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Performance of Double-Arm Digital Subtraction Angiography (DSA)-Guided and C-Arm-Guided Percutaneous Kyphoplasty (PKP) to Treat Senile Osteoporotic Vertebral Compression Fractures

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Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: Osteoporotic vertebral compression fracture (OVCF) is a common fracture in the elderly. Conservative treatment requires prolonged bedding, which may lead to serious complications. To explore optimized use of percutaneous kyphoplasty (PKP) in the treatment of senile osteoporotic thoracolumbar vertebral compression fractures, in this study, we used C-arm-guided and double-arm digital subtraction angiography (DSA)-guided PKP to treat OVCF in elderly patients and analyzed the effective recovery.

Material/Methods: In all, 60 patients who presented with osteoporotic vertebral compression fractures at our hospital between July 2017 and February 2019 were analyzed. They were randomly divided into C-arm-guided group and the double-arm DSA-guided groups. Both groups were treated with percutaneous kyphoplasty.

Results: A pain VAS score analysis revealed that there was no significant difference between the two groups before surgery ($P>0.05$). After surgery, the VAS scores showed a significant difference between the C-arm-guided group and the double-arm DSA-guided PKP treatment group ($P<0.01$). Moreover, with respect to the bone cement dosage, vertebral correction height, operation time, cumulative radiation dose, percolation rate, and volume of bone cement, the double-arm DSA-guided PKP treatment showed significantly better results than the C-arm-guided PKP treatment ($P<0.01$).

Conclusions: Our data revealed that double-arm DSA-guided PKP was more accurate in treatment of senile osteoporotic thoracolumbar vertebral compression fractures, producing excellent performance with more accurate intraoperative evaluation, shorter operative time, lower incidence of bone cement leakage, less intraoperative radiation dose, and higher safety, and thus, could be extensively applied to clinical surgery.

MeSH Keywords: Anesthesia Recovery Period • Hip Fractures • Kyphoplasty

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Background

Osteoporosis is a common geriatric disease in the clinic. The growing incidence of osteoporosis stems from the increasing trends of aging [1]. Epidemiological studies have revealed that osteoporosis has been listed as risk factor that significantly endangers human health [2–4], and different molecules or signaling pathways have been implicated in osteoblast differentiation and bone formation at the physiological and pathological levels [2,5–8]. These improvements have advanced our understanding of osteoporosis and the related regeneration in cases of fractures.

Osteoporotic vertebral compression fracture (OVCF) is common in the elderly [9], leading to symptoms of pain, height loss, curvature of the spine, and body shape change, and it is even linked to mortality. Traditional treatment leads to prolonged bed rest, which may cause serious complications [10,11]. Patients suffering from OVCF also have conditions related to reduced quality of bones, such as bone damage. Compression fractures of the thoracolumbar spine are common, which may cause intractable pain or even spine deformities [12]. Percutaneous kyphoplasty (PKP) is commonly used in the clinic to treat senile osteoporotic thoracolumbar vertebral compression fractures and can enhance spine stability [13–15]. However, the traditional method of PKP surgery is based on guidance of C-arm equipment, and monitoring the accuracy of puncture and injection of bone cement is difficult [16–18].

To improve the performance of PKP surgery, we applied dual-arm DSA-guided PKP treatment; although it has been used in the clinic, the amount of related data available is small. In this study, we compared performance of C-arm-guided PKP and dual-arm DSA surgery to treat OCVF disease on the basis of patient preferences. Our data revealed that double-arm DSA-guided PKP was more accurate in treatment of senile osteoporotic thoracolumbar vertebral compression fractures, and it is valuable in clinical applications to treat OCVF disease and promotes good recovery for patients.

Material and Methods

Study population

In all, 60 patients who presented with senile osteoporotic thoracolumbar vertebral compression fractures at our hospital between April 2017 and February 2019 were enrolled in this study. Inclusion criteria were as follows: patient age >65 years; osteoporosis with fracture; X-ray, computed tomography (CT), and magnetic resonance imaging (MRI) done before surgery; and vertebral fracture at the T12, L1, and L2 levels (Table 1). Patients with the following conditions were excluded from the data collection: lung, liver, and kidney dysfunction, or autoimmune disease; pathological fracture caused by bone tumor; vertebral fractured spinal cord; or a history of mental illness or CT imaging with incomplete posterior wall of the vertebral body.

All patients were informed about the surgery and related equipment, and of the potential risks and advantages. On the basis of final selection of patients, we named the experimental group the DSA and C-arm group. There were 30 patients in the DSA group: 7 males and 23 females. Average age was 71.6±10.31 years. In all, there were 13 cases of T12 fractures, 9 of L1 fractures, and 8 cases of L2 fracture; the average bone density STD value was –3.9±0.62).

Of the 30 cases in the C-arm group, there were 9 males and 21 females. Average age was 72.3±9.45 years. There were 11 cases of T12 fracture, 9 cases of L1 fracture, and 10 cases of L2 fracture; average bone mineral density STD was –3.7±0.71. No significant difference was observed between the two groups (P>0.05). Results of the two groups were comparable. All patients provided signed informed consent prior to the study (Table 2).

Table 1. Summary of patient population.

	Age	Symptom	Imaging diagnosis	Fracture
Criterion	>65 years	Osteoporosis	X-ray, CT, MR	T12, L1, L2 vertebral

CT – computed tomography; MR – magnetic resonance.

Table 2. Experimental group in the study.

Arms	Average age (years)	T12 fracture	L1 fracture	L2 fracture	Bone density
DSA group (n=30)	71.6±10.31	13	9	8	–3.9±0.62
C-arm group (n=30)	72.3±9.45	11	9	10	–3.7±0.71

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Experimental group

Patients' blood pressure, respiratory function, and electrocardiograms (EKGs) were monitored, and the venous channel was established. The C-arm machine was used to identify the damaged vertebrae and bilateral vertebral arches, and the needles were used to puncture the vertebral body before passing through the pedicle. At the edge, the channel was removed from the needle, and the vertebral body was drilled and retracted and placed with the balloon. Iohexol was injected to dilate the balloon, and the bone cement was prepared. The mixture was adjusted, and approximately 1 to 3 mL of the mixture was injected through the needle tube. During the injection process, patient pain and numbness were monitored at all times. Patient condition was closely monitored after surgery to ensure that bone cement did not leak outside the vertebral body. Patients had to stay still in bed for 6 h after surgery, and they could get out of bed for 24 h. Postoperative oral calcium, alendronate, calcitriol, and other anti-osteoporosis drugs were prescribed for patients. Similarly, for the dual-arm DSA group (SIEMENS Artis Q biplane, syngoXWP OT 20902), DSA fluoroscopy was used to locate the bilateral pedicle of the responsible vertebral body. CT scan was conducted, and the needle point was visualized during surgery, which was better for accurate injection. Then, similar treatments were carried out on the C-arm group, and detailed information was recorded about individual patients.

Dual-arm DSA-guided group

Patient blood pressure, respiratory function, and EKGs were monitored before surgery, and venous access was established. Patients were placed on the operating table in a prone position, sterile towels were disinfected, and DSA fluoroscopy was used to locate the bilateral pedicle of the responsible vertebral body. CT scan was displayed, and the puncture point was displayed in the infrared surface of the body surface. The skin surface was anesthetized using 1% lidocaine to the periosteum of the joint surface, and the arms simultaneously showed the angle of the lateral side puncture, which was outside the pedicle. CT scanning was performed again after the puncture needle was stabilized through the first layer of the cortex, showing the angle of the cross section, sagittal plane, and tubular surface, and simulating the position of the vertebral body. The lateral position simultaneously monitored the lower needle through the posterior edge of the vertebral body, which was inserted into the working channel through the puncture needle, and the balloon was inserted. Then, the bone cement sleeve was inserted into the vertebral body at an appropriate angle according to the horizontal level, and the lateral needle tip was behind the vertebral body.

The positive position of the rim did not break through the inner side of the pedicle. After the puncture needle was removed, the guidewire was placed and the distal end was located in the front one-third of the vertebral body. Then, the vertebral body drill was inserted into the front one-fifth of the vertebral body, the vertebral body drill was retracted, and the balloon was inserted. Next, we injected iohexol to expand the balloon, prepared the bone cement, mixed it thoroughly until the drawing period, and then injected 1 to 3 mL into each side through the needle. During the injection process, patient pain and numbness were monitored at all times, and their condition was closely monitored after survery to ensure that bone cement did not leak outside the vertebral body. After staying in bed for 1 h, patients were allowed out of bed and given anti-osteoporosis treatment; they were discharged the day after the surgery.

Observation parameters

Efficacy of the procedures was evaluated based on intraoperative treatment and postoperative imaging and change in symptoms. Vital sign alert (VSA) visual pain scores were measured using a scale of approximately 10 cm long, on a scale of 0 to 10 aliquots on the ruler ("0" means no pain; "10" means the most pain), and patients were marked to represent their pain. The position and the corresponding score indicated the degree of pain.

Vertebral body height

The height of the anterior and middle points of the vertebral body before and after treatment was measured. The average value of the vertebral body was estimated to be the average height change. The difference between the two was the corrected height. Surgical time and bone cement injection were recorded during surgery. The intraoperative cumulative radiation dose was displayed automatically by the C-arm machines and the DSA machines, and the radiation dose was automatically monitored by the machine based on the total time of irradiation and frequency of irradiation to evaluate the volume of radiation delivered. The cement leakage rate and the leakage volume were evaluated by x-ray after the treatment. During surgery, data from the dual DSA group were directly transferred to Artis Q Biplane 5.X workplace (VD10E), and then four-dimensional imaging technologies were used to calculate cement leakage. For the C-arm group, after surgery, CT images were obtained and transferred to Artis Q Biplane 5.X workplace (VD10E) to calculate cement leakage.

Statistical analysis

All of the data were analyzed using SPSS 13.0. The *t* test was used to assess the differences in age, operative time, intraoperative cumulative radiation dose, bone cement injection volume, vertebral correction height, VSA score, bone cement

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permeability, and leakage volume in the two groups. P<0.01 was considered indicative of a statistically significant difference.

Results

Results of surgery

Some patients showed no obvious traumatic lumbar but were in pain for half a month (Figure 1). MRIs were taken of a representative case with traumatic lumbar before surgery, as shown in (Figure 1). In all, 60 patients underwent successful surgery. There were no serious complications, such as balloon rupture or spinal cord injury, in the C-arm-guided group. One patient developed a lower-extremity root irritation symptom after surgery and had nutritional, anti-inflammatory, and pain relief, and physical therapy. After 2 months of symptomatic treatment, the root irritation symptoms disappeared. The DSA-guided group had no complications during or after surgery. All of the radiological images of the presentative intraoperative puncture, and the positioning and injection of bone cement in the patients were recorded (Figure 2); radiological images were taken to evaluate recovery in patients with OVCF after surgery (Figure 3).

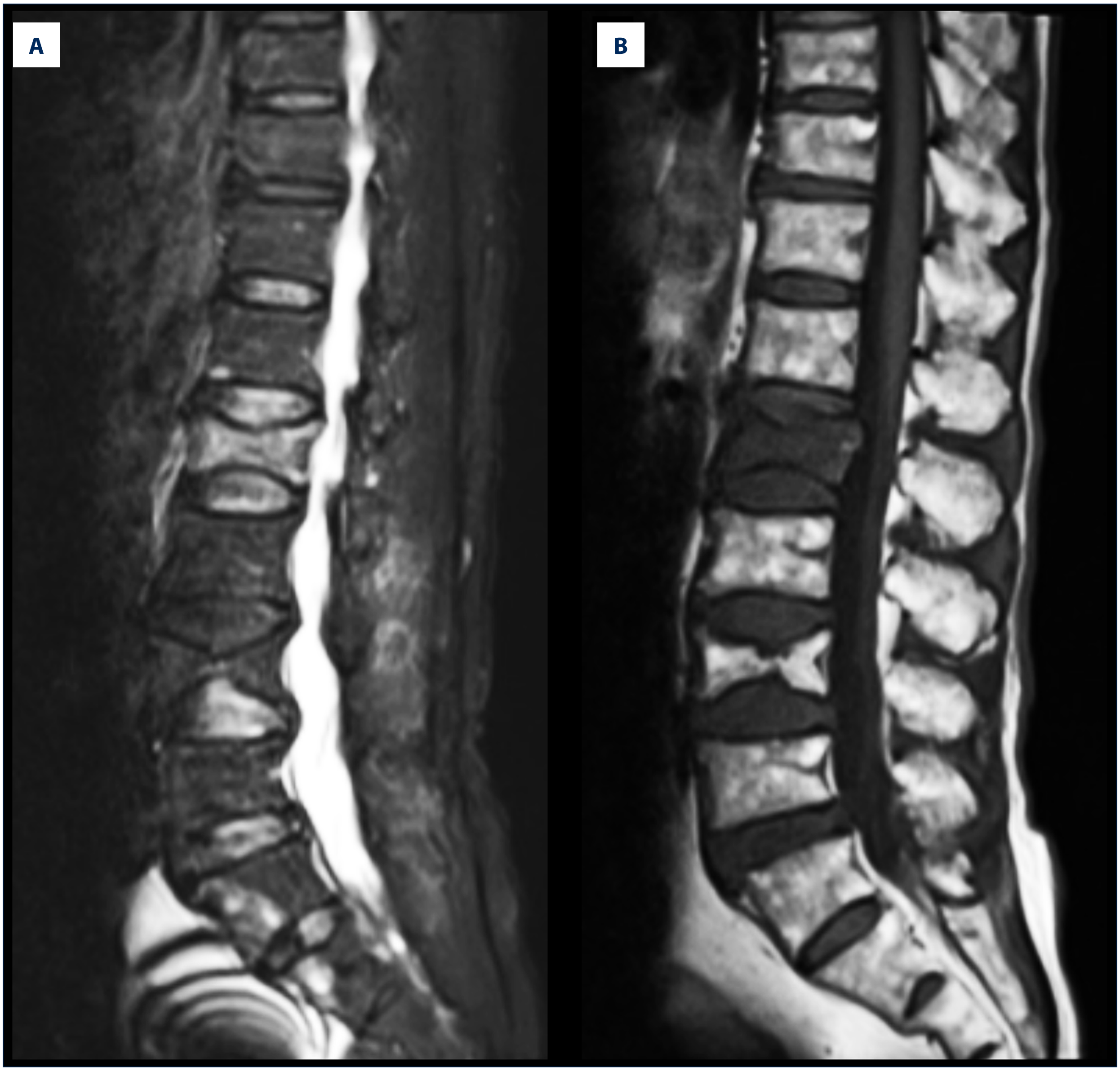

Figure 1. MR images of a representative case with traumatic lumbar before surgery. (**A, B**) Female, 85 years old, with no obvious traumatic lumbar symptom, but the patient has been in pain for half a month.

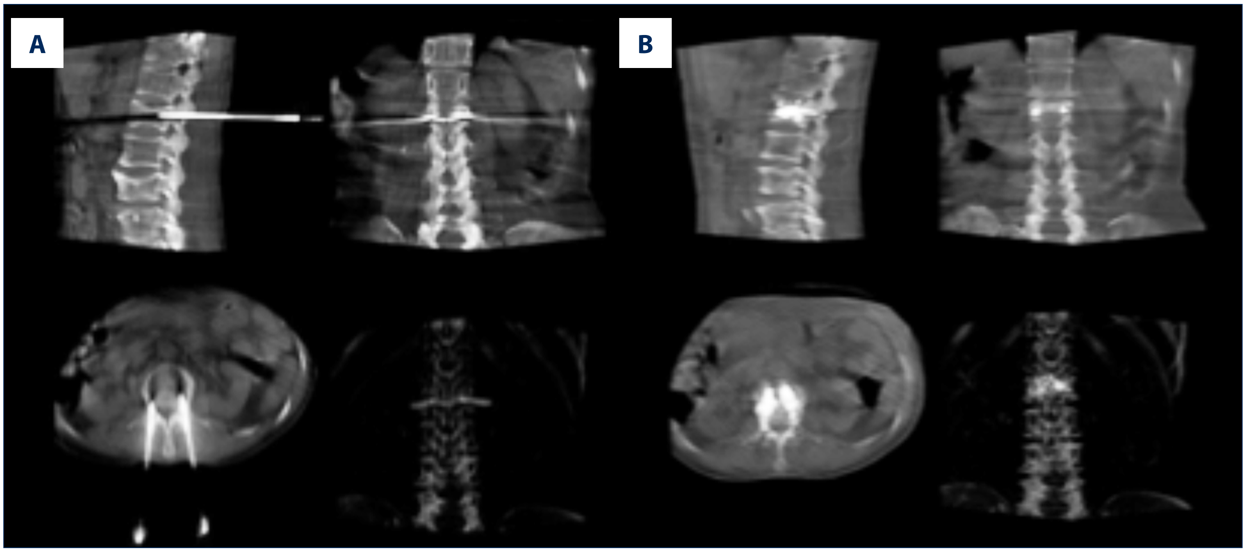

Figure 2. Radiological images of presentative intraoperative puncture, positioning, and injection of bone cement in patients using the double-arm DSA guide.

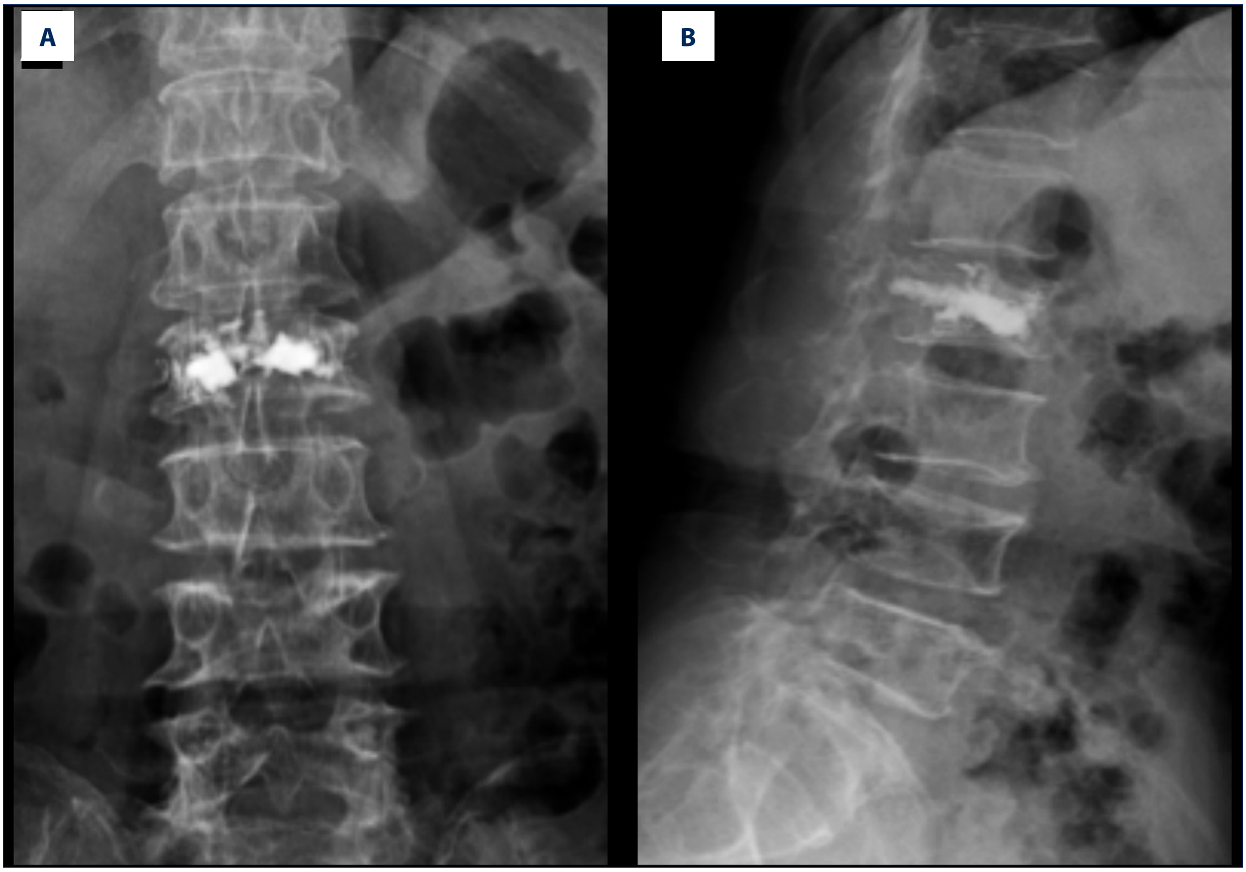

Figure 3. Radiological images taken to evaluate recovery in patients with OVCF after surgery using the double-arm DSA guide.

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Table 3. Comparison of VSA scores before and after treatment in both groups.

	Case	Before surgery	After surgery	*t* test	P
C-arm group	30	7.1±1.3	2.1±0.9	17.3	0.000
Double-arm DSA group	30	7.3±1.2	1.9±1.3	16.7	0.000
t test		–0.6	0.7		
P		0.54	0.039		

Table 4. Comparison of performance in the double-arm DSA group versus the C-arm-guided group.

	Case	Volume of bone cement (mL)	Vertebral correction height (mm)	Leakage rate (%)	Leakage volume (mm³)
C-arm group	30	3.53±1.11	6.3±1.6	9/30, 30%	0.3±0.15
Double-arm DSA group	30	4.21±0.62	4.7±1.4	2/30, 6.7%	0.1±0.07
t test		–2.93	4.1		6.61
P		0.005	0.000		0.000

DSA – digital subtraction angiography.

Table 5. Analysis of surgery duration and cumulative radiation dose.

	Case	Surgery duration (min)	Cumulative radiation dose (mGy)
C-arm group	30	57±10.8	2700±935
Double-arm DSA group	30	39.2±9.7	380±113
t test		6.7	13.5
P		0.000	0.000

DSA – digital subtraction angiography.

VSA scores

The pain VSA scores were used to analyze the difference between the C-arm-guided PKP group and the double-arm DSA-guided PKP group before and after surgery. Data showed that the double-arm DSA-guided group had significantly less pain after surgery (P<0.01) (Table 3).

Analysis of bone cement injection volume, vertebral correction height, and bone cement leakage

In our study, with respect to the complication of leakage, in the C-arm group, there were 9 cases (9/30, 30%), but only two cases were found in the two-arm DSA group (2/30, 6.7%) for incidence of bone cement leakage. For the two groups of bone cement with leakage, the C-arm group had three cases of anterior vertebral leakage, two cases of paravertebral, two cases of spinal canal, and two cases of intervertebral space. For rough measurement of leakage volume, the average in the C-arm group was 0.3±0.15 mm³ and in the DSA group was 0.1±0.07 mm³; the volume of cement leakage was significantly different in the two groups (t=–2.93, P=0.005). Overall, bone cement injection volume, vertebral body correction height, bone cement leakage rate, and bone cement leakage volume were significantly different, and the double-arm DSA group had better performance than the C-arm-guided group (P<0.01) (Table 4).

Surgical duration and cumulative radiation dose

During surgery, we recorded procedure duration and cumulative radiation dose, and the results showed that the procedures were shorter and the cumulative radiation doses lower in the double-arm DSA group than in the C-arm-guided group (P<0.01) (Table 5), mostly because the double-arm DSA-guided PKP surgery could be monitored very accurately, and thus, the time was reduced.

Cement leakage was greater using the C-arm in previous reports, mainly because of the different technical levels and

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iatrogenic factors. In addition, the C-arm could only be monitored in one direction during intraoperative injection of bone cement. Frontal and lateral monitoring could considerably reduce the leakage rate and leakage of bone cement. With the two sets of c-arm and dual-arm-DSA devices, surgical time and radiation dose could be measured, and thus, we concluded that procedure duration was shorter and the radiation dose smaller with the dual-arm DSA.

Discussion

With the aging of society, incidence of osteoporotic vertebral compression fractures (OVCFs) increases every year, particularly in postmenopausal women [4,19,20]. These patients have severe low back pain and even kyphosis, which seriously affects their activities and health. Oral medication and other conservative treatments are available, but because the elderly population is weak, bone loss can easily be exacerbated, and they may have complications such as hemorrhoids and hypostatic pneumonia [21,22]. The advantage of percutaneous vertebroplasty (PVP) is that the complication can be achieved immediately after surgery, and the pain relief achieved is remarkable. Patients can get out of bed 24 h after the procedure, avoiding complications caused by long-term bed rest, and their quality of life after surgery can be significantly improved [23–25].

PKP is minimally invasive spinal surgery that has been widely used in clinical practice. It is mainly used to inject bone cement into the vertebral body after balloon expansion under the guidance of the C-arm [11,26]. After the cement hardens, it improves stability of the spine. Clinical application has the advantages of less trauma and bleeding, and better prognosis. However, bone cement leakage is still an important complication of PKP that can easily cause spinal nerve injury and impose a heavy burden on patients. According to reports in the literature, incidence of bone cement leakage after PKP is as high as 25%. It has also been frequently reported that a small number of patients have severe symptoms and need to undergo revision surgery [27–30].

Because of the time it takes for the cement to solidify, C-arm x-ray machine operators need to be accurate and skilled., Use of the technology is still very limited, however, because of the single orientation of the C-arm machine results in more surgical time, and whereas the time it takes to harden bone cement is constant [21,31]. Therefore, intraoperative safety cannot be effectively guaranteed. Moreover, longer irradiation will increase damage to the surgeon. In this study, the double-lens DSA-guided puncture was used for dynamic observation from the right position and the lateral position. CT two-dimensional and three-dimensional imaging can also be performed. The position of the needle can be evaluated in the cross-section and sagittal and coronal planes, and determined accurately. The working channel is located in the pedicle, avoiding bone cement spillage due to bursting of the medial or lateral cortex of the pedicle [15,32]. Under DSA surveillance, when bone cement is injected during the operation, use of the two arms allows simultaneous observation of dispersion of cement in position [33,34]. If leakage occurs, the injection speed can be monitored, or the injection can be stopped. In our study, VSA scores in the same group were significantly improved compared with those before surgery. Postoperative VSA scores from the two groups both showed good symptom, but in the dual-arm DSA group, operative times were shorter and they received a smaller cumulative radiation dose during the procedure. For the surgeons, this undoubtedly reduced radiation damage.

In the case of C-arm monitoring, a surgeon will still use a conservative dose for injection, while the dual-arm DSA can simultaneously monitor bone cement dispersion and leakage from the positive side position, allowing the surgeon to achieve the maximum dose of bone cement per injection. In our study, bone cement leakage was seen in the C-arm group in 9 cases (9/30, 30%), versus only two cases in the two-arm DSA group (2/30, 6.7%). Among the patients with bone cement leakage, three cases in the C-arm group were anterior vertebral leakage, two cases were paravertebral, two cases were spinal canal, and two cases were in the intervertebral space. For rough measurement of leakage volume, the average in the C-arm group was 0.3 ± 0.15 mm^3 and that in the DSA group was 0.1 ± 0.07 mm^3; a statistical difference in volume of leakage cement in the two groups ($t=-2.93$, $P=0.005$) was observed. Although there was still some bone cement leakage in the case of dual-arm DSA monitoring, the leakage ratio and the amount of leakage were lower than in the traditional C-arm group. Leakage of bone cement determined the severity of the complications.

Conclusions

Taken together, we found that use of a double-arm DSA guide could considerably improve the accuracy and safety of surgery to treat osteoporotic vertebral compression fractures as compared to the traditional C-arm guide. The double-arm DSA guide exhibited excellent performance factors such as shorter operative time and less bone cement leakage. Therefore, the double-arm DSA guide is worthy of clinical application.

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