

Percutaneous kyphoplasty for osteoporotic vertebral compression fractures via unilateral versus bilateral approach

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Research article

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Abstract

Objective To evaluate the efficacy of percutaneous kyphoplasty (PKP) for thoracolumbar osteoporotic vertebral compression fractures (OVCFs) via unilateral versus bilateral approach.

Methods All patients who underwent PKP surgery for OVCFs in our hospital between June 2016 and December 2018 were included in this study. The pedicles were divided into two groups according to the manner of vertebral body puncture, which were as follows: unilateral pedicle puncture group (unilateral group, n=47) and bilateral pedicle puncture group (bilateral group, n=39). The operative time, amount of cement perfusion, correction angle of kyphosis, pain score before and after surgery, and leakage rate of bone cement were evaluated in all patients. The average follow-up was 19 months (range 13-34 months).

Results The average age of patients who met the inclusion criteria, but not the exclusion criteria, was 76 years, and a total of 121 vertebral bodies were studied. There were 7 cases of postoperative bone cement leakage (unilateral group, 14.9%) and 6 cases of postoperative bone cement leakage (bilateral groups, 15.4%). There were differences in operative time and amount of cement perfusion between the two groups were statistically significant ($P < 0.05$). There was no significant increase in age, body mass index, pain index during follow-up, treatment outcome, correction angle of kyphosis, and cement leakage rate between the two groups ($P > 0.05$). Moreover, there was no significant difference in sex and bone cement leakage rate between the two groups by Pearson χ^2 test ($P > 0.05$).

Conclusion Patients with OVCFs could obtain similar satisfactory clinical results via both unilateral and bilateral PKP approaches. However, the unilateral PKP approach is more advantageous as it has a shorter operative time, requires lesser cement volume, causes minimal trauma, is less costly, and results in lesser complications than the bilateral approach.

Background

Osteoporosis is a major public health problem characterized by loss of bone mass and increased skeletal fragility leading to the risk for OVCFs[1]. OVCFs are very common in the elderly, especially among women, and the incidence of OVCFs is approximately 1.4 million people per year[2, 3]. Moreover, 50% of postmenopausal women sustain mild to severe fractures as a result of osteoporosis[4]. OVCFs usually cause pain and deformities and can even lead to death in elderly populations[5, 6]. Most patients with OVCFs are managed with conservative treatments, including pain management, short periods of bed rest, and brace usage, but the pain caused by vertebral fractures may last for weeks or months.[7, 8] Moreover, symptoms of OVCFs could be improved successfully by conservative treatment,[9] but long-term clinotherapy causes various complications, such as early satiety, decreased self-esteem, mood disorder, and even increased mortality[9–11]. Some patients who fail conservative treatment may require hospitalization, long-term care, and surgical interventions[12]. Besides, the traditional open surgery is generally not recommended due to its high risk of hardware failure in patients with osteoporosis[13].

Today, PKP is a widely used procedure for the treatment of OVCFs[14, 15]. OVCFs are an important health issue for which minimally invasive techniques are a feasible treatment. Percutaneous cement augmentation techniques, such as the injection of polymethyl methacrylate (PMMA) into the fractured vertebral body, have shown effectiveness in terms of early pain relief and relatively low complications[16–18]. Minimally invasive spine surgeries, including percutaneous kyphoplasty (PKP) and percutaneous vertebroplasty (PVP), have been widely used for vertebral augmentation in patients with OVCFs.[19–21] In 1994, Ducp Lesnel first applied PVP for the treatment of osteoporotic vertebral fractures. In 1998, Dudeney et al. first utilized an expandable balloon to correct vertebral kyphosis on the basis of PVP, the initial PKP was developed[22]. A recent meta-analysis showed that both PKP and PVP could obtain satisfactory clinical results for the treatment of OVCFs, but PKP had a lower cement leakage rate and better kyphotic angle[20]. Another two studies involving a large sample size showed that PKP was superior to PVP in terms of overall survival rate, total costs, and decreased mortality risk in patients with OVCFs[23, 24]. Hence, more surgeons choose PKP for the treatment of OVCFs[25–27].

However, PKP for OVCFs could be divided into unilateral and bilateral approaches. Until now, there is still no consensus on the optimal approach. Our aim is to evaluate the efficacy of PKP for thoracolumbar OVCFs via unilateral versus bilateral approach.

Methods

General information

This retrospective study included 86 patients (31 female and 55 male, average age: 76 years (61-88 years)) who underwent PKP surgery for thoracolumbar OVCF in our hospital between June 2016 and December 2018. Indications for PKP included recent fractures with pain resistant to analgesics for at least 3 weeks, as per a Visual Analog Scale (VAS) score of >5 points and a kyphotic deformity >15°. Patients with neurological deficits, collapse rate >90%, unstable fractures, bleeding disorders, or any systemic or spinal infections were excluded. All PKP operations are performed by a doctor with more than 5 years of spine surgery experience. The surgical method according to the requirements of the patient and were divided into the following groups according to the manner of vertebral body puncture: unilateral pedicle puncture group (unilateral group) and bilateral pedicle puncture group (bilateral group). The average body mass index (BMI) of unilateral group was $23.10 \pm 3.8 \text{ kg/m}^2$ and that of the bilateral group was $23.02 \pm 3.7 \text{ kg/m}^2$ (Table 1). The average follow-up period was 19 months (13 to 34 months).

Surgical technique

For preoperative routine thoracic and lumbar spine X-ray, magnetic resonance imaging (MRI), and computed tomography (CT) examinations, the body was checked carefully, especially the vertebral body, to exclude malignant tumors, infections, obvious spinal stenosis, incomplete wall of the vertebral body, and so on. Preoperative imaging data are shown in Figure 1. Preoperatively, patients underwent administration of general anesthesia and were placed in prone position. Chest and ankle bolsters were

used for spinal over-extension to facilitate vertebral body reduction. C-arm X-ray machine fluoroscopy with Kirschner wire was performed to determine the puncture position. Conventional disinfection drape was applied. Then, percutaneous puncture under fluoroscopy was performed by inserting the needle at the 10 to 11 o'clock position in the left pedicle and at the 1 to 2 o'clock position in the right pedicle. When the tip of the needle reached the trailing edge of the vertebral body slightly forward, the working pin was inserted along the guide pin to the front of the posterior edge of the vertebral body by 5 mm. Then, the balloon channel was drilled through the sleeve and inserted into the balloon. The ideal position of the balloon should be within the first 1/3 of the vertebral body. The contrast agent was injected under fluoroscopy, and the balloon was slowly expanded until the height of the vertebral body was restored or the balloon was satisfactory. The injection of the contrast agent was stopped when the upper and lower endplates of the vertebral body met. The balloon pressure generally does not exceed 250 psi. The contrast agent and the balloon were withdrawn. The bone cement (acrylic resin bone cement) was stirred to the drawing stage. A push tube was used to inject the bone cement into the vertebral body. The typical amount of bone cement used in unilateral puncture was approximately 3 to 4.5 ml, and that used in bilateral puncture was approximately 4 to 6.5 ml. The position of the bone cement was verified by fluoroscopy. After the bone cement was dried, the working sleeve was removed and the needle eye was wrapped. The surgical method is shown in Figure 2. At the same time that patients received antibiotics to prevent infection and anti-osteoporosis treatment, they were mobilized to get out of bed early to exercise.

Clinical effects and imaging evaluation

The operative time and the amount of cement perfusion were recorded. The visual analog scale (VAS) was used to assess pain intensity before and after surgery to determine the clinical efficacy and recovery. X-ray radiographs were taken to determine fracture vertebral body reduction, local kyphosis angle, and presence of bone cement leakage. Measurements are shown in Figure 3. VAS scores and X-ray images (Figure 4) during follow-up were assessed to evaluate the treatment effect. All patients were followed up in the outpatient clinic after discharge, and the X-ray radiographs of the lumbar spine were reviewed.

Statistical methods

Statistical analysis was performed using the SPSS 19.0 software (SPSS, Inc., Chicago, IL, USA). The measurement data were expressed as mean \pm standard deviation ($\bar{x} \pm s$). Student's t-test and Chi-square test was used to analyze the differences between the two groups. $P < 0.05$ was considered statistically significant.

Results

Among the 86 patients (121 vertebral bodies) analyzed, 39 patients had a history of significant trauma. Fifty-six, 25, and 5 cases had single-, double-, and three-segment vertebral fractures, respectively. Twenty-one, 42, 37, and 16 cases involved the T11, T12, L1, and L2 segments, respectively. The history of low back pain ranged from 7 days to 12 weeks. The unilateral group consisted of 47 cases (51 vertebral bodies), whereas the remaining patients were categorized into the bilateral group. All patients underwent

pedicle puncture, balloon dilatation, bone cement filling, and intraoperative fluoroscopy. Postoperative X-ray radiographs showed that the cement was diffused across the midline of the vertebral body. When comparing the two groups, the operative time and amount of cement perfusion were statistically significantly different between the two groups ($P < 0.05$). There were no statistical differences with respect to sex, age, mean BMI, and preoperative VAS score ($P > 0.05$), consistent with the findings of Rebolledo et al. [25] (Table 2).

There were 7 cases of cement leakage in the unilateral group (4 cases of paraspinal vein and paravertebral leakage, 2 cases of leakage into the intervertebral disc, and 1 case of slight leakage into the spinal canal; Figure 5a-c.), with an incidence rate of 14.9%. In the bilateral group, there were 6 cases of cement leakage (3 cases of leakage along the paraspinal vein and paravertebral space, 2 cases of leakage into the intervertebral disc, and 1 case of slight leakage into the spinal canal), with an incidence rate of 15.4%. These complications are consistent in PVP and PKP [28]. In addition, there was no significant difference in the bone cement leakage rate between the two groups according to Pearson χ^2 test results ($P > 0.05$) (Figure 5d).

Discussion

Domestic and foreign scholars have confirmed the good therapeutic effect of PKP on OVCFs.[10, 11] Some authors concluded that the use of PMMA is an effective and safe surgical technique for the management of osteoporosis-related vertebral fractures (AO type A), with good clinical outcomes and low complications rates.[4] Meanwhile, PKP is effective for restoring vertebral body height and correcting kyphosis and has several advantages of being minimally invasive and safe, offering rapid pain relief, and involving simple manipulation techniques.[14, 15] However, PKP for OVCFs could be divided into unilateral and bilateral approaches. Until now, the best treatment option is still controversial for symptomatic OVCFs without neurological deficits. As it is known, traditional PKP utilizes the bilateral transpedicular approach, which has problems, such as long operative time and exposure of the operators and patients to large amount of radiation. Many scholars have proposed the unilateral approach and have carried out related research. Steinmann[29] found that the unilateral transpedicular approach to the bone cement improves the biomechanical properties of the vertebral body and the repair effect on the height of the vertebral body and bilateral vertebrae. Song et al.[30] reported that the improvement of VAS score was better in the unilateral group than in the bilateral group. Some authors[31] concluded that patients with OVCFs could obtain similar satisfactory clinical results via both unilateral and bilateral PKP approaches, but when considering the shorter operative time, lesser cement volume, lower mean radiation dose of patients, lower cement leakage rate, and lesser surgery-related costs, choose the unilateral PKP approach, which was later confirmed in a large meta-analysis in 2018.[32] Nevertheless, Liu et al. found that PKP and bipedicular approach can help improve the cement distribution and reduce the epidural cement leakage rate; thus, they should preferred over PVP or unipedicular approach in OVCFs of the mid-thoracic vertebrae. Therefore, we designed a control group to study which surgical method is best.

Our retrospective study exhibited that both unilateral and bilateral PKP markedly improved the outcome of patients with OVCFs. This was reflected in considerable change in sex, age, BMI, VAS scores, and correction angle of kyphosis after treatment. However, no statistically significant differences were observed between the two groups. These results support that both unilateral and bilateral PKP were effective methods in the treatment of OVCFs.

In our study, the operative time and amount of cement perfusion doses to the patient are significantly different between the unilateral and the bilateral groups. We found that the unilateral group has shorter operative time and lesser bone cement volume than the bilateral group. Besides, this means that the unilateral approach was less costly than the bilateral group, which was confirmed in a recent meta-analysis [33]. According to the abovementioned results, unilateral PKP can effectively restore the height of the injured vertebrae, can correct the kyphosis, has shorter operative time, and can be easily performed. The contralateral bone density was increased via one-sided puncture balloon inflation. The unilateral puncture balloon inflation push increases the contralateral bone density. Although the amount of bone cement is less, it can effectively enhance the support force of the injured vertebra and achieve therapeutic effect. There was no significant height loss of the surgical vertebral body during the outpatient follow-up.

In this study, the cement leakage in the unilateral level was not obviously more than that in the bilateral level. These complications may be related to the puncture errors, unclear images, and incorrect timing of cement perfusion. Besides, the incidence of bone cement leakage is related to the severity of vertebral fracture and the volume of balloon dilation. Most scholars believe that once the bone cement leakage is found, it is necessary to stop the injection immediately. There is also a literature introduction to the initial push of the bone cement lumps. Even if the bone cement leakage tendency is found, as long as the external leakage is not within the 1/4 part of the posterior vertebral body, more bone cement filling can be obtained by continuing the injection. On average, injecting 4 ml of bone cement into each vertebral body resulted in pain relief, bone cement leakage, new vertebral fractures, and so on. The situation reaches an optimal balanced state.[30] Cement leakage was described in several studies [13, 25, 26, 34–37], which reported that the rate of cement leakage in the unilateral PKP approach was significantly lesser than that in the bilateral PKP approach consistent with the results of a recent meta-analysis found [32]. This is consistent with the results of our research.

This study has certain limitations. First, we enrolled a relatively small number of patients. Therefore, a consecutive study is required. Second, although osteoporosis can be due to many causes before PKP, we were unable to investigate whether the cause of osteoporosis has an effect on PKP. Thus, the effect of the causes of osteoporosis was not considered in the present study.

Conclusion

Based on the abovementioned results, unilateral PKP results in satisfactory treatment outcomes for patients with OVCFs, because it effectively alleviates pain symptoms, corrects kyphosis, and remarkably

improves mobility. It is also advantageous as it further simplifies the surgical procedure, reduces surgical trauma, and shortens recovery time.

Abbreviations

PKP

percutaneous kyphoplasty

PMMA

polymethylmethacrylate

OVCFs

osteoporotic vertebral compression fractures

PVP

percutaneous vertebroplasty

CT

computed tomography

MRI

magnetic resonance imaging

VAS

visual analog scale

BMI

body mass index

Declarations

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Contributions

WY performed all the experiments and wrote the manuscript. WY, QL, and BZ participated in the collection of experimental data. RG guided the entire process of the experiment. SG conceived and designed the study. All authors have read and approved the final manuscript.

Ethics declarations

Ethics approval and consent to participate

The study protocol was approved by the First Affiliated Hospital of Nanchang University Medical School and the written informed consent was obtained from all patients.

Consent for publication

All involved subjects and the authors listed have approved the publication of the manuscript.

Competing interests

The authors declare that they have no competing interests.

Additional information

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Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Tables

Table1: Comparison of demographic and other characteristics of patients between the two groups

<i>characteristics</i>	<i>unilateral group</i>	<i>bilateral group</i>	<i>P-value</i>
<i>Sex (female:male)</i>	<i>15:26</i>	<i>16:29</i>	<i>0.942</i>
<i>Age(years)</i>	<i>79.0±4.8</i>	<i>73.0±3.8</i>	<i>0.321</i>
<i>Body mass index (kg/m²)</i>	<i>23.10±3.8</i>	<i>23.02±3.7</i>	<i>0.188</i>
<i>Preoperative Visual Analog Scale score</i>	<i>8.8</i>	<i>8.5</i>	<i>0.820</i>

Table2: Comparison of surgical conditions between the two groups

	Number	operation time [min]	cement amount (ml)	Vertebral local kyphosis correction [°]	VAS score at the last follow- up
unilateral group	47	28.2±3.4	3.8±0.6	14.26± 2.16	3.15±0.78
Bilateral group	39	50.1±4.6	5.4±0.5	13.81±2.38	2.66±0.86
t value		24.213	15.327	0.423	0.336
P		0.05	0.05	0.05	0.05

Figures

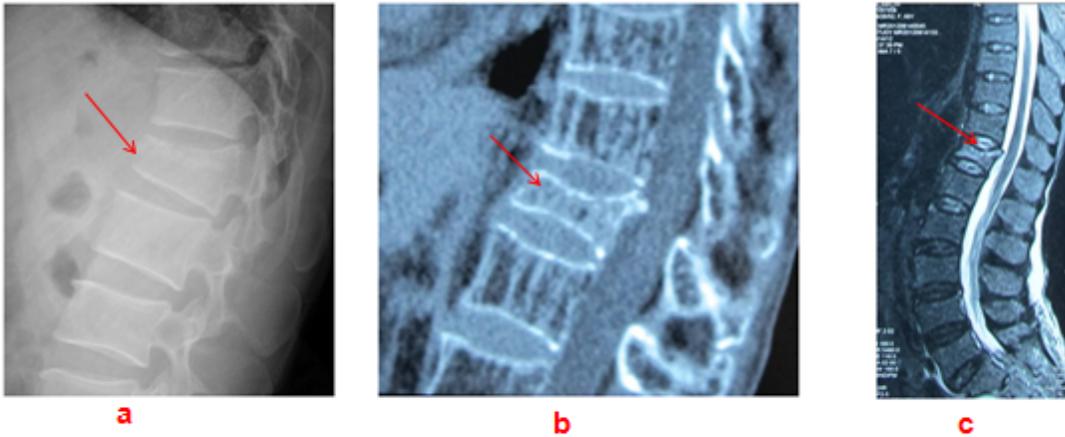
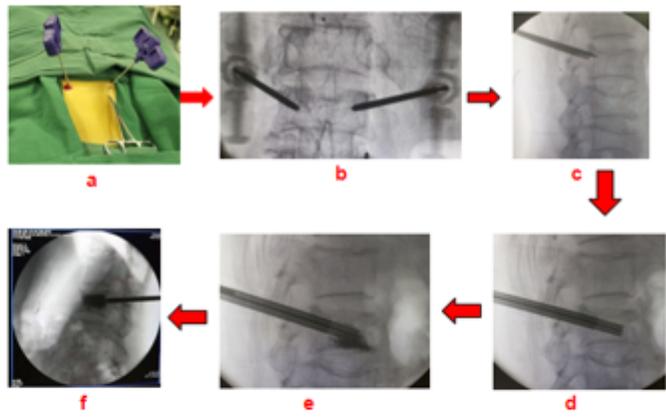


Figure1 preoperative imaging data .

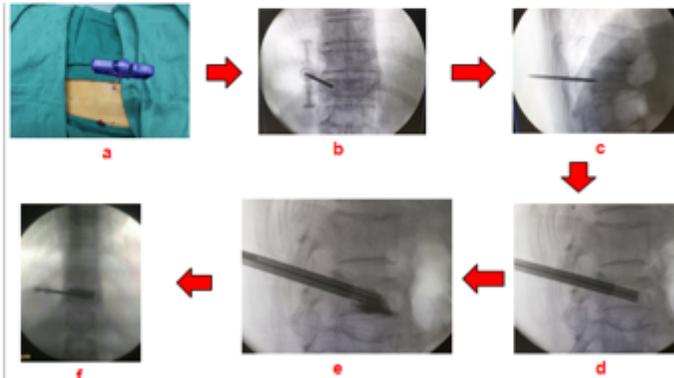
Figure 1

Preoperative imaging data are shown in Figure 1.

Part 1



Part 2



The surgical method Figure 2

Figure 2

The surgical method is shown in Figure 2.

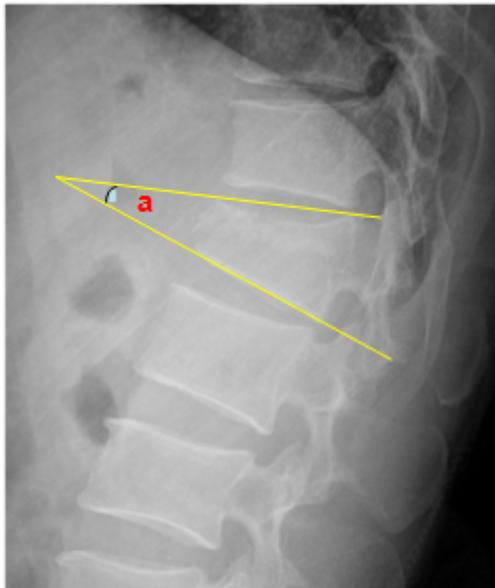


Figure3:a kyphosis angle

Figure 3

Measurements are shown in Figure 3.

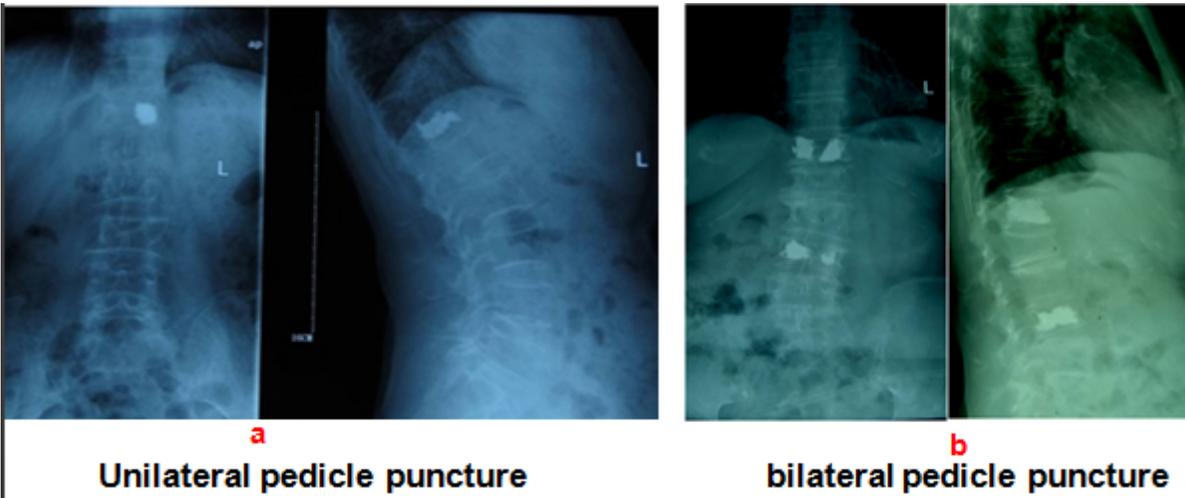


Figure 4

Figure 4

VAS scores and X-ray images .

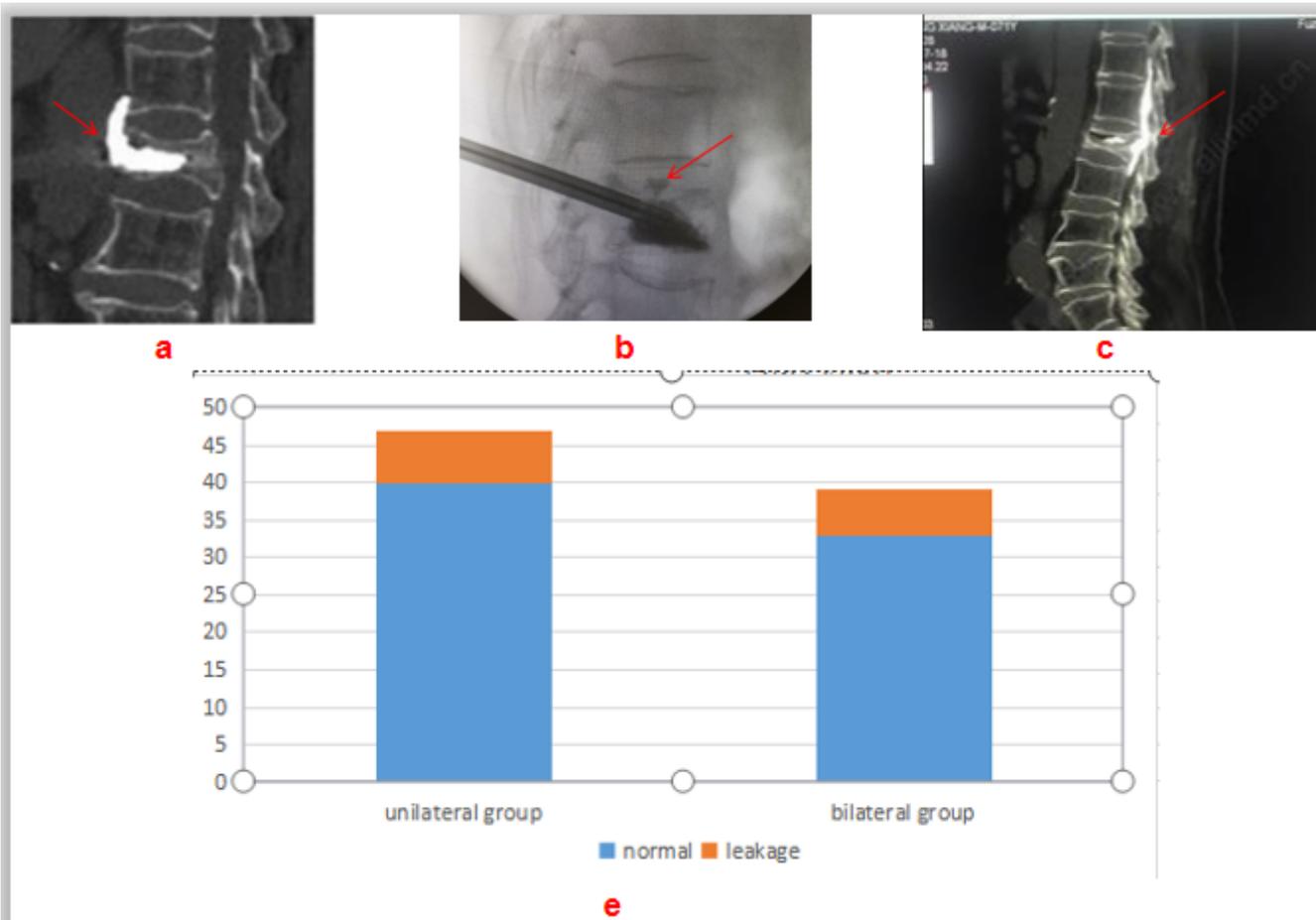


Figure 5

Figure 5

There were 7 cases of cement leakage in the unilateral group (4 cases of paraspinal vein and paravertebral leakage, 2 cases of leakage into the intervertebral disc, and 1 case of slight leakage into the spinal canal; Figure 5a-c.), with an incidence rate of 14.9%. In the bilateral group, there were 6 cases of cement leakage (3 cases of leakage along the paraspinal vein and paravertebral space, 2 cases of leakage into the intervertebral disc, and 1 case of slight leakage into the spinal canal), with an incidence rate of 15.4%. These complications are consistent in PVP and PKP [28]. In addition, there was no significant difference in the bone cement leakage rate between the two groups according to Pearson χ^2 test results ($P > 0.05$) (Figure 5d).

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