

Comparison of a flexible versus rigid bone cement injection system in unilateral percutaneous vertebroplasty

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Abstract

Background: Percutaneous vertebroplasty (PVP) has been demonstrated to be effective in the treatment of acute osteoporotic vertebral fracture (AOVF). However, bilateral puncture takes more time to accept more X-ray irradiation; some scholars apply unilateral puncture PVP, but the cement cannot be symmetrically distributed in the vertebral body, so we use a flexible cement injector that undergoes PVP through the unilateral pedicle puncture. This research aims to compare the clinical results of PVP for AOVF with unilateral pedicle puncture using a straight bone cement injector and a bendable cement injector, determine the value of a bendable cement injector.

Methods: We undertook a retrospective analysis of patients with thoracic and lumbar compression fracture treated with unilateral pedicle puncture Percutaneous vertebroplasty from our institution from June 2013 to July 2015. Operation time, radiation exposure, bone cement injection amount, and the incidence of bone cement leakage were recorded on presentation, the cement leakage was measured by x-ray and computed tomography scan. The patients were followed up postoperatively and were assessed mainly with regard to clinical and radiological outcomes.

Results: There was no significant difference in the operation time, radiation exposure time and incidence of bone cement leakage between the two groups. There was significant difference in the amount of bone cement injection and the difference between the two groups. there were no significant differences in VAS and the relative height of the vertebral body and local Cobb angle and QUALEFFO between 2 groups at 1 week after PVP, only significant difference was observed between 12 months after operation.

Conclusions: Application of flexible cement injector is safe and feasible, Compared with the application of straight bone cement injector, without prolonging the operative time, radiation exposure time and the incidence of bone cement leakage, it has the advantages of good long-term effect and low incidence of vertebral fracture recurrence.

Background

Osteoporotic vertebral fracture is one of the most common diseases of the elderly [1-4]. Percutaneous vertebroplasty (PVP) is widely used to treat painful vertebral compression fractures and strengthen the stability of vertebrae [5-6]. The usual standard in introduction of bone cement in PVP requires a bilateral pedicle approach to create a symmetrical distribution of bone cement [7]. However, pedicle puncture from both sides almost doubles the operation time and radiation exposure compared with a unilateral approach. Reducing operative time and radiation exposure is a valid objective. However there is controversy about the efficacy of a unilateral approach. One study has reported similar short-term efficacy to bilateral procedures [8]. Another has suggested that introduction of bone cement unilaterally may lead to asymmetric loading of the vertebral body and collapse of the contralateral side of the vertebral body under axial compression stress [9].

Materials And Methods

The study protocol was approved by the Institutional Review Board and the Ethics Committee of Luohe Medical College.

Patients

We undertook a retrospective analysis of patients with thoracic and lumbar compression fracture treated with unilateral pedicle puncture PVP from our institution over a two month period (June & July 2015). 78 patients were included according to the standard. Inclusion criteria includes: ☒Age from 60 to 99 years; ☒Bone attenuation (T score < - 2.5) on bone densitometry; ☒Collapse more than 15% of the vertebral height; ☒Severe back pain related to a single-level AOVF refractory to analgesic medication; ☒Using magnetic resonance (MR) imaging, the affected vertebral body showed a hypointense signal on T1-weighted images and hyperintense signal on T2-weighted images. The exclusion criteria included: ☒Secondary osteoporosis (Corticosteroids, endocrine disorders and an inflammatory process); ☒Failure to acquire informed consent; ☒Uncorrected coagulopathy; ☒Systemic or local spine infection; ☒Painless AOVF; ☒Spinal metastatic cancer; ☒Severe comorbidities of the cardiorespiratory, hepatic, renal or neurological symptoms. Patients were divided into two groups according to surgical procedure: a flexible cement injection group (36 cases) using a flexible-tipped bone cement injection and 3-point cement injection technique; a rigidbone cement injection group (42 cases) using a straight bone cement injection technique.

Surgical Instruments

Flexible bone cement injection equipment (Ningbo Branch Huakerun Biotechnology Co., Ltd). with angled bone cement injector. Rigid bone cement injection equipment (Shandong Guanlong Medical Products Co., Ltd).

Procedures

All the PVP procedures were performed in the operating theatre. Patients were placed prone, supported by two transverse bolsters under thorax and pelvis. Gentle distraction and extension was applied to reduce the vertebral fracture. During the procedure, a unilateral transverse process-pedicle approach was adopted with application of local anesthesia. The entry point in the vertebra was identified by fluoroscopy at the junction of the lateral edge of the pedicle s and vertebral plate. The trocar penetrated cortical bone at the lateral edge margin of the vertebral arch, and was advanced medially and inferiorly. Fluoroscopy was used to confirm that the needle tip reached the posterior wall of the vertebral body, No further advance was made beyond about 4 mm anterior to the posterior surface of the vertebral body. During the procedure all patients were observed closely with frequent fluoroscopy and the cement injection was stopped immediately if bone cement leakage occurred.

When using the rigid cement injector, an 11-13G core needle was advanced from a posterolateral entry point through the involved vertebral pedicle to the junction of anterior and middle thirds of the vertebral

body. The inner core was retracted and 3–4 ml PMMA was injected guided by continuous fluoroscopy. When bone cement began to fill the posterior third of the vertebral body, the injection was terminated. In contrast, the flexible bone cement injection method is more involved; detailed descriptions of the process, can be found in the legend of Figs. 1 and 2.

After injection of bone cement, all injection components were withdrawn and pressure was applied to the wound for haemostasis. All the patients were observed supine for 6 hours. Next-day rehabilitation included sitting and standing as tolerated. Bisphosphonates were generally used to treat osteoporosis after surgery.

Outcome Measures

The operation time, radiation exposure time, the amount of bone cement injection and the leakage of bone cement were recorded for each patient in two groups. Clinical assessments were evaluated before surgery, one week after surgery and 12 months after surgery. Radiographs and computed tomography (CT) scans were performed to assess the cement leakage in the vertebral body and other possible local complications, and all the complications and adverse events were recorded.

On pain measurement, VAS scores were used which ranged from 0 (no pain) to 10 (worst pain ever). Quality-adjusted life years (QALYs) and the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) were investigated in all patients, which comprises a 41 item questionnaire organized into 5 domains (Pain, Physical Function, Social Function, General Health Perception, and Mental Function). Each domain's score and QUALEFFO total scores are recorded on a 100-point scale, lower scores corresponding to better health-related quality of life.

Anteroposterior and lateral standing radiographs were observed to measure vertebral height and kyphotic angle of the vertebral body of all patients in three periods (preoperatively, one week after surgery, and 12 months after surgery). In the X-ray radiographs, the anterior height of the affected vertebral body and adjacent normal vertebrae were measured, and the relative anterior height (RAH) of the fractured vertebra was calculated according to the equation:

$$\text{RAH} = \frac{\text{fractured vertebral anterior height}}{(\text{Superior vertebral anterior height} + \text{inferior vertebral anterior height})} \times 100\%.$$

The kyphotic angle was based on the Phillips method, the angle between the superior endplate at one level above the fractured vertebrae and inferior endplate at one level below the fractured vertebrae were measured (Fig. 3).

Statistical Analysis

All statistical analyses were performed with the use of SPSS software, version 12 (SPSS Inc., Chicago, IL). The results were expressed as average \pm SD. One-way analysis of variance (ANOVA) was used to compare the VAS scores, quality of life, RAH, and the kyphotic angle between the 2 groups. Difference in

cement leakage rate of 2 groups was assessed using χ^2 test. $P < 0.05$ was considered to have statistical significance.

Results

All surgeries in two groups were completed successfully, and no intraoperative deaths were reported in this study. The average duration of follow-up was 15.8 months (range from 12 to 32 months). In terms of demographic data of patients, no significant difference was found between two groups (Table 1). Typical cases are shown in Fig. 4 ~ 5.

Intraoperative Measurement

There was no significant difference between two groups in the operation time and radiation exposure time ($P > 0.05$). The operation time was 28.4 ± 2.82 minutes (min) and 26.6 ± 2.35 min in the flexible cement injection (subject) group and rigid cement injection (control) group, respectively. In the flexible cement injection group, the radiation exposure time was 4.71 ± 0.95 min, compared with the radiation exposure time of 4.68 ± 0.80 min in the rigid cement injection group.

The average volume of the injected cement was 5.5 ± 0.35 ml and 3.2 ± 0.38 ml in flexible cement injection group and rigid bone cement injection group, respectively. A statistically significant difference was found between two groups ($P < 0.05$) (Table 2).

Clinical Results

No Statistically significant differences were found in the baseline VAS and quality of life scores in the two groups. All scores were reduced in both groups after PVP surgeries, and there was no statistically significant difference between two groups at one week after PVP. However, statistically significant differences were found at 12 months after surgery ($P < 0.05$) (Table 3).

Radiological Results

Preoperative and postoperative radiographical assessments of two groups were measured, and documented in Table 4. The RAH in the treatment group increased from $41.06 \pm 5.58\%$ preoperatively to $44.30 \pm 3.80\%$ at one week post operation, and was $43.04 \pm 5.19\%$ one year postoperatively. In the control group, RAH increased from $43.01 \pm 5.42\%$ preoperatively to $45.49 \pm 4.25\%$ at one week post operation but was $30.86 \pm 4.55\%$ at one year post-surgery. There was no significant difference in RAH either preoperatively or one week postoperatively ($P > 0.05$). However, there were statistically significant differences between two groups after 12 months.

The Cobb angle in the treatment group changed from $24.15 \pm 4.07^\circ$ before surgery to $22.68 \pm 3.26^\circ$ at one week after surgery and 23.14 ± 3.53 at one year. In the control group it decreased from $23.66 \pm 3.35^\circ$ to $22.60 \pm 3.38^\circ$ at one week after operation, but had increased to $31.36 \pm 5.41^\circ$ at one year. There was no significant difference ($P > 0.05$) between two groups preoperatively and one week after surgery, however, a

statistically significant difference was found between two groups after 12 months of follow-up, with the Cobb angle of the treatment group being smaller than that of the control group (Table 4).

Complications

No procedure-related adverse events were observed in this study. Some extra-vertebral cement leakages were found in the intraoperative and postoperative radiographs. According to radiographic analysis, the rate of cement leakages was 13.9% (5 of 36) and 14.3% (6 of 42) in therapy group and control group, respectively, and no significant difference was found between two groups ($P > 0.05$).

Discussion

1. Feasibility, safety and clinical efficacy of PVP with flexible cement injectors

Some studies showed that the relief of pain is associated with symmetrical distribution of bone cement in the vertebral body. The improvements of physical status are largely depending on the volume of cement infusion during PVP^[9-10]; insufficient cement volume may lead to poor efficacy and failure of surgery. Conversely, increasing the amount of cement injection may increase the incidence of cement leakage^[11-13]. Clinical studies have shown that 70% of complications of vertebral body forming are associated with the cement leakage^[14-17]. To overcome the shortcomings of PVP technology in the area of sufficient and symmetrical cement distribution, the flexible bone cement injector was designed to deliver bone cement at three zones in the vertebral body. Due to the multi-point injection, the injected cement is in the state of low pressure diffusion and subsequently bone cement leakage caused by high pressure has been avoided.

In traditional rigid injection cannulae, in order to distribute bone cement evenly on both sides of the vertebral body via the unilateral puncture, the angle of trocar approach should be as oblique as possible without damaging the medial cortex of the pedicle. This may risk neurological damage. This more oblique angle is not necessary in bilateral puncture, but the frequency of operative time and radiation exposure will be increased. These problems are overcome by using the flexible cement system^[18].

In this study, the results confirmed the efficacy of PVP in the treatment of AOVF, which were reflected in immediate and significant change in VAS and QUALEFFO scores. Meanwhile, using flexible bone cement injector and three-region injection technology, it was shown that bone cement can be distributed more evenly in the vertebral body even puncture through single side of the vertebral pedicle.

2. Long-term efficacy of the two systems

Murphy^[19] reported that uneven distribution of the bone cement in the vertebral body may lead to further pressure-loading in the injury side of vertebra, and subsequent instability of spine. Under the constant

loading, the vertebral body may buckle to the contralateral side, and thus causing further compression deformation of the vertebral body. The flexible bone cement injector cannula bends at its immediate exit from the interoducer due to the elastic energy of the inner wire of Ni-ti alloy, the curved angle channel reaches zones which a traditional rigid cannula cannot, thereby permitting a more uniform strengthening effect of the whole vertebra. In this study, compared with the control group, both vertebral height and back pain were significant worse in the control group than the treatment group at one-year follow-up. It seems likely that more uniform cement distribution and increased volume of cement improves the stability of the spine in the long-term.

There were some limitations in this retrospective study, and the sample of patients included is rather small. Moreover, follow-up periods in two groups were relatively short. Long-term follow-up data with a larger sample of patients is needed in future studies.

Conclusion

This study confirmed that both Flexible injector and straight bone injector PVP are safe and effective in the treatment of painful AOVF. During the period of follow-up(12-months), both methods showed good clinical outcomes. However, bone cement was distributed more evenly in the vertebral body via the flexible system without prolonging the surgical time, radiation exposure or increasing the incidence of bone cement leakage. The flexible cement injection technology demonstrated better long-term efficacy, compared with the traditional straight bone cement injection technology.

Abbreviations

AOVF

Acute osteoporotic vertebral fracture.

PMMA

Polymethyl methacrylate.

PVP

Percutaneous vertebroplasty.

QUALEFFO

Quality of life questionnaire of the European Osteoporosis Foundation

RAH

relative anterior height of the fractured vertebra

Declarations

1 Ethics approval and consent to participate

The study protocol was approved by the Institutional Review Boards and the Ethics Committees of Luohe Medical College. Before operation, informed consents were signed by all the patients after detailed

explanation of the therapeutic procedure to the patients. The study is conducted according to the guideline for case series.

2 Consent for publication

Written informed consent for publication was obtained from all participants.

3 Availability of data and material

All data generated or analysed during this study are included in this published article.

4 Competing interests

The authors declare that they have no competing interests.

5 Funding:

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6 Authors' contributions

All authors contributed to data collection and wrote the manuscript. Wei Cui and Yuwei Li drafted the study protocol. Peng Zhou and Cheng Li performed literature review. Wei Xiao and Yan Wen collected data. Peng Zhou performed the analyses. Yuwei Li, Wei Cui and Haijiao Wang drafted the paper. All authors critically reviewed the paper. Yuwei Li and Wei Cui had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Yuwei Li and Wei Cui are the guarantors of the paper. All authors approved the current manuscript to be published, attested that they contributed substantially to the current work, and disclosed that there was no writing assistance.

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Tables

Due to technical limitations, the tables are only available as a download in the supplemental files section.

Figures



Figure 1

Diagrams of the flexible bone cement injection device and its mode of operation. a. Flexible cement injector, showing its in-built curved tip b. Insertion of the flexible cement injector through the introducer c. A first mark on the flexible injector cannula identifies the point where the tip exits the introducer. d. Using gentle back-and-forth rotation, the bone cement injector is advanced into the vertebral body e. On reaching the second mark on the flexible injection cannula, , the tip of the cannula is located at the center of the vertebral body f. When reaching the second scale at the end of the cement injector, it indicates that the cement injector head is on the opposite side of the vertebral body g. The central wire is removed. h.

The bone cement is first injected on the contralateral side of the vertebral body i. Approximately 2ml of bone cement is used at this first point. j. The injector is retracted to the second mark and a further 2ml bone cement is injected. k. The injector is retracted to the first mark and a further 2ml bone cement is injected.

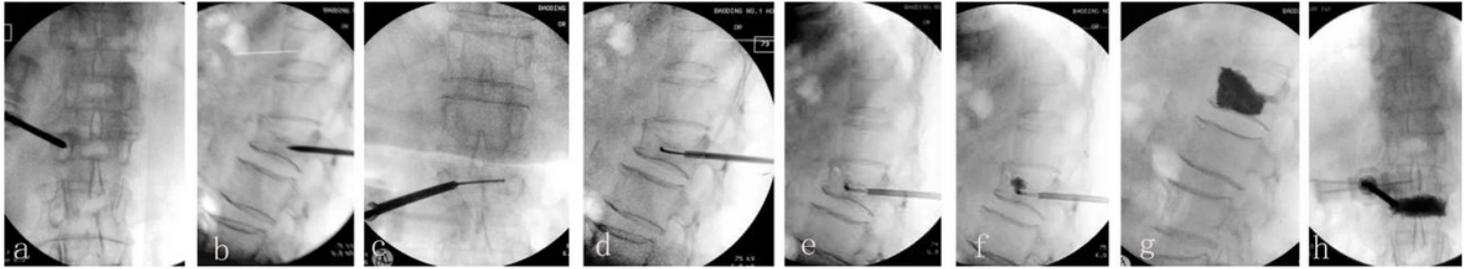


Figure 2

Intraoperative fluoroscopic images of the surgical procedure using the flexible injection system
a. Posteroanterior fluoroscopic image: the trochar introducer penetrates the bone at the lateral edge of the pedicle
b. Lateral fluoroscopy: The tip of the trochar reaches approximately 4mm anterior to the posterior cortex of the vertebral body
c./d. Posteroanterior and lateral fluoroscopies: The flexible cement injection cannula is directed towards the opposite side of the vertebral body
e./f. Lateral fluoroscopies: bone cement is sequentially injected as the cannula is gradually retracted according to the steps described in figure 1.
g./h. Lateral and posteroanterior fluoroscopies: bone cement injection is complete.

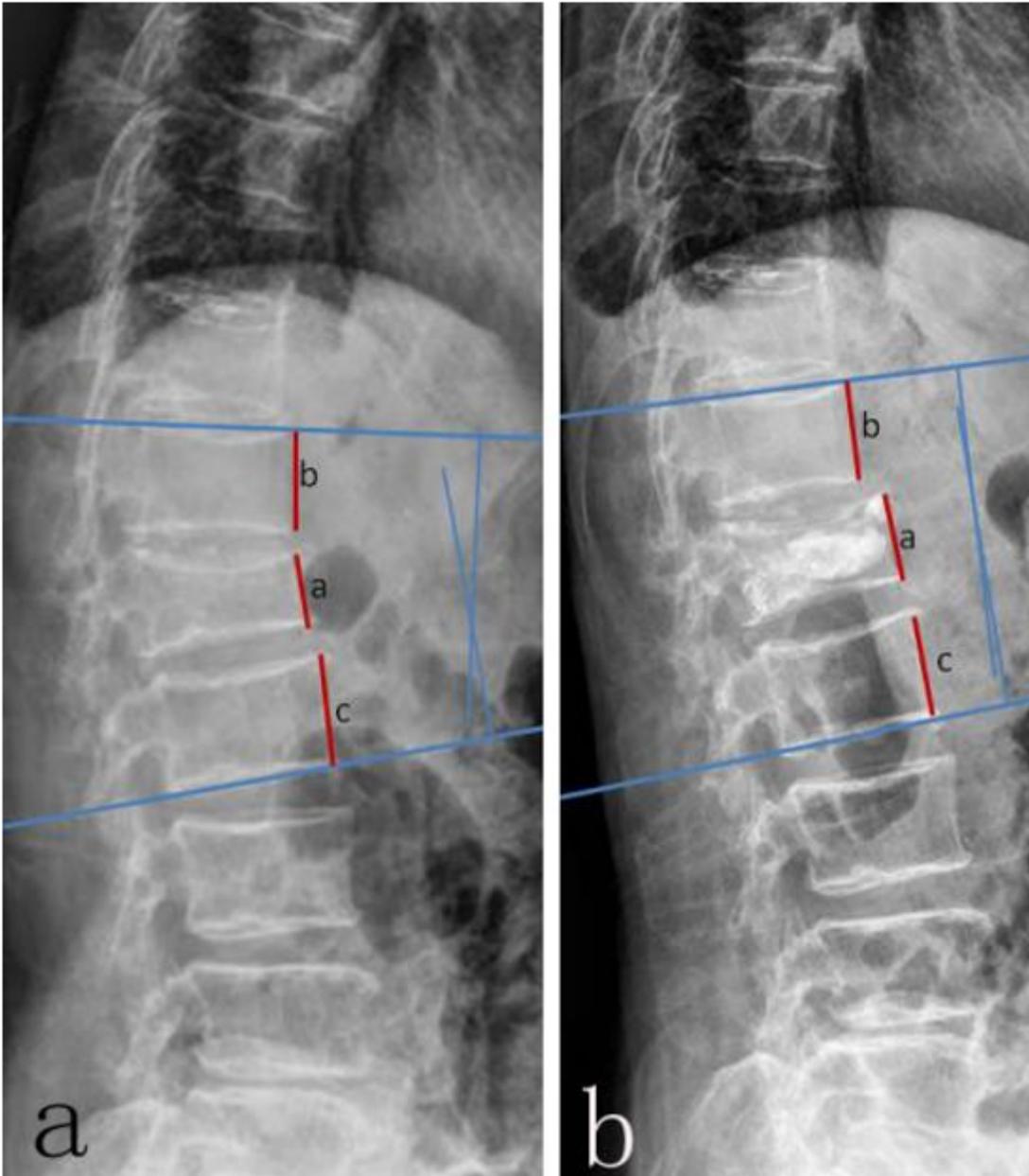


Figure 3

The relative anterior height of the fractured vertebra and the kyphotic angle measurement method a.
 $TRA = a / [(b+c)/2]$ b. kyphotic angle = α

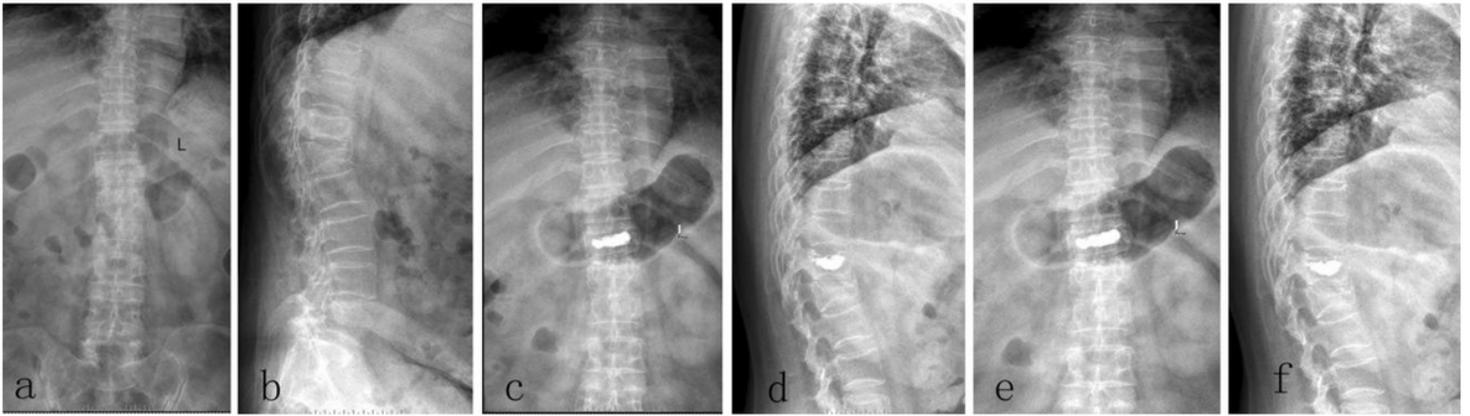


Figure 4

71-year-old woman with L2 vertebral fracture treated with flexible cement injector PVP a~b. Preoperative spinal column: L2 vertebral fractures c~d. One week after operation, spinal column: The distribution of bone cement is symmetrical e~f. Lumbar lateral position slice 2 years after operation: The bone cement remains symmetrically distributed, and the height of the injured vertebra has not changed.

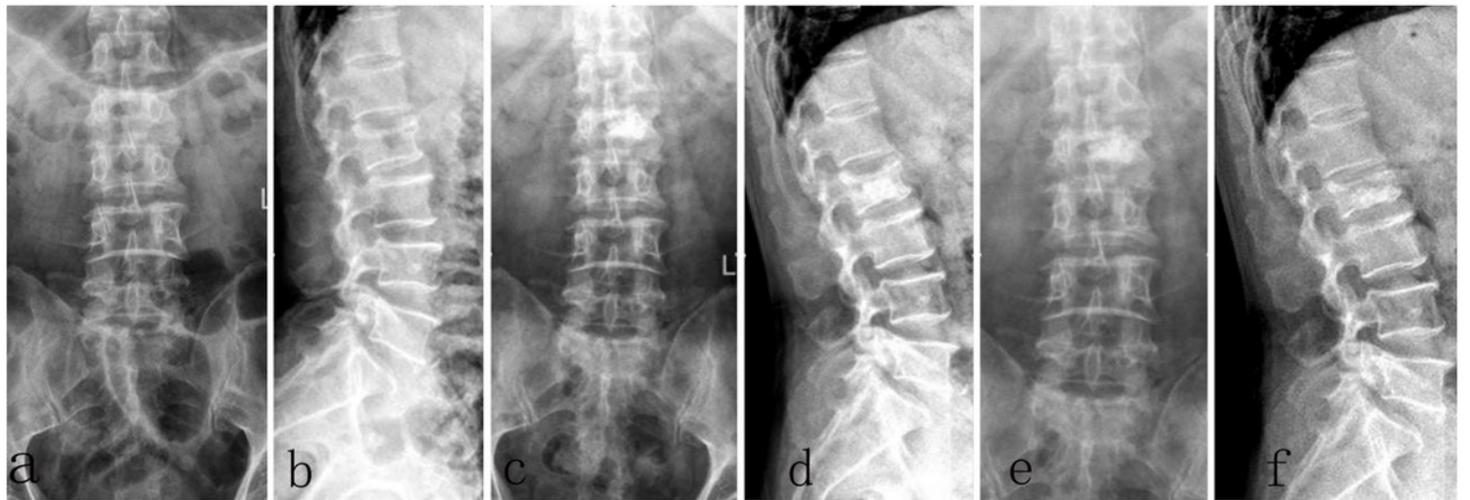


Figure 5

69-year-old woman with L2 vertebral fracture treated with straight bone cement injector PVP a~b. Preoperative spinal column: L2 vertebral fractures c~d. One week after operation, spinal column: Bone cement is seen on one side of the vertebral body e~f. 2 years postoperative spinal column: Vertebral height of the treated vertebra has diminished.

Supplementary Files

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