Precise Puncture Combined With Simplified Percutaneous Vertebroplasty to Treat Osteoporotic Vertebral Compression Fractures: A Comparative Analysis With Conventional Percutaneous Vertebroplasty

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Research article

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Abstract

Objective

This study aimed to investigate the feasibility and clinical efficacy of precise puncture combined with simplified percutaneous vertebroplasty (PVP) for treating osteoporotic vertebral compression fractures (OVCF).

Methods

A total of 82 patients with single-segment osteoporotic vertebral compression fractures (OVCF) were treated with PVP from Dec. 2016 to Nov. 2018. Among the patients, 45 cases in group A and accepted precise puncture combined with simplified PVP, 37 cases in group B and underwent conventional PVP. The operative time, number of intraoperative fluoroscopy, vertebral height restoration, postoperative bone cement distribution and bone cement leakage were observed and compared. The pain relief and improvement of quality of life (QOL) were assessed by visual analog score (VAS) and Oswestry disability index (ODI).

Results

There were no difference in injected cement volume and hospital stays in group A versus group B ($P > 0.05$). The operative time, number of intraoperative fluoroscopy and material cost were lower in group A compared with group B ($P < 0.05$). After surgery, both of the VAS scores and ODI had a significant decrease ($P < 0.05$). The average vertebral height and Cobb angle were significantly improved ($P < 0.05$), there was no statistically significant difference between groups at different time points ($P > 0.05$). The proportion of patients with bone cement dispersion exceeding the midline of vertebra in group A was significantly higher than that in group B (82.2% vs 62.1%) ($P < 0.05$), whereas the bone cement leakage rate was lower than group B (8.9% vs 27.0%) ($P < 0.05$). Patients were followed-up for 12-23 months (mean 17.6 months) after surgery, and 3 cases (6.6%) of adjacent vertebral fractures occurred in group A and 2 cases (5.4%) occurred in group B ($P > 0.05$).

Conclusion

Precise puncture can improve the accuracy of puncture needle through pedicle to vertebral body. It conducive to obtain a better diffusion of bone cement across the midline with lower bone cement leakage rate. Simplified PVP can reduce the surgery procedures, shorten the operatige time, reduces the X-ray frequency, but also saves material cost.

Background

With the aging of population structure, the incidence of osteoporotic vertebral compression fracture (OVCF) is increasing year by year. The pain symptoms induced have seriously affected the self-care ability and quality of life (QOL) of elderly patients [1]. As a mature minimally invasive technique, percutaneous vertebroplasty (PVP) has been widely used in many countries. It has become one of the quick and effective methods for treatment of OVCF, due to the advantages of simple operation, rapid relief of pain, recovery of vertebral height, improvement of kyphosis and fewer X-ray expose, etc [1-5]. Polymethyl methacrylate (PMMA) is infused directly after successful puncture through pediclle channel. The steps of establishing balloon channel and intravertebral balloon dilation are omitted. Therefore, intraoperative X-ray frequency and material cost reduce dramatically. High bone cement leakage rate during PVP is the biggest concern clinically. Young et al [3]. found that the bone cement leakage rate during PVP was up to 76%. Spinal surgeons attempted to improve conventional PVP, such as using percutaneous curved vertebroplasty technique [4], adopting high viscosity bone cement [5] and applying vertebral gelatin sponge debris pre-perfusion [6].

All approaches above remarkably reduced bone cement leakage. In fact, the most direct and effective way to reduce the bone cement leakage rate is to achieve the precise puncture to avoid the cracked vertebral cortex as far as possible. Because of the low resistance in the ruptured area, bone cement diffusion is more likely to occur during perfusion, thus cement leakage occurs [2]. How to precisely puncture the pedicle without using O-arm, CT or other large navigation equipment? In this study, anatomical site of vertebrae was used to achieve precise puncture, and PVP procedures were further simplified. A comparison with conventional PVP was given to show its advantages in improving the puncture accuracy and reducing the bone cement leakage.

Materials And Methods

1.1 General Information

A total of 82 patients with single-segment OVCF received PVP in Harrison international peace hospital of Hengshui City from Dec. 2016 to Nov. 2018 was retrospectively analyzed. Patients were divided into two groups according to the surgical procedure they accepted. Group A (45 cases) accepted precise puncture combined with simplified PVP and group B (37 cases) underwent conventional PVP. Written informed consent forms were obtained from all included patients. The study was approved by the hospital's medical ethics committee. Baseline data, including age, sex, injury time, bone mineral density (BMD) and fracture location, had no significant difference between the two groups ($P > 0.05$) (Table 1).

1.2 Inclusion and Exclusion Criteria

Inclusion criteria: Had local tenderness, percussion pain and other typical clinical manifestations; Fresh vertebral compression fracture, from injury to surgical treatment < 2 weeks; BMD T value ≤ -2.5SD, in compliance with the diagnosis criteria of osteoporosis; Clinical follow-up > 12 months.

Exclusion criteria: Patients with old vertebral compression fractures, vertebral tuberculosis or tumor; Coagulation disorders, recent infection and inflammatory reaction; CT scan confirmed vertebral bursting fracture, damage in posterior wall of vertebrae or lower extremity nerve symptom.

1.3 Imaging Examination

All patients were given routine X-ray, CT scan and MRI examinations after admission. The position of fractured vertebrae, the degree of vertebral height loss and the angle of local kyphosis can be roughly determined by X-ray. CT scan can determine whether the anterior edge of vertebrae was damaged, whether the posterior wall was intact and whether the fractured fragments were invasive to the spinal canal. The trajectory of puncture needle into pedicle can be recorded on cross section, and optimal abduction angle was measured (Figure.2B). Fresh or concealed fracture can be diagnosed by MRI based on the signal changes in vertebra (Figure.2A).

1.4 Surgical procedure

All surgeries were completed by the same senior surgeon (Dr. Zhang). Patient was kept in a prone position. A cushion was put under the chest and hip to suspend the abdomen. The diseased vertebral body was positioned with C-arm X-ray. Perspective position was adjusted to equate the distance of pedicle projection on both sides from spinous process. Thus, the upper and lower edges of vertebrae were in a straight line. The puncture site was located at 2cm-2.5cm beside the apical spinous process. Cut the skin at the puncture site longitudinally, approximately 4~5 mm. Vertebrae was punctured with vertebroplasty system (Shanghai Kinetic Co., Ltd, China) though unilateral pedicle.

Group A: Puncture needle (2.5 mm in diameter) was positioned in upper outer edge of vertebral pedicle. An insertion was made in accordance with the optimal abduction angle. Three reference points, including posterior wall of the pedicle, middle of the pedicle and junction of the vertebral body, were sequentially passed through on positive and lateral images (Figure.1A-D). Then, the needle entered vertebral body. Needle tip in lateral image reached the front 1/3 of vertebrae, and in positive image it was close to the midline of the vertebra. Inner core of puncture needle was pulled out. The prepared high-viscosity bone cement (Tianjin Institute of Synthetic Materials Industry, China) was aspirated with a 2 ml injector and infused slowly into the vertebral body while wire drawing. X-ray was performed once while 0.5 ml cement was infused. Infusion was stopped when bone cement diffused to upper or lower edge of vertebrae or to anterior edge of cortex (Figure.2C-H). Once the bone cement had hardened, puncture needle was removed.

Group B: Puncture needle was inserted at an abduction angle of 25°~35° to reach the outer upper edge of pedicle projection (left-side puncture at the 2 o'clock position, and right-side puncture at the 10 o'clock position). Once X-ray showed the needle had reached middle of vertebrae through pedicle, the needle core was pulled out. Insert the guide wire, and then establish a working channel (4.0 mm in diameter) along the guide wire. High-viscosity bone cement was slowly infused into vertebrae from catheter. Infusion was discontinued after bone cement diffused evenly. After removing the cannula, the patient was observed for 10 min and returned to the ward if no discomfort.

1.6 Evaluation parameters

The operative time, number of intraoperative fluoroscopy, injected cement volume, material cost and hospital stays were recorded. X-ray and CT scan were taken 1 day after surgery. The diffusion and leakage of bone cement in vertebra was observed. Vertebral body height and local Cobb angle were measured before and after surgery. Pain relief was evaluated with visual analogue scale (VAS) scores (10 points) [4]. QOL and self-care ability were assessed with Oswestry disability index (ODI) [7].

Vertebral body height: On the lateral radiograph, the distance between the upper and lower endplates of the anterior and midline of the vertebral body was measured respectively [7]. The average vertebral height = (anterior vertebral height + median vertebral height) /2. Bone cement dispersion exceeding the midline: A midline was drawn on the CT cross section of the film to observe whether the bone cement dispersion exceeded the midline (Figure.2I).

Cobb angle: On the lateral radiograph, straight lines parallel to vertebral endplate were drawn respectively on upper edge and lower edge of the vertebral body next to the diseased vertebra. The intersection angle of the two straight lines was the Cobb angle.[5]

1.7 Statistical Analysis

All statistical analyses were conducted using SPSS (Version 20.0; IBM, Chicago, IL, USA). A variance analysis of repeated measurements or a paired t-test was used to compare the measurement data. An X^2 test was used to compare the count data. Data were expressed as mean ± standard deviation. Two-sided P-values of <0.05 were considered statistically significant.

Results

In terms of operative time, number of intraoperative fluoroscopy and material cost, group A was significantly lower than group B ($P < 0.05$). There were no significant difference in injected cement volume and hospital stays in group A versus group B ($P > 0.05$). (Table 2)

The VAS scores and ODI decreased significantly in both groups after surgery ($P < 0.05$), and there was no significant difference between groups ($P > 0.05$). The average vertebral height and Cobb angle were significantly improved ($P < 0.05$), there was no statistically significant difference between groups at different time points ($P > 0.05$). (Table 3-4)

The proportion of patients with bone cement dispersion exceeding the midline of vertebra in group A was significantly higher than that in group B (82.2% vs 62.1%) ($P < 0.05$), whereas the bone cement leakage rate in group A was lower than group B (8.9% vs 27.0%) ($P < 0.05$). Patients were followed-up for 12-23 months (mean 17.6 months) after surgery, and 3 cases (6.6%) of adjacent vertebral fractures occurred in group A and 2 cases (5.4%) occurred in group B ($P > 0.05$).(Table 5)

Discussion

The emergency of PVP technique provides an option for rapid recovery of patients with OVCF. After this minimally invasive procedure, the symptoms of local pain were significantly improved, and the patients can get out of bed 2 days following surgery, realizing minimally invasive and rapid recovery effect [4-6]. Although PVP technique has been reported to be safe in all countries, with the widespread applied at different levels of hospitals and continues increasing of surgical cases, complications of intraoperative puncture and bone cement leakage have been more and more reported [2-4, 8-10]. Saracen et al [9].retrospectively analyzed the clinical information of 616 patients (1100-segment vertebra) who received PVP treatment, and found that the incidence of perioperative complications was as high as 41.7%. Among them, bone cement leakage was prevailed and accounted for 20%, paravertebral venous embolism was 13%, intervertebral disc leakage was 8%, and intraspinal leakage rate was 0.8%. Hsieh et al. [10] reported that the spinal leakage rate was 0.17%, and 4 patients need extra surgical decompression. In the study of Xu et al [8], 13 of 587 patients treated with PVP underwent open surgery again, including 9 cases with spinal cord injury and 4 cases with nerve root injury. The reasons for performing open surgery included bone cement extravasation (6 cases, 46.2%), puncture errors (3 cases, 23.1%) and error indication selection (4 cases, 30.8%). Thereby, it is vital to decrease intraoperative complications.

Currently, the safety of PVP procedure is improved mainly by two ways. Firstly, accuracy of puncture and channel establishment is increased, avoiding injury to important blood vessels and nerves around vertebrae, as well as the damaged region of vertebral cortex or endplate [11]. Secondly, PVP technique is improved, such as puncture needle with tip adjustable [4], bone-filling mesh bage (polyethylene terephthalates) [12], gelatin sponge debris pre-perfusion [6], etc. Thirdly, ratio of filling materials is changed to make bone cement be of high viscosity and low fluidity [5,13].

The site and trajectory of puncture needle not only determines the safety during surgery, but also is directly associated with the leakage rate of bone cement [11]. In the past, the abduction angle and puncture trajectory of puncture needle mainly depended on the experience of surgeons. However, muscle thickness of lower back of patients, as well as pedicle transverse and sagittal diameter width are different, the success rate of puncture will be affected once deviation of puncture site or puncture angle occurs [14]. Therefore, the precise puncture of PVP is particularly important. In this study, CT images were used to measure and obtain relevant data (group A). Thus, the optimal abduction angle and puncture needle trajectory in vertebrae were determined. Under monitoring of X-ray during surgery, a puncture needle with diameter of 2.5 mm was adopted to precisely pass through 3 reference points (a, b, c) of pedicle. As a result, the puncture needle was always traveling in cancellous bone with uniform texture, and high-viscosity bone cement was infused slowly with an injector when puncture needle reached the front 1/3 of vertebrae. During surgery, precise puncture was conductive to avoiding damaged region of anterolateral wall of vertebra, so that the bone cement was infused away from the fracture line. Thus, bone cement leakage was effectively prevented.

A puncture needle 2.5 mm in diameter was convenient to adjust the angle and increase the passing ability in pedicle. Operating steps and material cost was reduced without using secondary cannula. A graduated injector instead of an injection catheter can more accurately grasp the injection volume of bone cement. Comparison with conventional PVP (group B) showed that this technique is intimately associated with reduced duration of surgery (36.5 min vs 42.2 min), intraoperative X-ray frequency (26.9 times vs 34.3 times) and material cost (7629.5 vs 9813.2). More importantly, bone cement leakage was lower (8.9% vs 27.0%). In group A, a small amount of air (0.7 ml) in puncture cannula was likely to enter the vertebral body while bone cement was infused. However, no discomfort symptoms were observed in any patients. It was believed that the air entering vertebrae might diffuse from the vertebral tissue into the soft tissue without air embolism. Bone cement pulmonary embolism [9] and cerebral fat embolism [15] were reported clinically in literature, and no instances of air embolism were reported.

It was reported that the dispersion status of bone cement was closely correlated with biomechanical stability of vertebral body and postoperative efficacy [16-17]. Xie et al [16]. believed that the distribution of bone cement in vertebrae may affect the clinical effect after PVP procedure. The VAS scores of patients with bone cement dispersion tending to one side were significantly higher than those closing to midline. Therefore, it is recommended that the bone cement should be dispersed exceeding the midline. Mollo et al [17]. confirmed through biomechanics that the strength of the vertebral body can be restored by the volume of bone cement injected to 3.5ml. The vertebral mechanical stability with bone cement dispersing to one side was poor, but the occurrence of vertebral recompression was not influenced. In this study, symptoms of local pain were markedly alleviated in group A and group B, and daily life and self-care were significantly improved. The rate of bone cement dispersal exceeding the midline in group A under precision puncture was significantly higher than that of group B (82.2% vs 62.1%). No recompression of the cemented vertebral body occurred in any patients during follow-up. Adjacent vertebral fractures occurred in 3 cases (6.6%) in group A and 2 cases (5.4%) in group B, no significant difference existed between the groups. This fully demonstrates that the overall efficacy of these two minimally invasive techniques is the same, but the precise puncture method can make the channel closer to the midline of the vertebral body, which is conducive to the high-viscosity bone cement to be evenly dispersed in the vertebral body, and ultimately, make the vertebral body strengthening more uniform.

Intraoperative bone cement leakage is associated with a variety of factors, such as fracture severity grade, integrity of endplate and cortex, cement injection stage, injected cement volume, cement viscosity, injection techniques, puncture accuracy, etc [2,4-6,9-13]. Xie et al [2]. thought that the vertebral cortical bone defect and high bone density were independent risk factors for bone cement leakage. Zhu et al [17]. found that, among the many related factors of bone cement leakage, fracture severity and bone cement injection were the two strongest independent risk factors for leakage. During the operation, it is difficult for the surgeon to control the optimal amount of bone cement, small injection volume may lead to poor postoperative effect [19], and excessive injection volume is likely to cause irreversible bone cement leakage [18,20]. In order to restore the mechanical strength of the vertebral body, Liebschner et al [21]. recommended that the volume of bone cement in the upper thoracic vertebrae should be 2.5-3.0ml, thoracolumbar vertebrae was 3-4 ml, and lower lumbar vertebrae was 5-6 ml. To reduce the bone cement leakage rate, high-viscosity bone cement was used in both groups, and the injection volume was controlled as 3.4-3.6ml, combined with intraoperative precision puncture, the leakage rate was reduced to

8.9%, which was significantly lower than those reported in studies of Saracen et al [9] and He et al [6] (41.7% and 13.6%, respectively).

Conclusions

By adopting intraoperative precision puncture, the accuracy of puncture is dramatically improved so that the bone cement dispersion could exceed the midline better, and the bone cement leakage rate is reduced. By using simplified PVP technique, the operation steps and intraoperative X-ray frequency are reduced, the surgery duration is shortened and material cost is decreased. No significant difference is observed in vertebral height recovery and Cobb angle improvement compared with conventional PVP.

Abbreviations

PVP: Percutaneous vertebroplasty; OVCF: Osteoporotic vertebral compression fractures; PMMA: Polymethyl methacrylate; BMD: bone mineral density; VAS: visual analogue scale; ODI: Oswestry disability index

Declarations

Availability of data and materials

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

Authors' contributions

J-TP performed the data collection, analyzed and interpreted the patient data, and wrote the manuscript. X-HZ performed background research for the topic, conducted the whole study, and prepared the manuscript for submission. HC and BL performed the data collection. All authors read and approved the final manuscript.

Ethics approval and consent to participate

All experimental protocols in this research were approved by the Ethics Committee of Harrison international peace hospital of Hengshui City, and informed consent was obtained from all patients. The methods were carried out in accordance with the relevant guidelines, including any relevant details.

Consent for publication

Informed consent was obtained from all individual participants included in the study.

Competing interests

No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

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Tables

Table 1. Baseline characteristics of the 2 groups

Group	Gender		Age (years)	Injury time (days)	BMD	Fracture location (cases)		
	male	female			T score	thoracic	Thora-columbar	lumbar
Group A (45 cases)	15	20	67.5±9.2	5.3±2.2	-2.8±0.5	7	31	7
Group B (37 cases)	11	26	68.3±9.8	4.6±2.0	-3.0±0.6	8	24	5
t/ X^2 value	1.343		0.380	1.493	1.646	0.515		
P value	0.246		0.704	0.139	0.103	0.773		

Table 2. comparisons of intraoperative data between the 2 groups

Group	Operative time (min)	Intraoperative fluoroscopy times	Injected cement volume (ml)	Material cost (RMB)	Hospital days (days)
Group A (45 cases)	36.5±5.3	26.9±3.2	3.6±0.8	7629.5±116.5	4.8±0.9
Group B (37 cases)	42.2±6.7	34.3±4.4	3.4±0.7	9813.2±149.6	4.6±0.8
t value	4.301	8.804	1.191	73.913	1.052
P value	<0.001	<0.001	0.237	<0.001	0.296

Table 3. Comparisons of VAS score and ODI between the 2 groups

Group	VAS score			ODI (%)		
	preoperative	3 months postop	1 year postop	preoperative	3 months postop	1 year postop
Group A (45 cases)	7.8±1.7	3.4±1.1	2.6±0.9	62.3±9.4	29.5±4.3	24.6±3.2
Group B (37 cases)	7.6±1.5	3.3±1.2	2.7±0.8	61.0±9.1	27.9±4.1	23.4±3.0
t value	0.558	0.393	0.526	0.632	1.712	1.637
P value	0.577	0.695	0.600	0.529	0.091	0.106

Table 4. Comparisons of average vertebral height and Cobb angle between the 2 groups

Group	Average vertebral height (mm)			Cobb angle (°)		
	preoperative	3 months postop	1 year postop	preoperative	3 months postop	1 year postop
Group A (45 cases)	16.5±3.3	25.7±4.0	24.9±3.8	25.3±3.8	16.7±2.8	17.3±2.9
Group B (37 cases)	17.1±3.5	26.1±4.3	25.3±4.0	24.4±3.6	16.3±3.0	17.0±3.2
t value	0.797	0.435	0.463	1.092	0.623	0.440
P value	0.427	0.664	0.644	0.278	0.534	0.658

Table 5. Conditions of bone cement dispersed, cement leakage and adjacent vertebral fractures

Group	Bone cement dispersed surpass the midline (%)		Cement leakage rate(%)		Adjacent vertebral fractures (cases)	
	Yes	No	Yes	No	Yes	No
Group A (45 cases)	37（82.2%）	8（17.8%）	4（8.9%）	41（91.1%）	3（6.6%）	42（93.4%）
Group B (37 cases)	23（62.1%）	14（37.9%）	10（27.0%）	27（73.0%）	2（5.4%）	35（94.6%）
X^2 value	4.162		4.718		0.062	
P value	0.041		0.030		0.803	

Figures

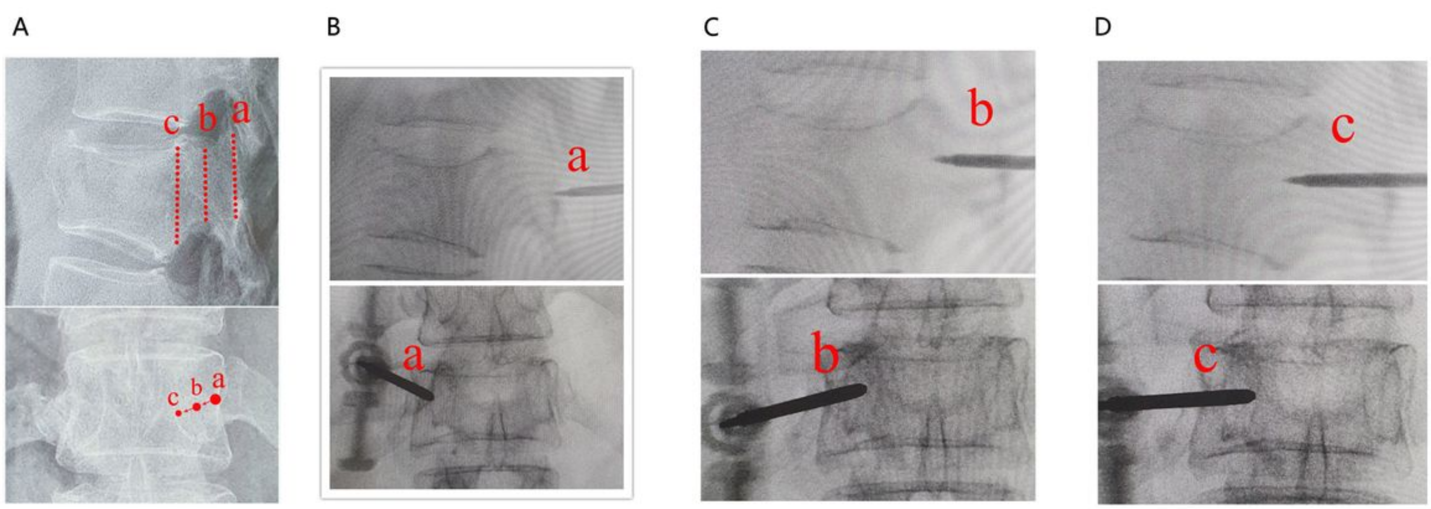
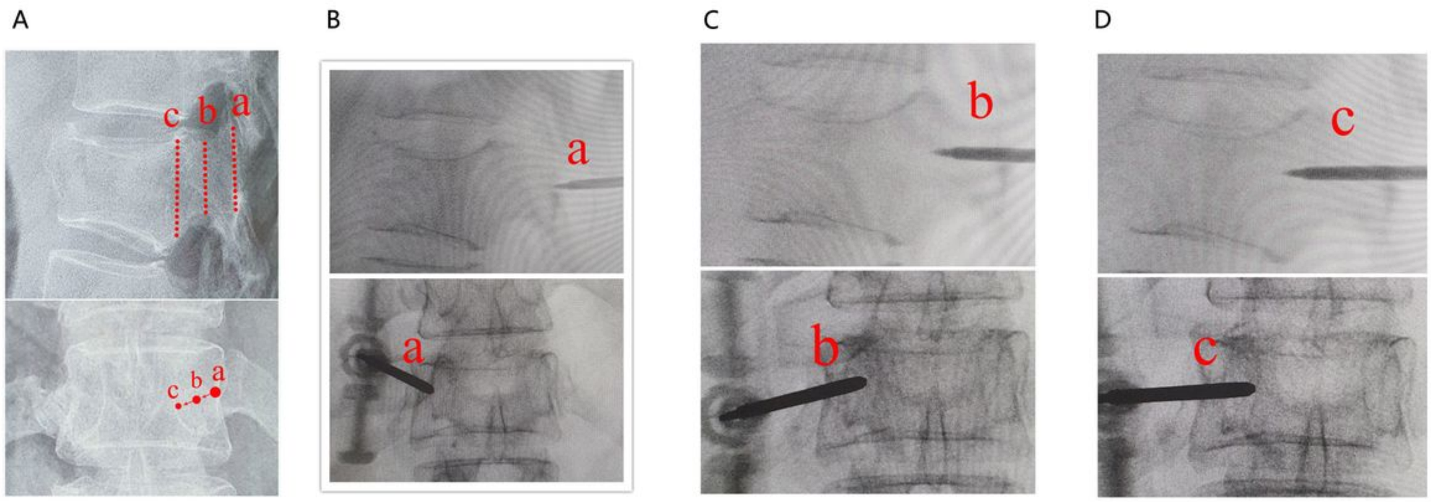


Figure 1

A: Three reference points (a, b, c) corresponding to the positive and lateral radiographs. B: Posterior wall of the pedicle – outer upper edge of pedicle projection (a). C: Middle segment of the pedicle – midpoint of pedicle projection (b). D: The transition of pedicle and vertebral body – inner lower edge of pedicle projection (c).



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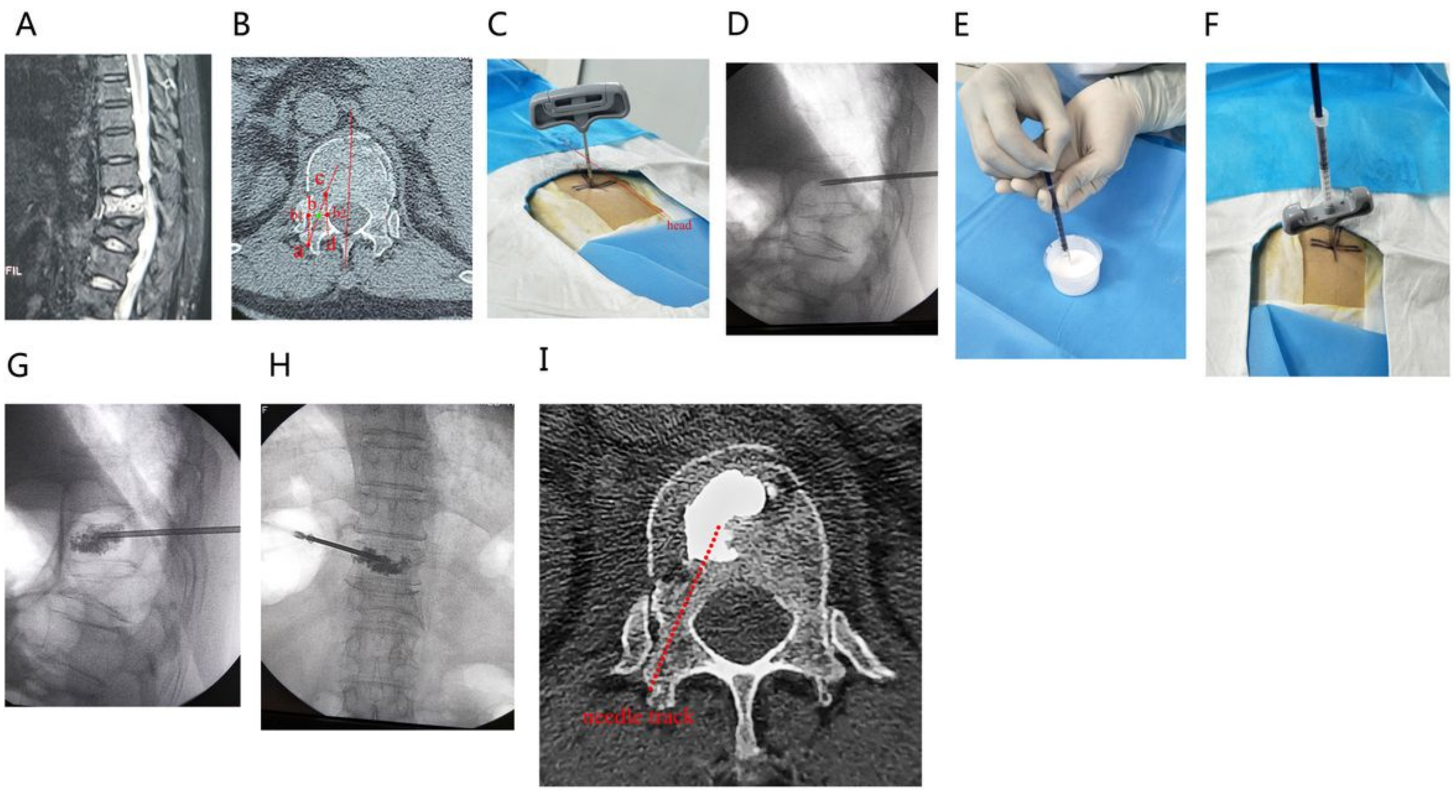
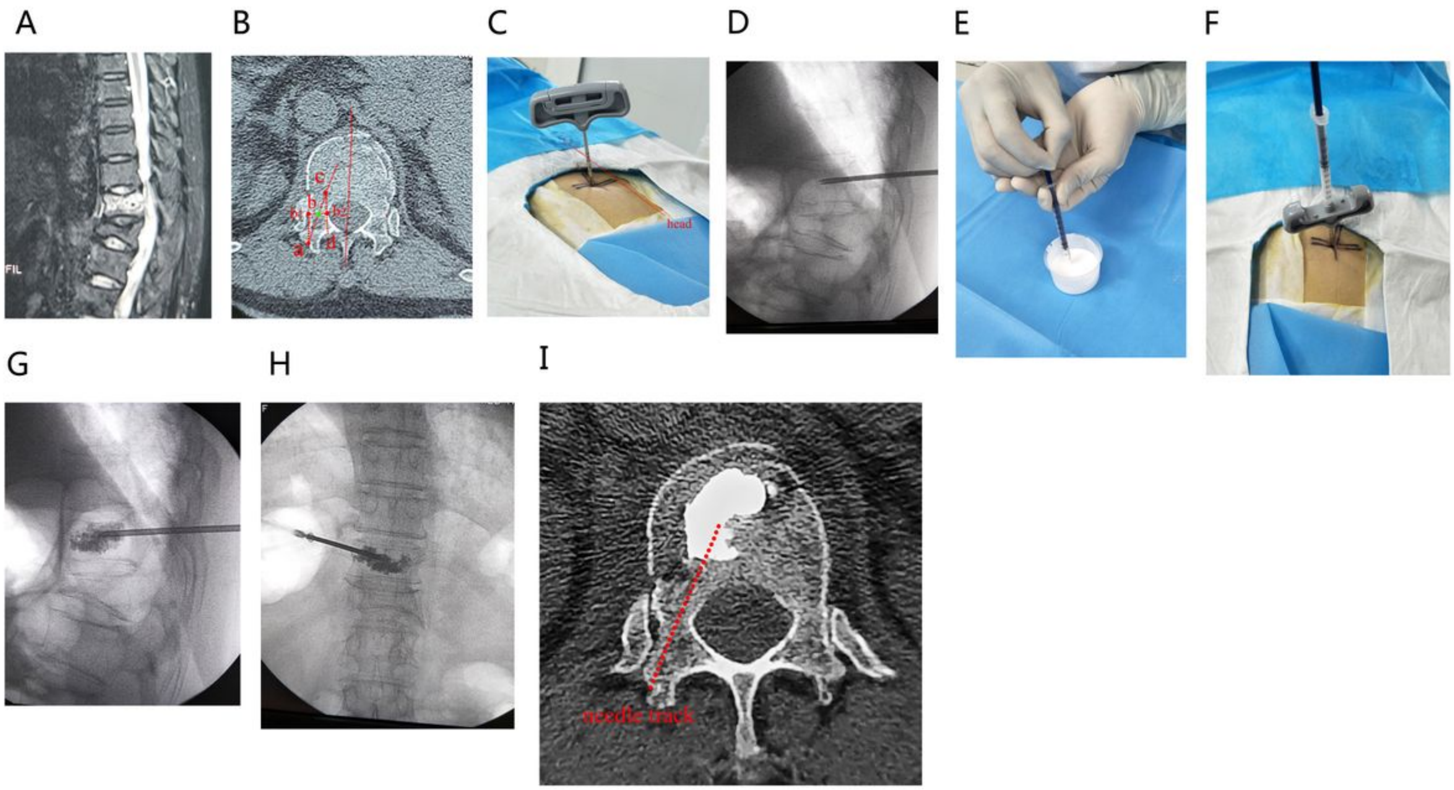


Figure 2

A 65-year-old female patient with falling caused backache for 4 days. A: MRI image showed a high signal changes on T12 vertebra. The L1 vertebra was in wedge-shaped but without edema signal. B: CT cross-section image illustrated that the projection of inner and outer lateral wall (b1, b1) of pedicle was (a, d). The midpoint was (b), and the puncture site was from a, passing through b to c. The optimal abduction angle was 18.9°. C: The puncture site was at 2.5 cm beside the midline, and puncture was performed from right side of the pedicle. D: The needle passing through a, b and c to the front 1/3 of vertebra body, and then pulled out the inner core. E-F: At wiredrawing stage the high-viscosity bone cement was aspirated into the syringe. G-H: Bone cement was dispersed well with no remarkable leakage. I: Puncture was performed in accordance with the trajectory set before the surgery, and the bone cement dispersion exceeded the midline.



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