Analysis of Influencing Factors of Residual Low Back Pain After PVP

Fengwei Qin
Guangzhou Hospital of Integrated Traditional and Western Medicine
Wencai Zhang (gskqfw@126.com)
Jinan University First Affiliated Hospital
Shuai Wang
Guangzhou Hospital of Integrated Traditional Chinese and Western Medicine
feng Jiao
Guangzhou Hospital of Integrated Traditional Chinese and Western Medicine
yonghui Feng
Guangzhou Hospital of Integrated Traditional Chinese and Western Medicine
zhaofei Zhang
Guangzhou Hospital of Integrated Traditional Chinese and Western Medicine
chunliang Xie
Guangzhou Hospital of Integrated Traditional Chinese and Western Medicine
donghua Liu
Guangzhou Hospital of Integrated Traditional Chinese and Western Medicine
sineng Zhang
Guangzhou Hospital of Integrated Traditional Chinese and Western Medicine
jie Liang
Guangzhou Hospital of Integrated Traditional Chinese and Western Medicine

Research

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Abstract

Background: PVP (Percutaneous vertebroplasty) has been used to treat patients with OVCFs, however, we found that some patients did not significantly relieve back pain after surgery. The purpose of this paper is to explore the possible risk factors for residual low back pain after PVP and to

Method: A retrospective study was conducted on 1120 patients hospitalized for osteoporotic vertebral compression fracture (OVCF) and treated with PVP between from July 2014 to June 2020 at our hospital. Baseline, clinical and surgical data were collected to analyze the factors associated with residual low back pain after PVP.

Results: A total of 61 patients complained of residual low back pain, and the prevalence was 5.4%. Among the observed indices included, there were significant differences in preoperative thoracolumbar fascia injury (TFI) and a liquefaction signal on magnetic resonance imaging (MRI) of the affected vertebrae; the number of responsible vertebrae and the distribution of bone cement were different 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 could 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, 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]. Currently, there are many factors that influence the differences in the treatment effects of PVP, but the specific reasons remain unclear[9,10]. Although it has been found that residual back pain following PVP has several factors, such as bone density, number of fractured vertebrae, fractured vertebral compression, and bone cement injection[11], the main factor cannot be effectively distinguish from the others. For example, some scholars have advocated that, after the diagnosis is clear, vertebral forming should be treated as soon as possible for pain relief and to improve the quality of life. It can also avoid fractures that do not heal and other serious complications, increasing the difficulty of late treatment, such as Kümmell's disease[12,13]. There are

also scholars who believe that, for OVCF, the patient should have absolute bed rest after the event for as long as possible; generally, after 1-2 weeks, back pain can be significantly reduced, and 4-6 weeks later, thoracic lumbar braces can be worn for out of bed activities. If the back pain after 4-6 weeks is still not significantly alleviated, then vertebral forming surgery should be performed. Therefore, there is still a great deal of controversy about the timing of vertebral forming surgery. In addition, most studies have focused on fractured vertebrae, ignoring the damage to soft tissue underlying the fractured vertebrae, which is likely to be one of the reasons for the residual back pain in patients after PVP surgery and should be paid sufficient attention. There is also controversy about the distribution of bone cement in the vertebral body; we found in previous research bone cement administered via an inverted U-type injection can achieve good clinical results, so it should also be paid attention to. In this study, multivariate analysis was performed to explore the possible risk factors for residual low back pain after PVP and to analyze their correlations. The purpose of this study was to improve clinical results by analyzing the factors influencing residual back pain after PVP surgery and to plan corresponding interventions at the appropriate time.

Data And Methods

Study subjects

A total of 1120 OVCF patients who were hospitalized in our department for PVP treatment between July 2014 and June 2020 were followed up for 3 months to 2 years, and all of the 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 analog 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; (2) OVCF was clearly diagnosed, and the patient provided consent for PVP and surgery; (3) patients with an intact posterior wall of the vertebral body and no nerve compression. 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; (6) patients with Alzheimer's disease, Parkinson's disease and other diseases or who could not tolerate local anesthesia; and (7) patients with clinical symptoms due to bone cement leakage and adjacent new fractures and vertebral infection.

Evaluation indicators

All of the patients underwent a preoperative MRI examination (Germany, Siemens 1.5 T) 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). The scope of TFI was limited to one vertebra adjacent to the fractured vertebral body, and either unilateral or bilateral TFI was recorded. 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 of the operations were performed by the same team of senior doctors. All of the operating procedures were standardized and uniform, but the operation levels of the doctors differed, which might have introduced bias to the results. All of the patients were given standard antiosteoporosis treatment after the operation. All of the patients were treated with high viscosity bone cement produced by the same manufacturer.

Statistical methods

Statistical analysis was performed using SPSS software, version 22.0. 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[14] and Sayed[15]; these differences could have been due to the different implementation standards of residual low back pain after PVP. Our study was based on patients needing oral analgesics to sleep when the VAS score was >3; 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[16-19]. 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 they show signs of intravertebral liquefaction on MRI; thus, such patients usually have residual low back pain after surgery. Of course, this difference might also be related to the difficulty of surgery, the amount of intraoperative bone cement injected, 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 reactions caused by cement aggregation are difficult to quantify, we excluded these factors from statistical analysis. In addition, the longer that the follow-up time was, the more complex that the factors that affected postoperative pain were, and the greater that the difference was. 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 occurred approximately 3 months after surgery[20] 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.[19] 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, indicating that TFI was a high-risk factor for residual low back pain after PVP, with an OR of 5.378. We believe that this finding could 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 can be masked by bone-derived pain, which is also why patients fall on their buttocks and land 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 causes bone-derived pain to disappear or significantly weaken, while pain caused by TFI via trauma appears more prominently 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 outcome also suggests that low back pain due to TFI can be improved by conservative treatment, and it explains why the difference in pain between the two groups occurred only in the early postoperative period. Although this study suggests that TFI might be one of the causes of residual back pain after PVP surgery, there has been no research or analysis of the scope and volume of TFI and changes in postoperative TFI, which might have biased the conclusions of the study, so we must next study this topic in depth.

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 or 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 could be explained by the failure to undergo timely and correct treatment after the fracture, resulting in delayed union or nonunion of the fracture, coupled with the pathological basis for osteoporosis, trabecular bone resorption at the fracture end, and liquefaction signals in the fracture area that mimic those observed in Kümmell's disease[12,13]. 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 can affect 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 it 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 requires further study.

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

The more fractured that the vertebrae are, the more collapsed that the vertebrae are; this outcome 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 on 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 might 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 they underwent PVP surgery at the same time. Excessive puncture in the lumbar and dorsal surgical area can lead to local soft tissue injury, and certain patients might experience local hematoma formation or increased hidden blood loss, ultimately leading 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, explaining the satisfactory distribution pattern of bone cement and indicating 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.[17]and Gaughen et al.[14] used secondary bone cement injection after PVP, which effectively alleviated residual low back pain.

Study limitations

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 fact 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.

For patients with TFI before the operation, treatment can be conducted according to the principles of the management of soft tissue injury in the lower back, and such patients should be informed that residual low back pain might 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 choose 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 poor filling with bone cement, a second injection of bone cement can be administered according to the pain degree and patient demand.

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.

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

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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 of the participants.

Consent for publication

Not applicable

Conflict of interest

The authors declare that they have no conflicts of interest.

Declarations

Not applicable

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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

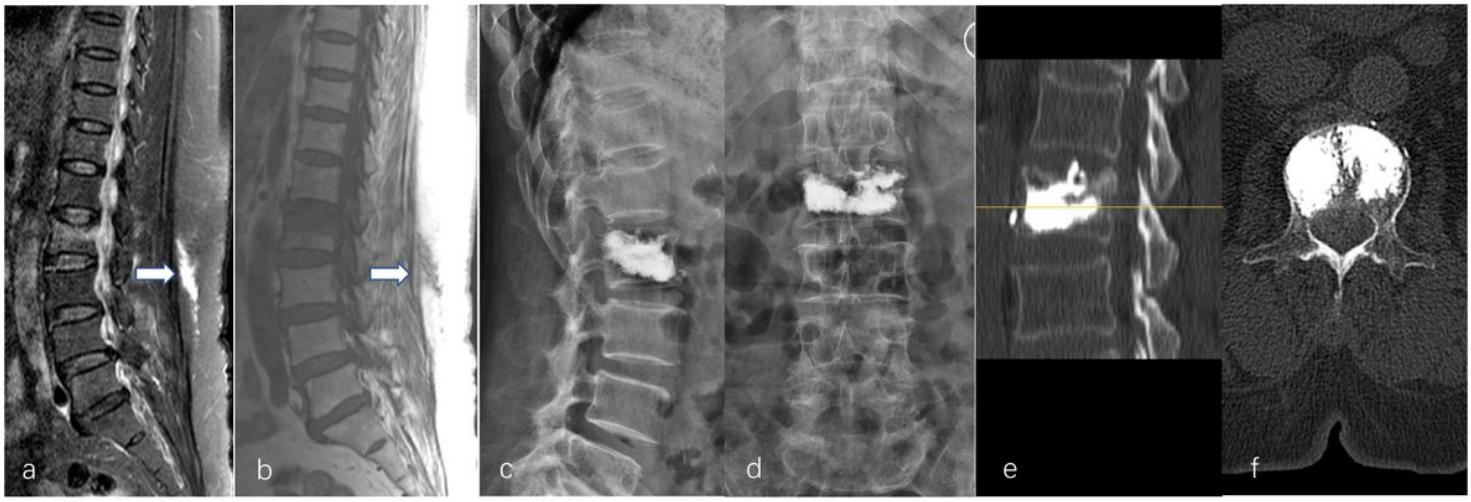

Figure 1

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.

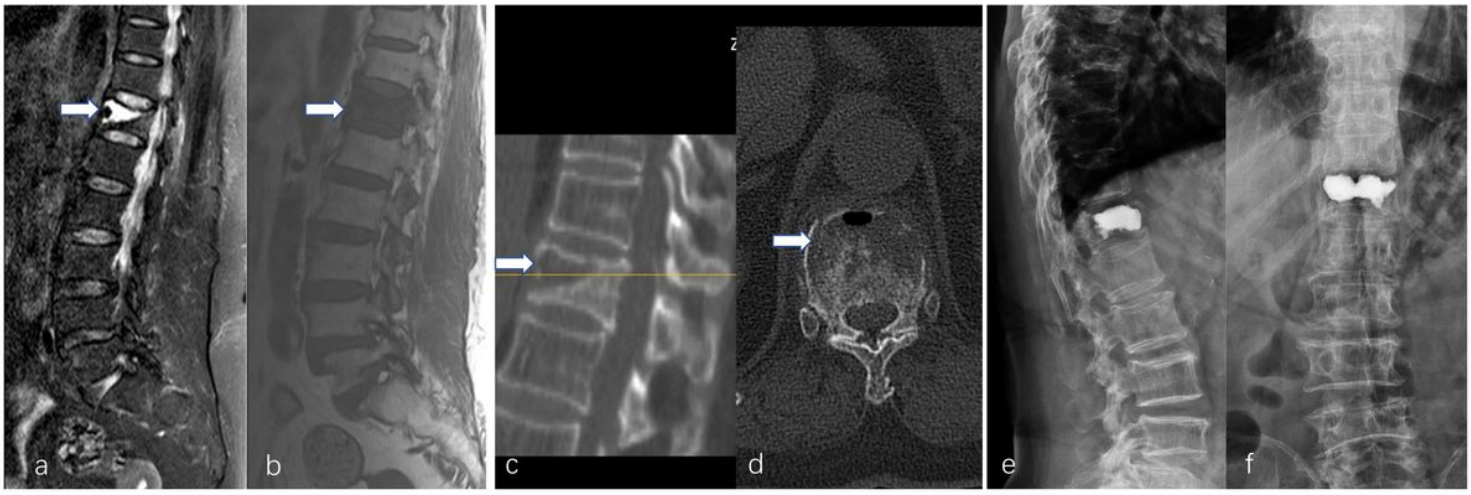

Figure 2

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.

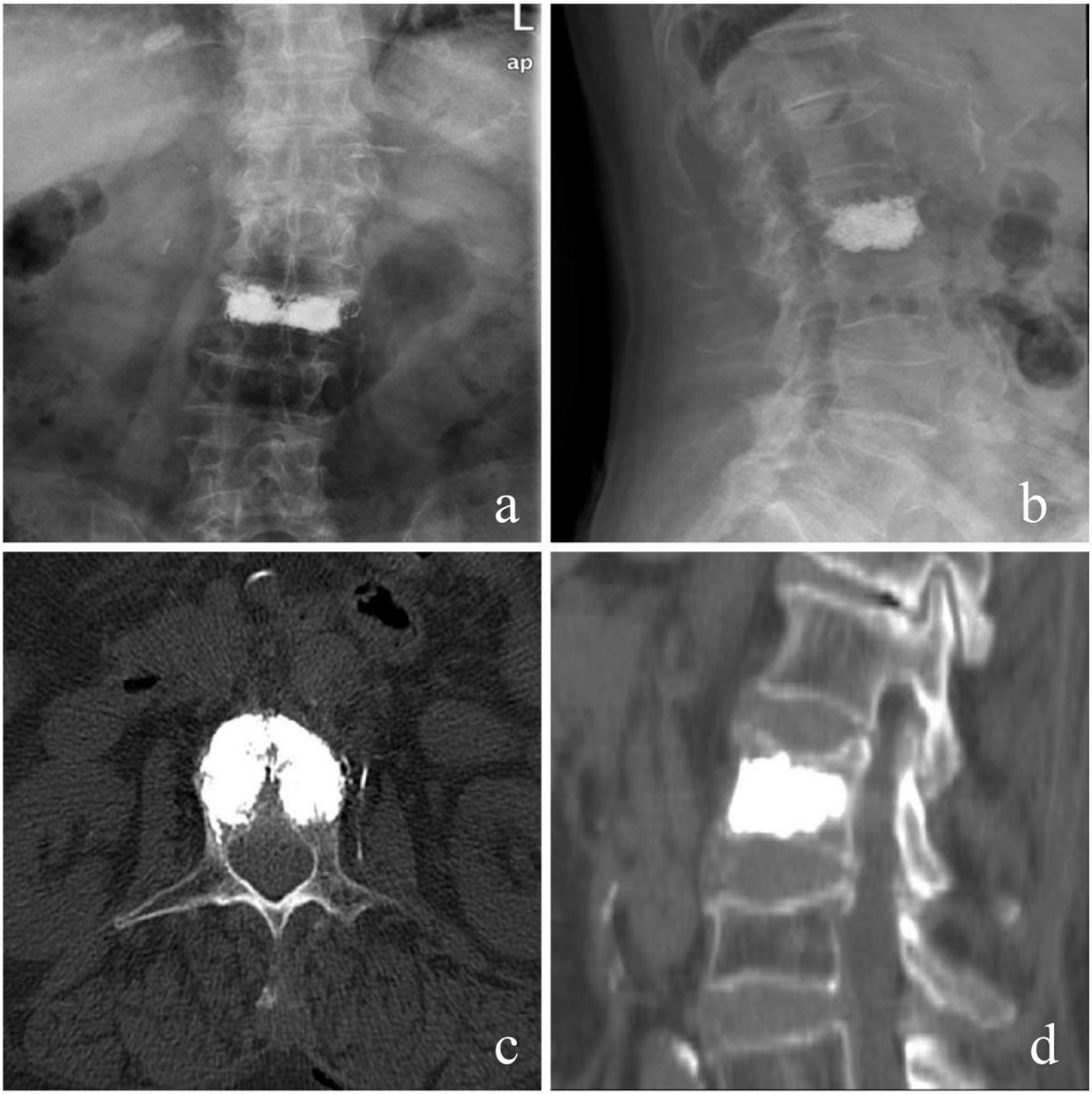

Figure 3

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