Kyphoplasty With a New Device: A Comparison Study

Jian Huang (wawayjs@sina.com)
Haikou Hospital of Traditional Chinese Medicine https://orcid.org/0000-0002-5434-1148
Ming Chen
Haikou Hospital of Traditional Chinese Medicine
Zongbo Zhou
Haikou Hospital of Traditional Chinese Medicine
Zhifu Lu
Haikou Hospital of Traditional Chinese Medicine
Chuangong Fu
Haikou Hospital of Traditional Chinese Medicine
Xuejian Gou
Haikou Hospital of Traditional Chinese Medicine
Zuqing Wu
Haikou Hospital of Traditional Chinese Medicine
Zhaodong Yan
Haikou Hospital of Traditional Chinese Medicine

Research article

Keywords: kyphoplasty, surgical method

Posted Date: May 10th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-489228/v1

Abstract

Study design: Retrospective cohort study.

Objective: To explore the effect of a new device for kyphoplasty.

Methods: 80 patients with kyphoplasty from January 2019 to December 2020 were selected and divided into experimental group (n = 40) and control group (n = 40) according to different surgical methods. The experimental group was treated with new puncture needle puncture technology, while the control group was treated with traditional puncture needle puncture technology. The operation time and intraoperative blood loss were recorded. The pain improvement was evaluated by VAS score. The operation effect was evaluated by anterior height of injured vertebral body, middle height of injured vertebral body and wedge angle of injured vertebral body. The number of fluoroscopy and the cost of operation were also evaluated.

Results: Compared with the control group, the operation time and intraoperative blood loss of the experimental group were significantly less than those of the control group, and the differences were statistically significant. There was no significant difference in the ratio of anterior height of injured vertebral body between the two groups on the third day and the last follow-up. There was no significant difference in the ratio of middle height of in injured vertebral body between the two groups on the third day and the last follow-up. There was no significant difference in wedge angle of injured vertebral body between the two groups at the third day and the last follow-up. There was significant difference in the number of fluoroscopy between the two groups. There was no significant difference in the operation cost between the two groups.

Conclusion: The new surgical method can shorten the operation time and reduce the radiation exposure rate of surgeons, but it has no effect on the operation effect and operation cost.

Backgroud

Kyphoplasty is a common surgical method for the treatment of osteoporotic vertebral compression fractures [1], malignant tumor bone metastasis, Kummell disease and so on [2]. It mainly through bilateral or unilateral pedicle puncture to establish a working channel, and through the working channel to expand the collapse of the vertebral body, to form a cavity in the vertebral body, inject PMMA (polymethyl methacrylate), and play an important role in analgesic effect through the polymerization exothermic effect and anchoring mechanism of bone cement [3]. Generally, patients can wear protective equipment to sit up in bed or even walk on the ground 2 hours after operation. The operation can be completed only by local anesthesia. The operation time is short, the analgesic effect is obvious, and the average length of hospitalization is short. In accordance with the indications,it has become the preferred treatment method for osteoporotic vertebral compression fractures [4–5]. However, due to the more times of exposure to radiation, it has an impact on the health of surgeons. In this study, a new type of kyphoplasty equipment was used to treat vertebral pathological fractures, which can shorten the operation time, reduce the number of surgeons exposure to radiation, and obtain a better fracture prognosis.

Materials And Methods

Patient selection method

Inclusion criteria include the following: (a) back and waist pain, limited activity; (b) MRI showed fresh vertebral compression fractures, vertebral bone metastases or Kummell disease; (c) CT scan diagnosed as thoracolumbar flexion compression fractures, Denis type A-D [6]; (d) Asia Grade E; (e) 18 years and older; (f) the responsible vertebral body of patient was a single segment.

Exclusion criteria include the following: (a) patients with other fractures; (b) patients with bone cement allergy; (c) patients with nerve injury and progressive aggravation; (d) patients with osteomyelitis and epidural cyst; (e) patients with coagulation dysfunction.

General information

80 patients with kyphoplasty from January 2019 to December 2020 were selected and divided into experimental group (n = 40) and control group (n = 40) according to different treatment methods.

Surgical technique

All operations were performed by the chief surgeon of spine surgery. All patients were treated with local infiltration anesthesia [7]. All patients were in prone position, with pillows on the chest and ilium [8]. The pedicle of the responsible vertebral body was located and marked by C-arm fluoroscopy. The 10'a clock and 2'a clock positions of the pedicle shadow on both sides of the responsible vertebral body were used as puncture points. The experimental group was punctured with a new puncture needle with a diameter of 4.0 mm (Fig. 1), and the puncture points by C-arm fluoroscopy was good, Maintain the appropriate lateral tilting angle and upper tilting inclination angle, continue to knock the needle inward, C-arm fluoroscopy showed that the needle tip had reached the medial edge of pedicle shadow in the anterior and posterior position, and the needle tip had reached the posterior edge of vertebral body in the lateral position, continue to knock the needle inward for 3mm, removed the inner core of the needle, and had established the working channel. The bone drill was inserted into the working channel on both sides to expand the bone channel in the vertebral body, and then the balloon was placed to expand. The edge of the balloon was close to the upper and lower endplates, reached the cortex around the vertebral body, or the vertebral fracture was restored,and the expansion was stopped. Appropriate PMMA was injected through the working channel (Fig. 2, 3).

The diameter of the puncture needle in the control group was 3.0 mm. After removing the inner core of the puncture needle, the guide needle was put in first, then the puncture needle cannula was removed, and then the expansion cannula and the working cannula were inserted along the guide needle to establish the working channel. The tip of the working cannula was 3mm in front of the posterior cortex of the vertebral body under C-arm fluoroscopy. Finally, the expansion cannula and guide needle were removed,

and the working channel was established. The remaining operations was the same as the experimental group.

Postoperative managements

All patients wear waist circumference by nurse guided to walk 2 hours after operation and change wound dressing on time.

Efficacy evaluation

All patients were followed up for at leat 12 months after treatment. The operation time and intraoperative blood loss of all patients were recorded. Intraoperative blood loss = (preoperative hemoglobin - postoperative hemoglobin) / preoperative hemoglobin × 100%. VAS pain score standard [9] was used to evaluate the improvement of pain. From 0 to 10 points, the higher the score, the more obvious the pain. VAS scores before operation, 2h, 4h and 48h after operation were recorded. The vertical height of the anterior edge of the upper and lower endplates in the median sagittal plane of the vertebral body was measured by lateral X-ray film [10]. The ratio of anterior height of injured vertebral body = (anterior height of injured vertebral body / average height of anterior edge of upper and lower vertebral body of injured vertebral body) × 100%. The anterior height of injured vertebral body was recorded before operation, 3 days after operation and the last follow-up. The vertical height of the middle of the upper and lower endplates in the median sagittal plane of the vertebral body was measured by lateral X-ray film. The ratio of middle height of injured vertebral body = (middle height of injured vertebral body / average height of middle of upper and lower vertebral body of injured vertebral body) × 100%. The middle height of injured vertebral body was recorded before operation, 3 days after operation and the last follow-up.The angle between the extension lines of the upper and lower endplates in the median sagittal plane of the vertebral body was measured by lateral X-ray film. The wedge angle of injured vertebral body was recorded before operation, 3 days after operation and the last follow-up [11]. The number of C-arm fluoroscopy during the operation and the total cost of the operation were recorded.

Statistical methods

SPSS 26.0 was used for data analysis. The measurement data were expressed by mean ± standard deviation. For intergroup comparison, variance homogeneity F test was used first, then independent sample t / t' test was used, and paired sample t test was used for intragroup comparison. The count data were expressed by the number of cases and percentage, and the comparison of counting data was performed by chi-square test. Test level $\alpha = 0.05$, bilateral test.

Results

General results

All patients had no serious complications, Such as PMMA leakage, nerve root and spinal cord injury, wound infection. There were no significant difference in gender, age and clinical manifestations between the two groups (Table 1).

Comparison of operation time、intraoperative blood loss

There were significant difference in operation time and intraoperative blood loss between the two groups (Table 2).

Comparison of VAS scores

There was no significant difference in VAS scores between the two groups on preoperation. In each group,there were significant difference in VAS scores between the preoperation and 2h, 4h and 48h after operation. But there was no significant difference in VAS scores between the two groups at 2h, 4h and 48h after operation (Table 3).

Comparison of ratio of anterior height of injured vertebral body

There was no significant difference in the ratio of anterior height of injured vertebral body between the two groups before operation. In each group, there were significant difference in the ratio of anterior height of injured vertebral body between the preoperation and 3 days after operation, last follow-up. But there was no significant difference in the ratio of anterior height of injured vertebral body between the two groups at 3 days after operation and last follow-up (Table 4).

Comparison of ratio of middle height of injured vertebral body

There was no significant difference in the ratio of middle height of injured vertebral body between the two groups before operation. In each group, there were significant difference in the ratio of middle height of injured vertebral body between the preoperation and 3 days after operation, last follow-up. But there was no significant difference in the ratio of middle height of injured vertebral body between the two groups at 3 days after operation and last follow-up (Table 5).

Comparison of wedge angle of injured vertebral body

There was no significant difference in the wedge angle of injured vertebral body between the two groups before operation. In each group, there were significant difference in the wedge angle of injured vertebral body between the preoperation and 3 days after operation, last follow-up. But there was no significant difference in the wedge angle of injured vertebral body between the two groups at 3 days after operation and last follow-up (Table 6).

Comparison of the number of C-arm fluoroscopy during the operation and the total cost of the operation

There were significant difference in the number of C-arm fluoroscopy during the operation between the two groups. But there was no significant difference in the total cost of the operation between the two

groups (Table 7).

Discussion

In the 1980s, Deramand and Galibert of France injected PMMA into C2 vertebral body under X-ray fluoroscopy to treat osteonecrosis of vertebral body caused by hemangioma, in order to alleviate long-term pain of patients, and achieved satisfactory clinical effect after 3 years of follow-up. This technology was known as PVP [12], which opened up a precedent for minimally invasive treatment of osteoporotic vertebral fracture. However, PVP can not effectively restore the height of vertebral body, correct kyphosis deformity, and better reconstruct the stability of spine, and bone cement is easy to leak outward along the fracture, which increases the risk of surgery [13]. In 1994, American medical scientists designed PKP, that was, percutaneous implanting expandable balloon into the diseased vertebral body to restore the compression fracture and form a cavity in the vertebral body, and then filling the cavity with bone cement, increasing vertebral strength and stiffness [14], which can relieve pain, correct kyphosis, reconstruct spinal stability, and improve the quality of life of patients [15]. The possible analgesic mechanism was that bone cement is anchored in the vertebral body to fix osteoporotic microfracture, increase the stability of vertebral body and reduce the stimulation of pain nerve endings in vertebral body. Or the polymerization exothermic and toxic effect of bone cement destroy the nerve endings and inflammatory pain factors in the vertebral body, change the microenvironment in the vertebral body, reduce the pain sensitivity, block the generation of pain mediators, and achieve the analgesic effect [16–18].

PKP has a wide range of applications. For primary osteoporotic vertebral compression fractures. It can be selected if the pain can not be alleviated or wanting to prevent the related complications caused by long-term bed rest. For vertebral benign tumor or malignant tumor vertebral bone metastasis, PKP surgery can also be selected to improve the pain symptom. For old vertebral compression fractures or the diagnosis is Kummell disease, if MRI indicates that the vertebral body still has high signal, and the pain symptoms are consistent with imaging, PKP can also improve the pain symptom [19]. Tohmeh Ag et al. [20] compared the biomechanical efficacy of unilateral and bilateral transpedicular kyphoplasty through uniaxial compression test, and found that there was no significant difference between unilateral and bilateral approaches. However, we believe that bilateral pedicle puncture and bilateral balloon dilatation can effectively restore the collapsed endplate and reduce the risk of scoliosis.

In the traditional PKP, the puncture needle was used first, and the puncture needle position by C-arm fluoroscopy was satisfied, pulled out the core of the puncture needle, inserted the guide needle, pulled out the puncture needle cannula, inserted the expansion cannula along the guide needle, then inserted the working cannula to 3mm in front of the posterior cortex of the vertebral body, and finally removed the expansion cannula and the guide needle. We used a new puncture needle device instead of the traditional puncture needle. After the position by C-arm fluoroscopy was satisfied, we pulled out the inner core of the puncture needle and left the puncture needle cannula in the body as the working channel. Compared with the traditional operation method, it reduces the process of inserting the guide needle, and then gradually

inserting the expanding cannula and working cannula through the guide needle. Through comparative study, it was found that the operation time, intraoperative blood loss and the number of C-arm fluoroscopy during the operation of the experimental group were better than those of the control group, while there was no significant difference in VAS pain score, anterior and middle height of injured vertebral body, wedge angle of injured vertebral body and operation cost between the two groups. It can be seen that the new operation method can shorten the operation time and reduce the radiation exposure rate of surgeons, but it has no effect on the operation effect and operation cost.

However, the sample size of this study is small. In the future work, we will further expand the sample size, and try to improve the operation technology to further shorten the operation time and reduce the radiation exposure rate of surgeons, so as to improve the popularity of PKP.

Conclusion

The new operation method can shorten the operation time and reduce the radiation exposure rate of surgeons, but it has no effect on the operation effect and operation cost, so it can be widely used in clinic.

Abbreviations

PVP
percutaneous vertebroplasty; PKP:percutaneous kyphoplasty; MRI:Magnetic resonance imaging; VAS:Visual analog scale; OVCF:osteoporotic vertebral compression fractures

Declarations

Acknowledgements

Not applicable.

Authors' contributions

The author(s) read and approved the final manuscript.

Funding

Supported by Hainan Provincial Natural Science Foundation of China(820RC787).

Scientific research projects of health and family planning industry in Hainan Province(19A200127).

Academic experience inheritance project of the Sixth Batch of national elder traditional Chinese medicine and pharmacology experts([2017]No.29).

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.

Competing interests

The authors declare that they have no competing interests.

Author details

1Department of Orthopedics, Haikou Hospital of Traditional Chinese Medicine, 2 Poxiang Road, Longhua District, Haikou City, Hainan Province, People's Republic of China.

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Tables

Table 1 Patient characteristics

	experimental group	control group	P▽
Number	40	40	
Gender (male to female)	6:34	7:33	0.531
Clinical manifestations			
Pain	40	40	0.313
Percussion pain	40	40	0.313
Constipation	30	31	0.402
Bulbocavernous reflex was positive	40	40	0.313
Anal reflex was positive	40	40	0.313
Responsibility section			
Thoracic vertebra	21	18	0.492
Lumbar vertebra	19	22	0.424

▽P values are calculated by chi-square test

Table 2 Comparison of operation time、intraoperative blood loss in two groups

	experimental group	control group	t / t'	P
operation time(min)	28±3.26	50±6.27	4.907	0.007*
intraoperative blood loss(%)	1.91±0.84	2.10±0.47	3.599	0.028*

Values are mean ± SD

*Statistically significant

Table 3 Comparison of VAS scores in two groups

	experimental group	control group	t / t'	P
Preoperation	8.14±0.93	8.03±0.58	0.385	1.039
2h after operation	3.41±0.04*	3.03±0.41*	0.471	0.825
	$t = 4.084$, $P < 0.05$	$t = 4.531$, $P < 0.05$		
4h after operation	1.26±0.03*	1.36±0.12*	0.427	0.899
	$t = 5.525$, $P < 0.01$	$t = 5.611$, $P < 0.01$		
48h after operation	0.14±0.08*	0.16±0.06*	0.501	0.839
	$t = 5.904$, $P < 0.01$	$t = 5.893$, $P < 0.01$		

Values are mean ± SD

*Statistically significant

Table 4 Comparison of ratio of anterior height of injured vertebral body in two groups

	experimental group	control group	t / t'	P
Preoperation	49.53±6.03	48.42±5.25	0.752	0.628
3 days after operation	86.97±6.02*	87.74±5.59*	0.425	0.899
	$t = 4.264$, $P < 0.05$	$t = 4.252$, $P < 0.05$		
Last follow-up	87.13±6.16*	86.64±6.93*	0.593	0.766
	$t = 4.706$, $P < 0.05$	$t = 4.637$, $P < 0.05$		

Values are mean ± SD

*Statistically significant

Table 5 Comparison of ratio of middle height of injured vertebral body in two groups

	experimental group	control group	t / t'	P
Preoperation	51.93±7.03	53.42±5.91	0.682	0.712
3 days after operation	91.07±3.29*	90.24±3.68*	0.504	0.837
	$t = 4.581$, $P < 0.05$	$t = 4.636$, $P < 0.05$		
Last follow-up	89.37±4.68*	88.37±5.83*	0.603	0.754
	$t = 5.078$, $P < 0.01$	$t = 5.146$, $P < 0.01$		

Values are mean ± SD

*Statistically significant

Table 6 Comparison of wedge angle of injured vertebral body in two groups

	experimental group	control group	t / t'	P
Preoperation	24.28±3.89	23.34±4.51	0.374	1.042
3 days after operation	3.29±1.12*	3.26±1.46*	0.358	1.061
	$t = 4.678$, $P < 0.05$	$t = 4.963$, $P < 0.05$		
Last follow-up	3.56±1.02*	3.84±1.89*	0.421	0.991
	$t = 4.213$, $P < 0.05$	$t = 4.596$, $P < 0.05$		

Values are mean ± SD

*Statistically significant

Table 7 Comparison of the number of C-arm fluoroscopy during the operation and the total cost of the operation in two groups

	experimental group	control group	t / t'	P
number of C-arm fluoroscopy during the operation	16.35±5.27	19.94±6.30	5.472	0.005*
total cost of the operation(million)	2.84±0.37	2.62±0.70	0.670	0.739

Values are mean ± SD

*Statistically significant

Figures

Figure 1

New puncture needle with a diameter of 4.0mm

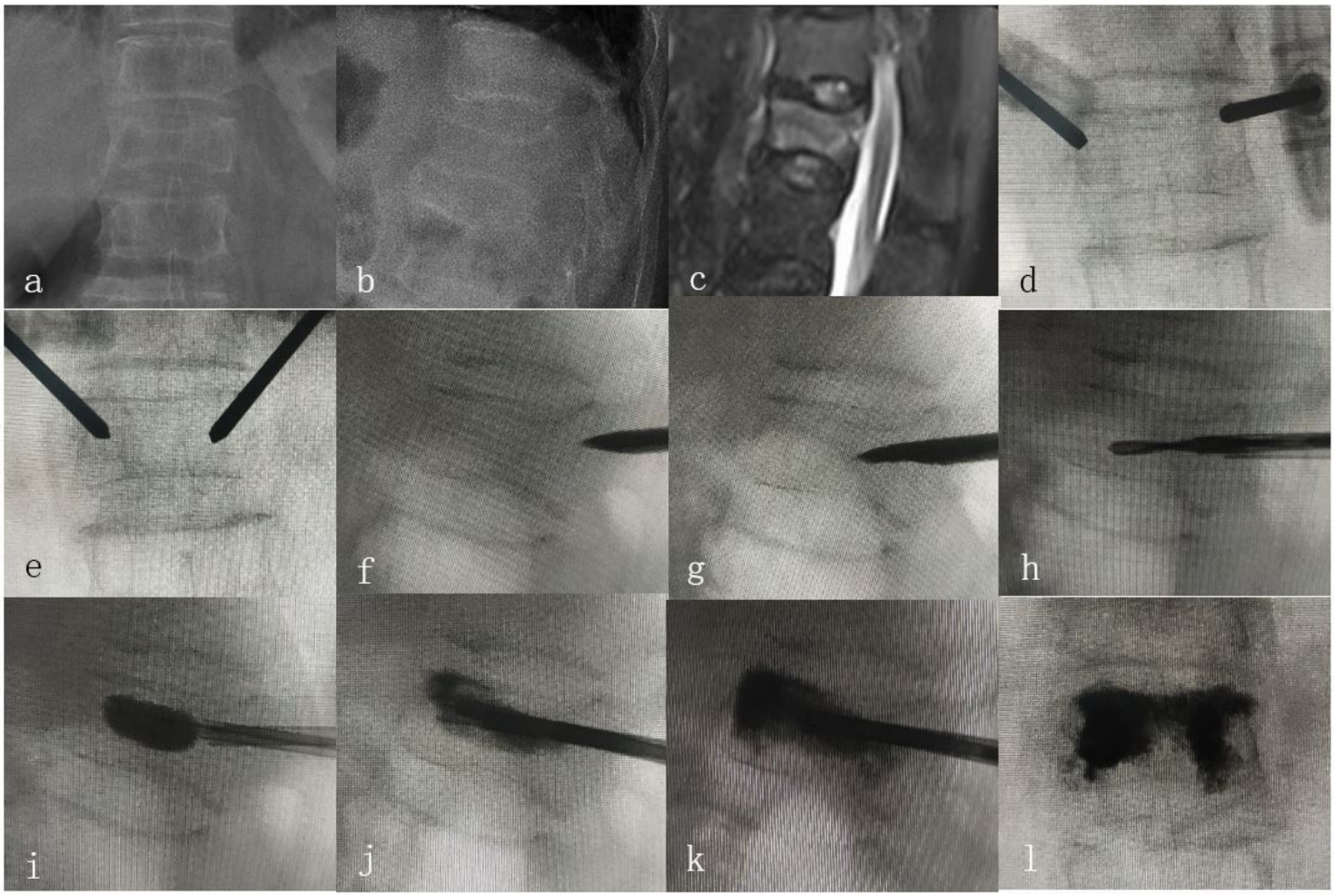

Figure 2

A 64 year old woman was diagnosed with T12 OVCF. a Preoperative anterior and posterior X-ray of thoracic spine. b Preoperative lateral X-ray of thoracic spine. c Preoperative MRI sagittal position. d Puncture. e Needle tip had reached the medial edge of pedicle shadow in the anterior and posterior position. f Needle tip had reached the posterior edge of vertebral body in the lateral position. g 3 mm in front of the posterior edge of the pedicle. h Expanded the bone channel by bone drill. i Restored the compression fracture and formed a cavity by expandable balloon. j-l PMMA was injected through the working channel.

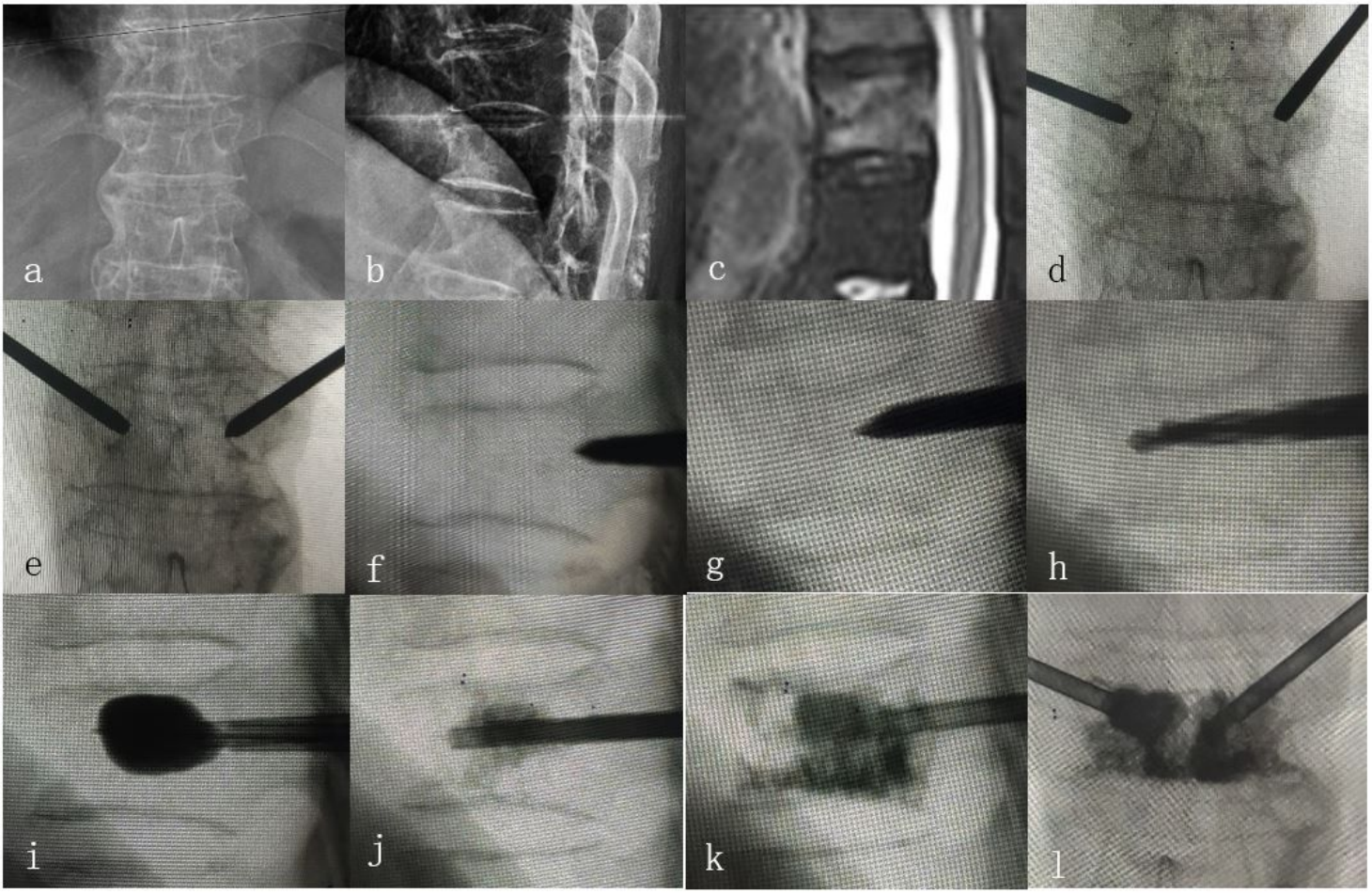

Figure 3

A 80 year old man was diagnosed with T11 vertebral bone metastases. a Preoperative anterior and posterior X-ray of thoracic spine. b Preoperative lateral X-ray of thoracic spine. c Preoperative MRI sagittal position. d Puncture. e Needle tip had reached the medial edge of pedicle shadow in the anterior and posterior position. f Needle tip had reached the posterior edge of vertebral body in the lateral position. g 3 mm in front of the posterior edge of the pedicle. h Expanded the bone channel by bone drill. i Restored the compression fracture and formed a cavity by expandable balloon. j-l PMMA was injected through the working channel.