



# Cement leakage in osteoporotic vertebral compression fractures with cortical defect using high-viscosity bone cement during unilateral percutaneous kyphoplasty surgery

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#### Abstract

The purpose of this study was to investigate cement leakage (CL) in osteoporotic vertebral compression fractures (OVCFs) with cortical defect using high-viscosity bone cement during unilateral percutaneous kyphoplasty (PKP) surgery.

This study included a series of 77 patients (23 males, 54 females) with single level osteoporotic vertebral body fracture (OVCF) who underwent unilateral PKP in our hospital. Preoperative x-ray, computed tomography (CT) scan, and 3-dimensional reconstructions were studied. During the PKP procedure, needle was carefully put to avoid too near to the cortical defect according to CT image. High-viscosity bone cement was used via unilateral PKP. Radiographic outcomes were evaluated by assessment of vertebral body wall breakage, fracture type, and vertebral body change. The exact rate of CL was analyzed.

A total of 77 patients with single-level OVCF were included in this study. The mean age of the patients was  $74.8 \pm 8.0$  years. Among these cases, 7 (9.1%) involved the thoracic spine (T3–T10), 60 (77.9%) involved the thoracolumbar spine (T10–L2), and 10 (13.0%) involved the lumbar spine (L3–L5). There were 27 vertebral bodies found posterior wall breakage, 51 vertebral bodies found endplate breakage, and 49 vertebral bodies found anterior-lateral wall breakage. CT scan was more efficient in detecting vertebral body wall breakage and CL than x-ray (P < .001). No neurological symptoms were found after surgery. Both cases with CL (CL group) and cases without cement leakage (NCL group) experienced vertebral height restoration (HR) with similar cement volume CV. There were no significant difference between the two groups about the parameter HR and CV. Severe vertebral body fracture and biconcave fracture had more CL than other groups. OVCF cases with cortical defect had more CL rate than those without cortical defect; however, no significant difference was found in the correlation between vertebral wall breakage and CL.

Cortical defect remains a potential risk of CL during PKP surgery. Careful preoperative evaluation and using high-viscosity bone cement during the unilateral PKP procedure could prevent serious leakage and clinical symptoms.

**Abbreviations:** CL = cement leakage, NCL = non-cement leakage, OVCF = osteoporotic vertebral compressed fractures, PKP = percutaneous kyphoplasty, VBW = vertebral body wall.

Keywords: breakage, fracture, kyphoplasty, osteoporosis, vertebral body wall

# 1. Introduction

Osteoporosis-associated fractures are becoming more and more common nowadays<sup>[1]</sup>; the prevalence of osteoporotic vertebral

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compression fracture (OVCF) in China is increasing from 5% in women in their 50s to 37% and even more when older than 80 years.<sup>[2]</sup> Because of OVCF, patients suffered from severe chronic pain, deformity, compromised mobility, weakening pulmonary function, and increased mortality.<sup>[3,4]</sup> Many minimally invasive procedures like percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) have been increasingly prescribed to patients who are irresponsible to conservative treatments and achieve satisfied results. Generally, these procedures are safe, but there are also certain related complications.

Cement leakage (CL) is one of the major complications, which may cause severe consequence such as remote organ embolism or local chemical or compress symptoms.<sup>[5–7]</sup> Cement leaking into the disc is found to increase the risk of new fractures of adjacent vertebral bodies.<sup>[8]</sup> In OCVFs with compromised vertebral body walls, the risk seemed to be higher as surgical maneuvers may further aggravate cortical fragments. The polymethylmethacrylate (PMMA) could leak from vertebral body deficiencies, fracture of the cortex, or through vertebral venous system. Many previous reports also suggested vertebral body cortex fracture as a risk factor to cause CL in PVP.<sup>[6,9–11]</sup> So it is important for clinicians to pay more attention to the defect of the cortex to prevent the leakage. There are various factors that can effectively reduce the incidence of CL, including timing, injection volume, and so on. If the surgery is delayed, leakage through a

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cortical defect is also less frequent. Unilateral PKP can reduce the risk of puncture and leakage than bilateral PKP. It also can easily control the needle position and avoid too near the crack of the cortical wall. High-viscosity cement is thought to be associated with low leakage rates and volumes. However, there are scarce reports investigating the relationship between cortical defect and leakage when using high-viscosity cement during unilateral PKP procedure. Moreover, most of these studies were based upon x-ray or magnetic resonance imaging (MRI), which showed inferior in identifying bony injuries compared to CT,<sup>[12]</sup> as preoperative CT is now becoming a routine examination for PKP surgical procedure. Vertebral cortical walls, endplate, and pedicle breakages as well as tiny CL can be clearly detected through CT scans and 3-dimensional reconstruction.

The purpose of this study was to investigate the relationship between CL and cortical defect when using high-viscosity cement during unilateral PKP through a CT-based method.

#### 2. Materials and methods

#### 2.1. Patients

From January 2013 to December 2015, 77 consecutive patients with unrelieved back pain who were diagnosed with osteoporotic fractures and underwent surgery in our hospital were included in this study. Inclusion criteria were first-time, single-level osteoporosis fracture patients, who failed conservative treatment at least 4 weeks. Diagnosis was further confirmed by CT and hyperintense signals in the vertebra through MRI T2-weighted images and fat-suppressed short tau inversion recovery images. Exclusion criteria were pathologic fractures and fractures after any previous surgical treatments. Patients having undergone open surgical procedures were also excluded.

#### 2.2. Clinical assessments and surgical procedures

Preoperative and postoperative clinical evaluations were performed by the surgeon who perform the surgery. Preoperative x-ray and CT scan were carefully studied. Preoperative vertebral body wall breakage was recorded. All the patients underwent unilateral PKP procedure. The needle was carefully positioned to avoid to be too near the cortical defect according to the preoperative CT image. Balloon inflation and high-viscosity cement injection were carefully done under the fluorescence. All patients underwent a postoperative CT scan within a week after surgery. If the patients had chest symptoms or pulmonary embolism was suspected during the operation, chest x-ray was prescribed.

### 2.3. Radiographic evaluations

Two spine surgeons independently evaluated the pre- and postoperative x-ray and CT scan. The fracture was classified according to Genant et al<sup>[13]</sup> as wedge, biconcave, and crush. Each type was subdivided into mild (20%-25%), moderate (26%-40%), and severe (>40%) by the percentage of vertebral body collapse. Preoperatively, the vertebral body wall integrity was carefully examined through both CT and x-ray. Cortical defect was further divided into anterior-lateral cortical defect, posterior cortical defect and endplate defect. Radiographic features of cases with CL (CL group) and cases without CL (NCL group) were compared. The occurrence of CL was evaluated by x-ray and CT scan within a week immediately postoperatively. CLs were measured as a proxy for leakage volume according to Capel et al and Tome-Bermejo et al.<sup>[14,15]</sup> Briefly, type B was defined as leaking through basivertebral vein, type S was through the segmental vein, type C through a cortical defect, type D through intradiscal leakage. Intradiscal leakage was further divided into upper endplate leakage and lower endplate leakage. The direct relationship between the leakage and cortical defect was also studied.

#### 2.4. Statistical analysis

All data were presented as the mean value±standard deviation (SD). Continuous data were compared between 3 groups using student *t* test. Discontinuous data were analyzed using  $\chi^2$  test, with a *P* value <.05 considered to be statistically significant. Wilcoxon rank test was used to compare delta CL and NCL. Statistics analysis was performed using SPSS software package version 21 (SPSS Inc, Chicago, IL).

### 3. Results

There were 23 male patients and 54 female patients in this case series. The mean age of the patients was  $74.8\pm8.0$  years. Among the 77 cases, 7 cases (9.1%) involved the thoracic spine (T3–T10), 60 cases (77.9%) involved the thoracolumbar spine (T10–L2), and 10 cases (13.0%) involved the lumbar spine (L3–L5). Preoperative data were summarized in Table 1. After operation, patients with or without CL both experienced vertebral height restoration, and no significant difference was found between the 2 groups (Table 2). The cement volume in CL group was  $3.48\pm1.00$  mL and in NCL group was  $3.64\pm1.17$  mL, which also showed no significant difference between the 2 groups.

Preoperative x-ray and CT scan were carefully examined to detect the fractured vertebral wall deficiency. Table 3 showed the relationship between vertebral wall breakage and CL distribution. CT scan was more efficient in detecting vertebral body wall breakage than x-ray (P < .001), and the cortical breakage was found most in thoracolumbar area. In patients with posterior VBW break, we only found 1 CL case direct leaking through the crack accordingly, whereas in upper endplate break patients, we found 9 CL cases leaking through the crack.

| Number of Patients             | 77       |
|--------------------------------|----------|
| Sex                            |          |
| Male                           | 23       |
| Female                         | 54       |
| Mean age                       | 74.8±8.0 |
| Location of fracture vertebrae |          |
| Thoracic                       | 7        |
| Thoracolumbar                  | 60       |
| Lumbar                         | 10       |
| Fracture type                  |          |
| Wedge                          | 37       |
| Biconcave                      | 32       |
| Crush                          | 8        |
| Severity                       |          |
| Mild (20%–25%)                 | 41       |
| Moderate (26%-40%)             | 19       |
| Severe (>40%)                  | 17       |
| Presence of cleft in MRI       | 10       |

MRI = magnetic resonance imaging.

Table 2

Pre-and postoperative vertebral height change and cement volume.

| i io ana | pooloporativo vorte | brai noight change |                | 01            |       |                 |      |
|----------|---------------------|--------------------|----------------|---------------|-------|-----------------|------|
|          | Factors             | Preop              | Postop         | Delta         | Р     | Cement volume   | P    |
| CL       | AVB height          | $21.6 \pm 5.2$     | 23.2±4.7       | $1.8 \pm 3.5$ | .631  | $3.48 \pm 1.00$ | .565 |
|          | PVB height          | 28.3±4.5           | 28.4±4.2       | $0.9 \pm 3.3$ | 1.000 |                 |      |
| NCL      | AVB height          | $19.6 \pm 5.0$     | 21.4±4.7       | $1.6 \pm 3.1$ | _     | $3.64 \pm 1.17$ |      |
|          | PVB height          | $28.0 \pm 4.9$     | $28.9 \pm 4.7$ | 0.1 ± 3.1     |       |                 |      |

AVB = anterior vertebral body, CL = cement leakage, Delta = postop-preop, NCL = non cement leakage, P' = cement volume comparison of CL and NCL, P=Wilcoxon rank test of delta CL and NCL, Postop = postoperation, Preop = preoperation, PVB = posterior vertebral body.

# Table 3 Vertebral wall breakage and accordingly cement leak distribution.

| Posterior wall break (N) | CT | Х  | CT-X | Р     | Cement leak |
|--------------------------|----|----|------|-------|-------------|
| Thoracic                 | 3  | 0  | 0    |       | 0           |
| Thoracolumbar            | 23 | 2  | 2    |       | 8           |
| Lumbar                   | 1  | 0  | 0    |       | 1           |
| Summary                  | 27 | 2  | 2    | <.001 | 9 (1)       |
| Upper endplate break (N) |    |    |      |       |             |
| Thoracic                 | 2  | 0  | 0    |       | 1           |
| Thoracolumbar            | 24 | 14 | 11   |       | 4           |
| Lumbar                   | 5  | 5  | 2    |       | 4           |
| Summary                  | 31 | 19 | 13   | .001  | 9 (9)       |
| Lower endplate break (N) |    |    |      |       |             |
| Thoracic                 | 0  | 0  | 0    |       | 0           |
| Thoracolumbar            | 18 | 4  | 4    |       | 2           |
| Lumbar                   | 2  | 2  | 2    |       | 0           |
| Summary                  | 20 | 6  | 6    | .003  | 2 (1)       |

Cement leak=checked by CT, number in brackets meant leak from direct vertebral wall breakage, CT=computed tomography results, CT-X=CT and x-ray simultaneously, X=x-ray results.

According to the basis of the postoperative CT data, 39 (50.6%) patients of the 77 treated cases were detected as having CL. None of the CL gave rise to clinical symptoms such as nerve injury, pulmonary embolism, and so on. The most common place of CL was anterior-lateral vertebra body wall breakage following with upper endplate breakage, following anterior-lateral wall breakage. We further studied the correlation between VBW breakage and CL using  $\chi^2$  test. No significant difference was difound between VBW breakage and CL (Tables 4 and 5).

CL and fracture type are summarized in Table 6. The relationship between each group showed no significant difference. However, CL rate in different type of fracture was similar (37.5%–58.8%). Severe vertebral body fracture had more CL than other groups, whereas in mild vertebral fracture group, there was more CL (type S, B) fracture than other groups. Accordingly, in biconcave group, there were more CL than the other groups, whereas in wedge group, there were more CL (type S, B).

#### 4. Discussion

OCVFs are often associated with peripheral vertebral wall breakage, which are thought to increase the risk of CL during the surgery.<sup>[8,16]</sup> As osteoporosis increases the vulnerability of vertebral bone structure, inflation of balloon when performing

|                         |       | CL summary |       |          |      |
|-------------------------|-------|------------|-------|----------|------|
|                         | Yes   | No         | %     | $\chi^2$ | Р    |
| Upper endplate break    | (     |            |       |          |      |
| Yes                     | 5     | 26         | 16.1% | 0.402    | .526 |
| No                      | 4     | 42         | 8.7%  |          |      |
| Lower endplate break    | <     |            |       |          |      |
| Yes                     | 1     | 19         | 5%    | 0.541    | .462 |
| No                      | 1     | 56         | 1.8%  |          |      |
| Anterior-lateral wall b | oreak |            |       |          |      |
| Yes                     | 11    | 38         | 22.4% | 0.326    | .568 |
| No                      | 4     | 24         | 14.3% |          |      |
| Posterior wall break    |       |            |       |          |      |
| Yes                     | 1     | 26         | 3.7%  | 2.237    | .135 |
| No                      | 7     | 44         | 13.7% |          |      |

CL = cement leakage.

Table 4

## Table 5

Relationship between type S and type B leakage and vertebral body wall breakage.

|               | Cement leak (type S, B) | VBW | Endplate | χ <b>2</b> | Р    |
|---------------|-------------------------|-----|----------|------------|------|
| Thoracic      | 1                       | 1   | 0        |            |      |
| Thoracolumbar | 10                      | 8   | 7        |            |      |
| Lumbar        | 3                       | 2   | 3        |            |      |
| Summary       | 14                      | 11  | 10       | 0.088      | .767 |

Endplate = include upper and lower endplate, VBW = vertebral body wall including anterior, lateral, and posterior.

PKP may further displace the fractured fragment, and consequently result in CL. Although most cases with CL were asymptomatic, CL in vertebral canal or foramen could lead to neuro symptoms. It is thought CL resulted in vertebral body wall damage can be prevented by meticulous evaluation, careful manipulation, and appropriate precautionary measures.<sup>[17]</sup> In the present study we tried to study whether driving needle away from the crack and using high-viscosity cement can prevent CL in cortical defect cases. In this cohort, the correlation between preoperative vertebral body wall breakage and CL was not significant (P > .05).

The incidence of CL in our study was 50.6% through the postoperative CT scan, which was similar to the previous report.<sup>[15,18]</sup> From CT scan and 3-dimensional reconstruction images, it is easy to detect vertebral wall deficiency exactly that is hard to find on x-ray. Theoretically, it is safer to drive the needle away from the crack; preoperative CT scan could help to decide a more appropriate surgical site. The leakage rate may also be related with the vertebral body height reduction and cement volume. In this study, the vertebral body height difference and cement volume between CL group and NCL group were not significant.

This study also proved CT scan was more sensitive to detect cortical breakage than x-ray (P < .001), especially in posterior vertebral body wall breakage (27:2). Although preoperative CT scan detected cortical breakages in more cases, we did not find a correspondingly increased CL postoperatively. It was because the needle was usually put more anterior to avoid leakage to the canal when posterior wall breakage was detected. Among the cortical breakage-related CL, the upper endplate breakage had highest CL rate (29%, 9/31), whereas posterior wall breakage had the least CL (3.7%, 1/27). This was a little different with previous study that broken posterior wall related with higher rate of CL into the spinal canal.<sup>[5]</sup> It was because the maneuver to reduce fracture by inflating the balloon might further damage the fragile broken upper endplate, especially through transpedicle approach. Also CL through endplate cortical disruption may be very quick that it can be hard to stop.<sup>[16]</sup> When a breakage was found in posterior wall, surgeons would try to insert the trocar and balloon more anteriorly and far away from the crack to avoid CL. Further study was done to analyze the relationship between preoperative vertebral body wall breakage and postoperative cortical CL; however, no significant difference was detected between cortical breakage and CL rate.

Relationship between CL and fracture type and severity was also studied in this cohort. Severe fracture and biconcave type both had higher leakage rate, which was similar to Ding et al's result.<sup>[11]</sup> As in these cases, it is very hard to drive the needle away from the cortical defects. However, none of the leakage incidents were symptomatic. Driving the needle away from the defect of

| Table 6      |         |                |              |       |
|--------------|---------|----------------|--------------|-------|
| Relationship | between | cement leakage | and fracture | type. |

|           | Cement leakage |    |       |               |            |      |
|-----------|----------------|----|-------|---------------|------------|------|
| Severity  | Yes            | No | Total | Summary       | χ <b>2</b> | Р    |
| Severe    | 10 (8)         | 7  | 17    | 58.8% (10/17) |            |      |
| Moderate  | 9 (7)          | 10 | 19    | 47.3% (9/19)  |            |      |
| Mild      | 20 (10)        | 21 | 41    | 48.8% (20/41) | 0.594      | .743 |
| Туре      |                |    |       |               |            |      |
| Wedge     | 18 (10)        | 19 | 37    | 48.6% (18/37) |            |      |
| Biconcave | 18 (14)        | 14 | 32    | 56.3% (18/32) |            |      |
| Crush     | 3 (2)          | 5  | 8     | 37.5% (3/8)   | 1.021      | .600 |

Number in brackets meant leak from direct vertebral wall breakage.

vertebral body may provide some safety distance for cement spread and avoid leaking. In this cohort, the most common site of CL was the paraspinal soft tissue, which also agrees with previous reports.<sup>[15,18]</sup> The second most common site of CL was the upper endplate, as most fracture happened there. But we did not find correlation between fracture severity (or type) and CL. Appropriate needle position could result a safe place to inflate the balloon and consequent using high-viscosity cement could reduce leakage.

However, this study also had limitations. Owing to the retrospective design of this study, we did not set low viscosity cement treatment group as control. This study just observed and compared the results of dealing OVCF with cortical defect with high viscosity cement during unilateral PKP. Another limitation was that the cement could leak from several pathways; this study only focused on leaking from cortical defect.

In conclusion, there were more vertebral body wall breakages than expected from preoperative CT scan and 3-dimensional reconstruction. Careful preoperative evaluation and using highviscosity cement during the unilateral PKP procedure could prevent serious leakage and clinical symptoms.

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