# Analysis of Influencing Factors of Residual Low Back Pain After PVP

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# Abstract

**Study design:** Retrospective study

**Objective:** The purpose of this paper is to explore the possible risk factors for residual low back pain after PVP and to analyze their correlation.

**Method**: A retrospective study was conducted on 1120 patients hospitalized for OVCF and treated with PVP between from July 2015 to June 2019 at our Hospital. Baseline, clinical and surgical data were collected to analyze the factors associated with residual low back pain after PVP.

**Results:** 61 patients complained of residual low back pain, and the prevalence was 5.4%. Among the observed indexes included, there were significant differences in preoperative Thoracolumbar fascia injury (TFI), a liquefaction signal on magnetic resonance imaging (MRI) of the affected vertebrae, the number of responsible vertebrae and the distribution of bone cement between the two groups (P<0.05). Multivariate analysis revealed that preoperative TFI (OR=5.378, 95% CI: 1.713~16.888, P=0.004), a liquefaction signal on MRI of the affected vertebrae (OR=6.111, 95% CI：1.898~19.673, P=0.002), the number of responsible vertebrae (OR=0.098, 95% CI: 0.039~0.249, P=0.004), and the distribution of bone cement (OR=0.253, 95% CI: 0.079~0.810, P=0.021) were risk factors for residual low back pain after PVP.

**Conclusion:** TFI, a liquefaction signal on MRI of the affected vertebrae, the number of responsible vertebrae and the distribution pattern of bone cement may be risk factors for residual low back pain after PVP.


# Background

Percutaneous vertebroplasty (PVP) has been used to treat patients with osteoporotic vertebral compression fractures (OVCFs), and its rapid and effective analgesic effect greatly improves the quality of life of such patients[1–5]. However, in clinical practice, we found that in some patients with OVCFs after PVP, pain relief is not obvious, and these patients experience poor pain relief. A systematic review in 2006 found that although nearly 90% of patients with OVCFs had high overall satisfaction after PVP, but approximately 13% still had poor treatment outcomes[6]. Additional clinical studies have also confirmed that residual low back pain after PVP is not uncommon[7, 8]. At present, there are many factors that influence the differences in the treatment effect of PVP, but the specific reasons are still unclear[9, 10]. In this study, multivariate analysis was performed to explore the possible risk factors for residual low back pain after PVP and to analyze their correlation.

# Data And Methods

### Study subjects

A total of 1120 OVCF patients who were hospitalized in our department for PVP treatment between July 2015 and June 2019 were followed up for 3 months to 2 years, and all patients were definitively diagnosed with an OVCF. Age, sex, body mass index (BMI), course of disease, preoperative bone mineral density (BMD) (Hitachi dual energy X-ray absorptiometry, DCS-900FX), preoperative visual analogue scale (VAS) score, thoracolumbar fascia injury (TFI), a liquefaction signal on magnetic resonance imaging (MRI) of the affected vertebrae, the number of responsible vertebrae, surgical approach, operation time, single vertebral bone cement injection volume, and the distribution pattern of bone cement were statistically analyzed. The inclusion criteria were as follows: (1) older than 60 years of age; and (2) OVCF was clearly diagnosed and the patient provided consent for PVP and surgery. The exclusion criteria were as follows: (1) patients who did not meet the inclusion criteria; (2) pathological vertebral compression fractures caused by vertebral tumors or myelomas; (3) long-term use of hormones; (4) patients with more than three surgical segments; (5) patients who underwent surgery under general anesthesia; and (6) patients with Alzheimer's disease, Parkinson's disease and other diseases who could not tolerate local anesthesia.

## Evaluation indicators

All patients underwent a preoperative MRI examination (Siemens 1.5T) to confirm the diagnosis and determine the responsible vertebral body. When TFI occurred in the lumbar region, MRI showed an edema signal, sagittal T1-weighted imaging (T1WI) showed strip or sheet hypointensity, T2-weighted imaging (T2WI) showed hyperintensity, and the T2W spectral attenuated inversion recovery (SPAIR) sequence showed hyperintensity **(Fig. 1)**. Some patients had a long disease course; in these patients, MRI showed a bone liquefaction signal in the responsible vertebral body, sagittal T1WI showed an irregular quasi-circular or oval low signal, T2WI showed a high signal, and the T2W-SPAIR sequence showed a high signal **(Fig. 2)**. The standard satisfactory distribution of bone cement in the vertebral body on CT (Siemens, SOMATOM sensation 40) showed that the bone cement was inverted (U-shaped) in the vertebral body **(Fig. 3)**. The degree of low back pain after surgery was recorded according to the VAS score, and a VAS score > 3 was defined as residual low back pain after surgery. A database was then established. To avoid potential differences caused by different follow-up times, we included only patients with residual low back pain in the early postoperative period (the second day to 1 month after PVP). All operations were performed by the same team of senior doctors. All operating procedures were standardized and uniform, but the operation levels of the doctors differed, which may have introduced bias to the results. All patients were given standard antiosteoporosis treatment after the operation. All patients were treated with high viscosity bone cement produced by the same manufacturer.

## Statistical methods

Statistical analysis was performed using SPSS 22.0 software. Measurement data are expressed as the mean±standard deviation and were compared by the independent sample t-test. Count data were compared by the chi-square test. Logistic regression analysis was performed on the factors that were

statistically significant and correlated with postoperative residual low back pain, and P < 0.05 was considered statistically significant.

# Results

1. **General conditions**

A total of 1120 OVCF patients were treated with PVP, 61 of whom had postoperative residual low back pain, accounting for 5.4% of the total number of patients. These patients were included in the observation group. The remaining 1059 patients had no residual low back pain. Due to the large difference in the number of patients between the two groups, the number of interference factors between the two groups of patients was reduced. Among the remaining patients, 61 with complete follow-up data were randomly selected as the control group and compared with patients with residual low back pain after surgery (Table 1). There were no significant differences in age, sex, BMI, course of disease, preoperative BMD, preoperative lumbar VAS score, surgical approach, operation time or single vertebral bone cement injection volume between the two groups (Table 1). There were significant differences in preoperative TFI, a liquefaction signal on MRI of the affected vertebrae, the number of responsible vertebrae and the distribution of bone cement (Table 1, P < 0.05).

2. **Risk factors leading to postoperative residual low back pain**

Preoperative TFI, a liquefaction signal on MRI of the affected vertebrae, the number of responsible vertebrae, the distribution pattern of bone cement and postoperative residual low back pain were assessed by multivariate analysis. Logistic regression showed that preoperative TFI (OR=5.378, 95% CI: 1.713~16.888, P=0.004), a liquefaction signal on MRI of the affected vertebrae (OR=6.111, 95% CI: 1.898~19.673, P=0.002), the number of responsible vertebrae (OR=0.098, 95% CI: 0.039~0.249, P=0.004), and the distribution of bone cement (OR=0.253, 95% CI: 0.079~0.810, P=0.021) were risk factors for residual low back pain after PVP (Table 2).

# Discussion

### Screening risk factors for residual low back pain after PVP

Approximately 5.4% of OVCF patients in this study had residual low back pain after PVP, which is lower than that reported by Gaughen[11] and Sayed[12]; these differences may be due to the different implementation standards of residual low back pain after PVP. Our study is based on the fact that when the VAS score was>3, patients needed oral analgesics to sleep; otherwise, it seriously affected quality of life. Therefore, a VAS score > 3 was used as the threshold to assess residual low back pain after PVP. We analyzed the current literature on residual low back pain after PVP and found that many factors affect residual low back pain after PVP. The main factors include preoperative TFI, cement leakage, postoperative vertebral infection, recurrent vertebral fracture, secondary fracture of an adjacent vertebral body, amount of bone cement injected, poor distribution of bone cement, the number of responsible

vertebral bodies, increased intravertebral pressure and an inflammatory reaction caused by cement aggregation[13-16]. In clinical practice, we have found that most OVCF patients do not accept standard conservative treatment, eventually leading to nonunion or delayed union of the vertebrae and show signs of intravertebral liquefaction on MRI; thus, such patients usually have residual low back pain after surgery. Of course, this difference may also be related to the difficulty of surgery, the amount of intraoperative bone cement injection, the operation time, etc. Therefore, in this study, we analyzed whether a liquefaction signal on MRI of the preoperative vertebrae affected residual low back pain after PVP. Because factors such as pain or spinal cord injury in the nerve root innervation area, increased intravertebral pressure, and inflammatory reaction caused by cement aggregation are difficult to quantify, we excluded these factors from statistical analysis. In addition, the longer the follow-up time was, the more complex the factors that affected postoperative pain, and the greater the difference. To avoid potential differences caused by different follow-up times, we included only patients with residual low back pain in the early postoperative period (the second day to 1 month after PVP). Postoperative vertebral infection, secondary vertebral fracture, nonunion of bone cement and contact surface fracture occur approximately 3 months after surgery[17] and do not belong to the category of early residual low back pain after surgery. Finally, we included age, sex, BMI, course of disease, preoperative BMD, preoperative VAS score, TFI, a liquefaction signal on MRI of the affected vertebrae, the number of responsible vertebral bodies, surgical approach, operation time, the volume of single vertebral bone cement injection, and the distribution of bone cement in the univariate analysis. The above factors were analyzed, and we found significant differences in preoperative TFI, a liquefaction signal on MRI of the affected vertebrae, the number of responsible vertebrae and the distribution of bone cement (Table 1, $P < 0.05$).

### Effect of TFI on residual low back pain after PVP

Yan et al.[16] reported an association between TFI and residual low back pain after PVP. They also showed that the VAS score of the low back in patients with TFI was significantly lower than that in patients without TFI. However, our study reached the opposite conclusion, which indicated that TFI was a high-risk factor for residual low back pain after PVP, with an OR of 5.378. We believe this finding may be explained by the following reasons. First, after osteoporotic thoracolumbar fracture, especially one caused by trauma, and after fracture because of bone-derived pain, TFI immediately exists but may be masked by bone-derived pain, which is also why the patient fell on his/her buttock and landing conscious with intense thoracolumbar pain. However, when PVP was performed, patients felt more lumbosacral pain. The main reason for this observation is that the injection of bone cement in a short time makes bone-derived pain disappear or significantly weaken, while pain caused by TFI via trauma appears more prominent at this time. However, it is worth noting that with prolonged follow-up time, MRI hyperintensity resembling lumbar and dorsal soft tissue injury will gradually subside, mainly because the self-repair of local soft tissue alleviates inflammatory reactions such as edema. This also suggests that low back pain due to TFI can be improved by conservative treatment and explains why the difference in pain between the two groups occurred only in the early postoperative period.

### Effect of a liquefaction signal on MRI on residual low back pain after PVP

Because OVCF is classified as a fragile fracture, most patients have no obvious history of trauma and differences in the regional level of diagnosis. Some patients have no obvious clinical symptoms after onset and usually miss the best time for diagnosis and treatment (resulting in a missed diagnosis and/or misdiagnosis), and some patients have a liquefaction signal on vertebral MRI when confirmed. These phenomenon may be explained by the failure to undergo timely and correct treatment after the fracture, resulting in delayed or nonunion of the fracture, coupled with the pathological basis of osteoporosis, trabecular bone resorption at the fracture end, and liquefaction signals in the fracture area that mimic those observed in Kümmell's disease[18, 19]. When PVP is performed in such patients, it is usually difficult for the cement to diffuse. In most cases, the cement is confined to the liquefied area of the fracture and distributed in a mass. The presence of liquefaction signals on MRI of the affected vertebrae may effect cement leakage, cement distribution, and cement volume, eventually leading to residual low back pain after surgery. This study found that a liquefaction signal on vertebral MRI was a risk factor for postoperative residual low back pain, with an OR of 6.111, and should be considered. Of course, although there was no significant difference in the course of disease between the two groups, some patients could not accurately describe the time of the initial injury or fracture. Theoretically speaking, the presence of a liquefaction signal on MRI of the affected vertebrae generally indicates that the patient has a long disease course. Whether the disease duration is related to a liquefaction signal on MRI still needs further study.

### Effect of the number of fractured vertebral bodies on residual low back pain after PVP

The more fractured the vertebrae, the more collapsed the vertebrae are; this can easily lead to kyphosis and secondary sagittal imbalance. For a long period of sagittal imbalance of the spine, patients will compensate for the increasing thoracic kyphosis deformity by flexing the hip and increasing pelvic retroversion and the lumbar lordosis angle, thus maintaining the balance of the spine in the sagittal plane. This nonphysiological compensation can easily lead to thoracodorsal muscle strain and intermittent low back pain. With late sagittal decompensation of the spine, there will eventually be persistent low back pain, which may be one of the causes of residual low back pain after PVP in multiple vertebral bodies. In addition, the patients included in this study had multiple vertebral bodies with osteoporotic compression fractures and underwent PVP surgery at the same time. Excessive puncture in the lumbar and dorsal surgical area may lead to local soft tissue injury, and certain patients may experience local hematoma formation or increased hidden blood loss, which ultimately leads to lumbar and dorsal pain shortly after surgery. However, with the prolonged follow-up time, the soft tissues in the surgical area were gradually repaired, and residual low back pain was relieved.

### Effect of the distribution pattern of bone cement on residual low back pain after PVP

The distribution of cement depends on the degree of fracture, the course of the fracture line and the surgical method. In general, it is easy to obtain a satisfactory distribution of cement by injecting cement via a bilateral pedicle puncture. However, this study showed that a unilateral or bilateral puncture does not affect the clinical outcome, but obtaining satisfactory cement distribution can effectively reduce the

occurrence of postoperative residual low back pain. This study also found that the OR of the distribution pattern of bone cement was less than 1, which explains the satisfactory distribution pattern of bone cement and indicates its role as a protective factor in the relief of low back pain. For patients with poor cement distribution and residual low back pain, He et al.[14]and Gaughen et al.[11] used secondary bone cement injection after PVP, which effectively alleviated residual low back pain.

### Deficiencies of this study

Residual low back pain after PVP in OVCF patients is affected by many factors. Only patients with residual low back pain occurring within 1 month after surgery were included in this study, and the relevant factors during this period were analyzed. Late- and midterm influencing factors, such as delayed union, nonunion and secondary adjacent vertebral fractures, were excluded. These factors tend to become more important after 3 months. As a result, the risk of related factors in the early postoperative period was gradually weakened. This is a shortcoming of the present study, as was the lack of an analysis of long-term risk factors for residual low back pain after PVP.

## Conclusion

This study showed that preoperative TFI, a liquefaction signal on MRI of the affected vertebrae, the number of responsible vertebrae and the distribution pattern of bone cement were risk factors for residual low back pain in OVCF patients after PVP. Patients with these risk factors should be informed of the possibility of postoperative residual low back pain during the preoperative conversation. For patients with TFI before the operation, treatment can be conducted according to the principles of management of soft tissue injury in the lower back, and such patients can be informed that residual low back pain may exist after the operation but will gradually be relieved following the repair of soft tissue in the lower back. For patients with a liquefaction signal on vertebral MRI, an adequate amount of bone cement should be injected as thoroughly as possible during the operation to spread to the whole affected vertebra, effectively fill the fracture fissures and improve the analgesic effect. It is important that the physician chooses to inject cement through the bilateral pedicles as thoroughly as possible to improve cement filling and distribution. Concerning postoperative residual low back pain caused by the poor filling of bone cement, a second injection of bone cement can be administered according to the pain degree and patient demand.

## Abbreviations

percutaneous vertebroplasty (PVP); osteoporosis vertebral compression fracture (OVCF); Thoracolumbar fascia injury (TFI); magnetic resonance imaging (MRI); body mass index (BMI); bone mineral density (BMD); visual analogy score (VAS); Confidence interval (CI); odds ratio(OR).

## Declarations

### Acknowledgements

Not applicable.

### Funding

No funding was obtained for this study.

### Availability of data and materials

Not applicable.

### Ethics approval and consent to participate

This study was performed following the principles of the Declaration of Helsinki and was conducted according to the National Ethics Guidelines Statement. Informed consent was obtained from all participants.

### Consent for publication

Not applicable.

### Conflict of interest

The authors declare that they have no conflicts of interest.

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# Tables

**Table 1. Basic information on the two groups of patients**

| | Observation group （n=61） | control group （n=61） | P value |
|---|---|---|---|
| Age | 73.13±6.88 | 72.48±7.07 | 0.605 |
| Sex (male/female) | 14/47 | 20/41 | 0.226 |
| BMI | 21.77±2.17 | 21.49±2.02 | 0.465 |
| Course of disease | 5.98±2.69 | 5.96±3.14 | 0.578 |
| Preoperative BMD | -2.80±0.57 | -2.78±0.63 | 0.794 |
| Preoperative VAS score | 6.28±1.45 | 6.18±1.19 | 0.683 |
| TFI | | | 0.000 |
| Yes | 44 | 16 | |
| No | 17 | 45 | |
| Liquefaction signal on MRI of the affected vertebrae | | | 0.000 |
| Yes | 38 | 15 | |
| No | 23 | 46 | |
| Number of vertebral fractures | 2.41±0.74 | 1.33±0.57 | 0.000 |
| Surgical approach | | | 0.844 |
| Unilateral | 19 | 18 | |
| Bilateral | 42 | 43 | |
| Cement distribution | | | 0.010 |
| Satisfied | 28 | 42 | |
| Dissatisfied | 33 | 19 | |
| Operative time (min) | 42.93±11.82 | 46.80±12.25 | 0.078 |
| Volume injected per level (ml) | 3.27±0.92 | 3.43±0.92 | 0.327 |

**Table 2. Multivariate logistic regression analysis of postoperative residual low back pain**

| | Partial regression coefficient | Standard error | Wald value | P value | Odds ratio | OR（95% CI） |
|---|---|---|---|---|---|---|
| **TFI** | 1.682 | 0.584 | 8.304 | 0.004 | 5.378 | 1.713~16.888 |
| **Liquefaction signal on MRI of the affected vertebrae** | 1.810 | 0.597 | 9.206 | 0.002 | 6.111 | 1.898~19.673 |
| **Number of vertebral fractures** | -2.319 | 0.473 | 24.018 | 0.004 | 0.098 | 0.039~0.249 |
| **Cement distribution** | -1.376 | 0.595 | 5.351 | 0.021 | 0.253 | 0.079~0.810 |

# Figures

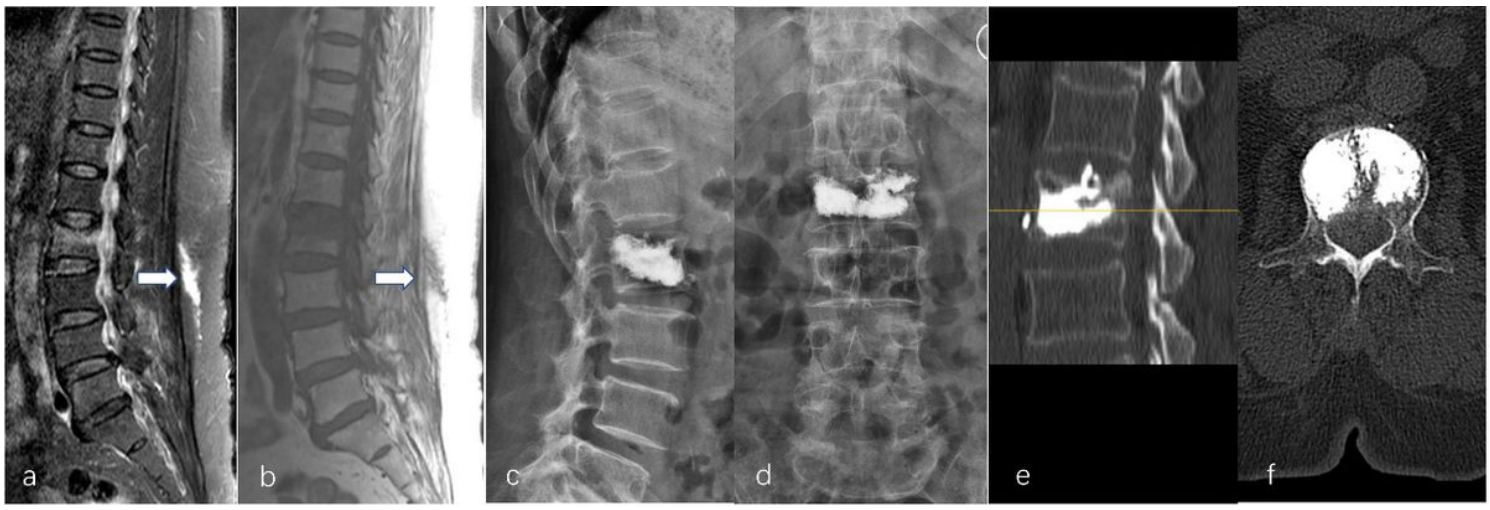
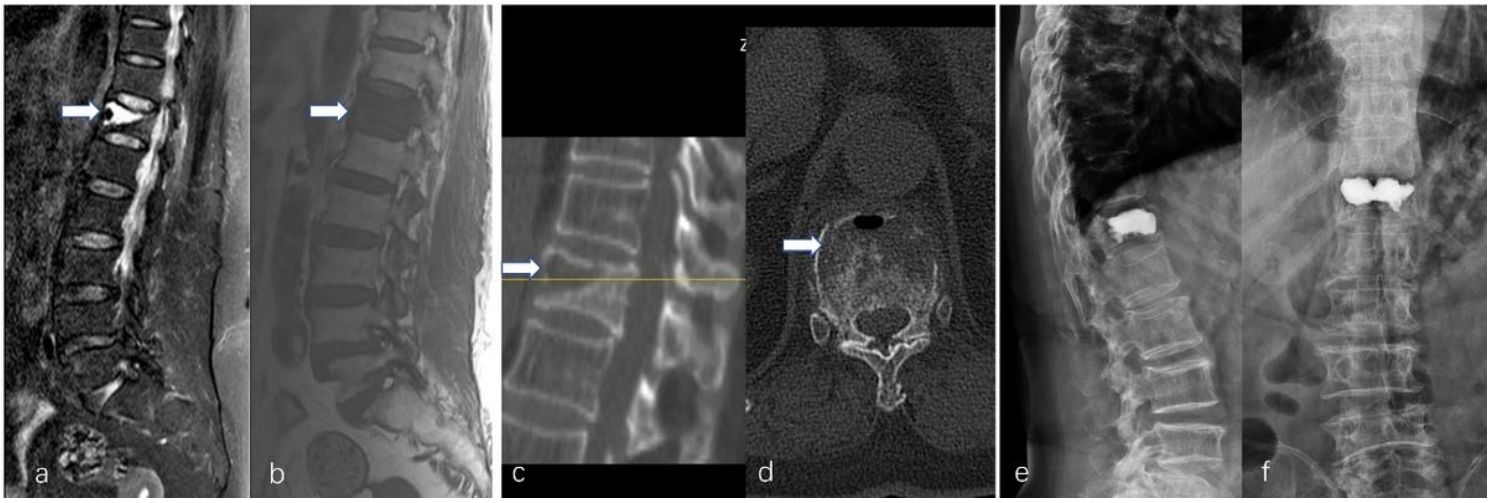


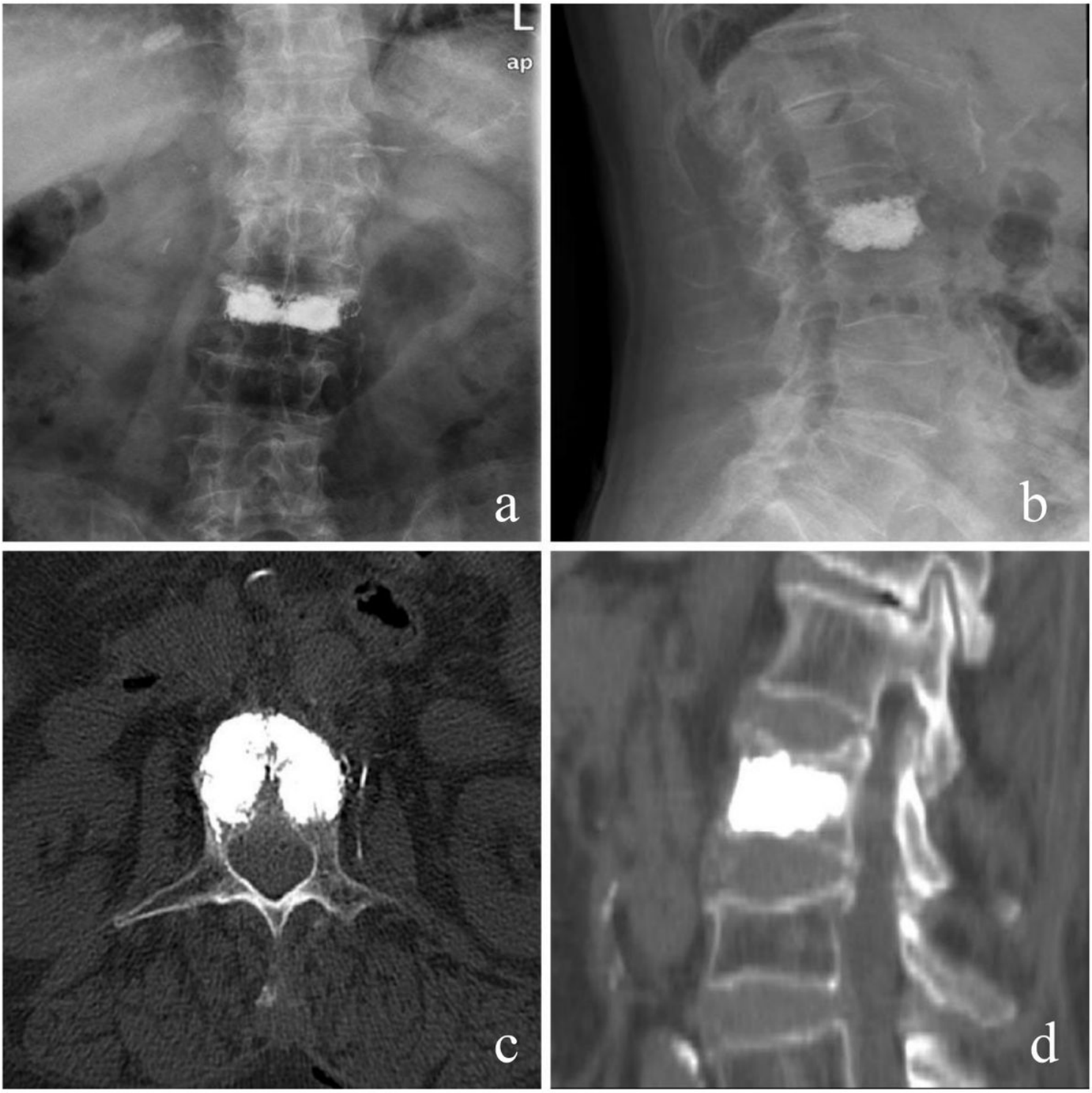

**Figure 1**

a, T2W-SPAIR sequence, TFI region showed a high signal. b, Sagittal T1WI sequence, TFI showed a low signal. c, Postoperative X-ray lateral position. d, Postoperative X-ray anteroposterior position. e, Cross-sectional CT reconstruction. f, Sagittal CT reconstruction.



## Figure 2

a, T2W-SPAIR sequence, liquefaction signals in the fractured vertebra. b, Sagittal T1WI sequence, liquefaction signals in the fractured vertebra. c, Cross-sectional CT reconstruction. d, Sagittal CT reconstruction. e, Postoperative X-ray lateral position. f, Postoperative X-ray anteroposterior position.




## Figure 3

a, Anteroposterior position X-ray. b, Lateral position X-ray. c, Sagittal CT reconstruction. d, Cross-sectional CT reconstruction.

## Supplementary Files

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