).

The height restoration rate and reduction in wedge angle in the vertebral compression body were observed in DR-CIVAS group (32.3 ± 13.1%; 5.68 ± 5.2°) and control group (32.5 ± 13.3%, 5.83 ± 5.3°). Differences in cement leakages, the height restoration rate, and reduction in wedge angle in the vertebral compression body between two groups were not significant ($P = 0.4$, 0.95, 0.93). There was a significant decrease in the VAS scores in both groups at 1 week, 1 month, 3 months, and 6 months after the procedure, from a mean of 7.9 to a mean of 4.4, 4.2, 3.6, and 3.1 ($P < 0.001$) in the DR-CIVAS group and from a mean of 7.9 to a mean of 4.3, 4.2, 3.7, and 3.2 ($P < 0.001$) in the control group. However, there was no statistically significant difference between the two groups in the VAS scores (Table 2). Of the 22 patients in DR-CIVAS group, the subsequent fractures occurred in 2 cases (9.1%) located in the nonadjacent levels. One case was diagnosed at 3 months follow-up and the other one came to the hospital for back pain at 159 days after PVA. In the control group, the subsequent fractures occurred in 6 cases (25.0%) located in the adjacent level ($n = 1$, found at 3 months) and the augmented levels ($n = 5$), among whom 2 cases were found at 1 month follow-up, 1 case at 3 months follow-up, 1 case at 178 days after PVA, and 1 case at 254 days after PVA (Fig. 4). Although DR-CIVAS

**Table 1** Patient characteristics and treated vertebral levels of the two groups

| Characteristic | DR-CIVAS ($n = 22$) | Control ($n = 24$) | *P* value |
|---|---|---|---|
| Age, years (mean ± SD) | 79.7 ± 2.7 | 78.5 ± 2.4 | c |
| Male/female (NO.) | 10/12 | 10/14 | 0.96 |
| BMD (T-score) | − 3.4 ± 1.6 | − 3.5 ± 1.1 | 0.78 |
| Baseline VAS score | 7.9 ± 1.5 | 7.9 ± 1.4 | 0.94 |
| Bisphosphonate use | 18 (81.8%) | 19 (79.2%) | 0.95 |
| Treated vertebral level | | | |
| T10 | 1 | 0 | |
| T11 | 0 | 1 | |
| T12 | 6 | 7 | |
| L1 | 7 | 8 | |
| L2 | 4 | 4 | |
| L3 | 2 | 2 | |
| L4 | 2 | 2 | 0.91 |

Values in parentheses are percentages and patient numbers. *DR-CIVAS* drill rotation (DR) with cement injection under vacuum aspiration (CIVAS), *VAS* visual analog scale, *BMD* bone mineral density

**Table 2** Clinical outcomes of the two groups

| Outcome | DR-CIVAS ($n = 22$) | Control ($n = 24$) | $P$ value |
|---|---|---|---|
| Cement volume (mL) | 5.48 ± 1. 3 | 4.17 ± 1.3 | 0.001* |
| Cement leakage | 3 (5) | 5 (7) | 0.4 |
| Intervertebral disc space | 2 | 3 | |
| Puncture path | 1 | 1 | |
| Perivertebral space | 2 | 3 | |
| Height restoration rate (%) | 32.3 ± 13.1 | 32.5 ± 13.3 | 0.95 |
| Wedge angle correction | 5.68 ± 5.2 | 5.83 ± 5.3 | 0.93 |
| Subsequent fractures | 2 | 6 | 0.25 |
| Adjacent level | 0 | 1 | |
| Nonadjacent level | 2 | 0 | |
| Augmented level | 0 | 5 | 0.04* |
| VAS score | | | |
| Pre-procedure | 7.9 ± 1.5 | 7.9 ± 1.4 | 0.94 |
| Post-procedural follow-up | | | |
| 1 week | 4.4 ± 1.3 ($n = 22$) | 4.3 ± 1.3 ($n = 24$) | 0.85 |
| 1 month | 4.2 ± 1.3 ($n = 22$) | 4.2 ± 1.3 ($n = 24$) | 0.95 |
| 3 months | 3.6 ± 1.2 ($n = 19$) | 3.7 ± 1.2 ($n = 18$) | 0.93 |
| 6 months | 3.1 ± 1.0 ($n = 19$) | 3.2 ± 1.1 ($n = 18$) | 0.88 |

Values in parentheses are patient numbers and cement leakage locations. *DR-CIVAS* drill rotation (DR) with cement injection under vacuum aspiration (CIVAS), *VAS* visual analog scale, *BMD* bone mineral density

*Significant at $P < 0$ .05

group did not demonstrate a statistical reduction of the incidence of subsequent fractures ($P = 0.25$), the subgroup analysis revealed that subsequent fractures frequently involved the augmented level in the control group ($P = 0.04$).

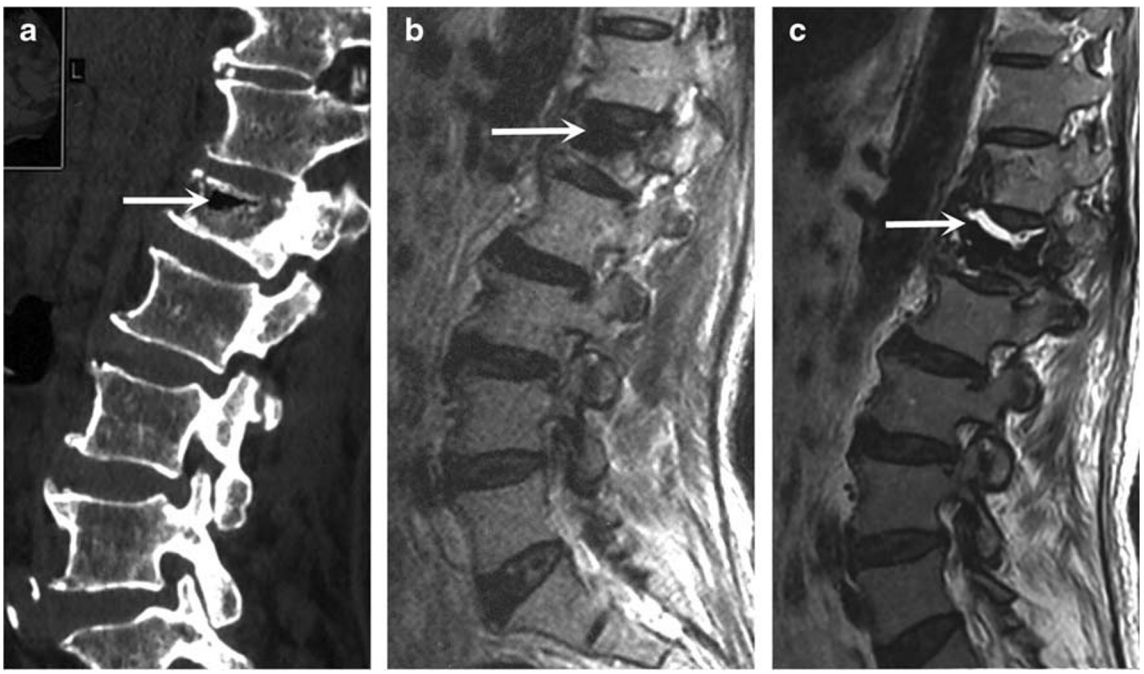


**Fig. 4** A 72-year-old woman with a subsequent compression fracture at L1 with a cleft. **a** Preoperative CT with sagittal reformation shows a compression fracture at L1 with a cleft (arrow). **b** Postoperative STIR T2-weighted MR image obtained 7 days after treatment shows the treated L1 vertebral body without other fractures. **c** Postoperative T2-weighted MR image obtained 37 days after treatment recompression fractures at L1 level with a fluid sign of cleft in the interface between the cement and residual bone (arrow)

## Discussion

IVC signs of OVCFs have long been recognized in the imaging studies and considered to be pathognomonic of ischemic necrosis [14, 16, 17]. A study on IVC sign in the osteoporotic spine found that the IVC was covered with a fibrocartilaginous membrane [18]. As previously reported, IVC may create instability within the fractured vertebral body, which usually causes severe back pain that refractory to conservative treatments such as bed rest and medication [19, 20]. It is, therefore, necessary to treat such patients by PVA to restore spinal stability and stop the progressive collapse of the affected vertebrae [5]. However, there have been reported high incidences of subsequent vertebral compression fractures, including the fractures in the augmented level after PVA during long-term follow-up in patients with OVCFs with IVC [7, 8, 21]. Heo et al. [7] reported that 6 out of 21 patients suffered a recollapse of the augmented vertebrae. Kim and Rhyu [8] reported that 10 out of 24 patients with IVC had a recollapse. It was speculated that the distribution pattern of cement might be an important predisposing factor. It was also possible that the fibrocartilaginous membrane at the periphery of the IVC prevented cement being interdigitated with the surrounding cancellous bone. Thus, cement was injected into the cleft in a solid lump rather than being contiguously interdigitated. Consequentially, the load did not transfer through the non-cemented bony area and caused a stress-shielding effect, leading to the subsequent fractures of the augmented vertebrae.

In order to decrease the subsequent fractures in the non-augmented level and augmented vertebrae, Lane et al. [14] recommended that cement injected should fill the IVC area completely to maximize the stability of fractured fragments. However, larger cement volume could increase the risk of cement leakage and tend to result in the subsequent fracture [5]. Koike et al. [11] developed a method of cement injection by vacuum aspiration (CIVAS) under cleft decompression. The vacuum aspiration enabled cleft content removal for sufficient interdigitation between the cement and residual bone, allowing sufficient cleft filling with cement without putting excess pressure to reduce the risk of cement leakage. However, the fibrocartilaginous membrane at the periphery of IVC did not break and had a similar incidence of the subsequent fractures in the non-augmented level and augmented vertebrae between the CIVAS group and the control group. We, therefore, considered that interdigitation with the surrounding cancellous bone was still insufficient when the CIVAS technique was adopted.

Cement leakage and subsequent fractures are common complications of PVA. Krauss [22] reported that cement leakage occurred in 18.2% of patients with painful OVCFs with IVC sign, and we found a similar incidence. There was no significant difference in cement leakage rate between DR-CIVAS and control groups (13.6%, 20.8%, respectively), although the amount of cement injected in DR-CIVAS group was significantly larger than that in the control group ($P = 0.001$). When comparing the incidence of subsequent fractures after PVA by different techniques, we found that the DR-CIVAS group showed lower but not statistical subsequent fractures than that of the control group (9.0% vs. 25.0%). The non-significant statistical difference between the two groups ($P = 0.15$) may be explained by the limited number of patients included in the study. Further analysis demonstrated that the incidence of subsequent fractures in DR-CIVAS group, at the augmented level, was significantly lower than that in the control group. Of the 22 patients in DR-CIVAS group, the subsequent fractures occurred in 2 cases (9.1%) located in the non-adjacent levels. Of the 24 patients in the control group, the subsequent fractures occurred in 6 cases (25.0%) located in the adjacent level ($n = 1$) and the augmented level ($n = 5$). In this study, we adopted DR-CIVAS technique in which the drill rotation (DR) could partly break the fibrocartilaginous membrane on the interface of the cleft and residual bone, and communicate with IVC and the peripheral residual bone area. It could allow the cement to be more interdigitated between in the IVC and the surrounding cancellous bone, and CIVAS under cleft decompression with sufficient IVC filling of cement without putting excess pressure. This might explain the significantly lower incidence of subsequent fractures in the augmented level with DR-CIVAS technique and a similar incidence of cement leakage in DR-CIVAS and control groups.

Our study demonstrated the efficacy and safety of DR-CIVAS technique in OVCFs with IVC. We found that, compared with the IVC filling pattern of cement by the traditional technique, the interdigitated and IVC sufficient filling with cement by DR-CIVAS technique improves the stability of the augmented vertebral body, causing less the subsequent fractures and better clinical outcomes at clinical follow-up. In theory, kyphoplasty can also breach the fibrocartilaginous tissue theoretically. However, the cavity caused by the inflated balloon also leads to compressed trabecula, which might prevent the cement expanding into the surrounding cancellous bones.

However, our study has some limitations. First, we did not evaluate the sizes of clefts and matched between the two groups. Second, the follow-up time was only 6 months, which possibly affected our results. Third, the study was retrospectively performed and not randomized. Fourth, as we could detect blood clots during fluoroscopy, it is hard to analyze the impact on cement injection. Fifth, we would expect bone marrow edema following PVA. As we only perform MRI, if there was recurrent back pain, we did not analyze the discrimination between post-interventional and new traumatic edema. Six, the small number of patients in both groups is another factor influencing the reliability of the results. A prospective study with a larger number of patients and longer-term follow-up is needed to verify the conclusion.

## Conclusion

Our study showed that PVA techniques are feasible and effective for OVCF patients with IVC sign. In comparison with the traditional technique used in PVA, the DR-CIVAS technique can result in a lower incidence of refractures at the augmented vertebra.

### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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