Original Article

Percutaneous balloon kyphoplasty of osteoporotic vertebral compression fractures with intravertebral cleft

Bao Chen, Shunwu Fan[1], Fengdong Zhao[1]

Abstract

Background: Intravertebral cleft is a structural change in osteoporotic vertebral compression fractures (OVCF), which is the manifestation of ischemic vertebral osteonecrosis complicated with fracture nonunion and pseudoarthrosis and appears in the late stage of OVCF. Despite numerous studies on OVCF, few aim to evaluate the clinicoradiological characteristics and clinical significance of intravertebral cleft in OVCF. This study investigates clinicoradiological characteristics of intravertebral cleft in OVCF and the effect on the efficacy of percutaneous balloon kyphoplasty (PKP).

Materials and Methods: PKP was performed on 139 OVCF patients without intravertebral cleft (group A) and 44 OVCF patients with intravertebral cleft (group B). The frequency distribution of the affected vertebral body, bone cement infusion volume, imaging manifestation, leakage rate and type, preoperative and postoperative height of the affected vertebral body, visual analog scale (VAS) and Oswestry disability index (ODI) score were evaluated.

Results: Significant differences were found in the frequency distribution of the affected vertebral body and bone cement leakage type between the two groups ($P < 0.05$). However, differences in bone cement infusion volume and leakage rate ($P > 0.05$) were not detected. In both groups, the postoperative height of the affected vertebral body was significantly improved ($P < 0.05$). The restoration of vertebral body height in group B was more evident than that in group A ($P < 0.05$). The preoperative VAS and ODI scores in group B were significantly higher than those in group A ($P < 0.05$). After surgical treatment, pain relief and daily activity function in both groups were significantly improved ($P < 0.05$), and no significant difference in postoperative scores was detected between the two groups ($P > 0.05$).

Conclusion: Intravertebral cleft exhibits specific clinical and imaging as well as bone cement formation characteristics. PKP can effectively restore the affected vertebral body height, alleviate pain, and improve daily activity function of patients.

Key words: Intravertebral cleft, osteoporosis vertebral compression fracture, percutaneous kyphoplasty

Introduction

Osteoporosis (OP) is a systemic disease characterized by low bone mass, bone microstructure damage and increased bone fragility. One of the most severe consequences of OP is osteoporotic vertebral compression fracture (OVCF), which can increase the disability rate and mortality rate. Percutaneous vertebroplasty (PVP) is a new minimally invasive spinal surgical technique that is mainly indicated in OVCF. In this surgery, the filler material polymethylmethacrylate (PMMA) is infused into the fracture site to stabilize the vertebral body and eliminate pain. However, the rate of bone cement leakage is high. In contrast to PVP, percutaneous balloon kyphoplasty (PKP) can effectively reduce bone cement leakage and correct kyphosis in OVCF,[1,2] therefore is preferred for managing OVCF.

Departments of Orthopedics, Jiaxing Second Hospital, Jiaxing 314000, [1]Sir Run Run Shaw Hospital Affiliated to Zhejiang University School of Medicine, Hangzhou 310016, China

Address for correspondence: Dr. Shunwu Fan,
Department of Orthopedics, Sir Run Run Shaw Hospital Affiliated to Zhejiang University School of Medicine, No. 3 Qingchun East Road, Hangzhou 310016, China.
E-mail: shunwufancn@yeah.net

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Intravertebral cleft is a structural change in OVCF. With the advancement of preoperative radiographic evaluations of vertebral status, in particular with the population of MRI and CT reconstruction, more and more OCVFs are found to be with concomitant intravertebral cleft. This change is the manifestation of ischemic vertebral osteonecrosis complicated with fracture nonunion and pseudoarthrosis, which appears in the late stage of OVCF.[3] Theoretically, nonunion and pseudoarthrosis can induce instability of the fracture and thus lead to more severe pain than those without intravertebral cleft.[3] Further, OVCF with the presence of intravertebral cleft is a potential risk factor for bone cement leakage and may predict the trend and type of bone cement leakage.[4]

Despite many studies on OVCF, few are available in literature regarding the distribution, clinicoradiological characteristics and clinical significance of intravertebral cleft in OVCF. In this study, the distribution and characteristics of the intravertebral cleft and the effect of PKP in OVCF are evaluated. The clinical significance of the intravertebral cleft in OVCF was also discussed.

Materials and Methods

183 patients who were subjected to PKP to treat OVCF from December 2009 to December 2011 were enrolled in this study. OVCF was confirmed preoperatively by bone density measurement, X-ray, computer tomography (CT) scans, and magnetic resonance imaging (MRI). Radiograph result was re-examined 2 days after the treatment. The included OVCFs were from T6 to L5 vertebrae [Figure 1]. Patients with previous spine surgery, infection or tumor were excluded. According to the intravertebral cleft manifestation, the selected patients were divided into two groups: group A (without intravertebral cleft, n = 139) and group B (with intravertebral cleft, n = 44). Group A comprised of 22 males and 117 females, with an average age of 70.2 years (range 51-91 years). Group B comprised of 5 males and 39 females with an average age of 71.6 years (range 56-89 years). The average number of vertebral bodies involved in Group A and B was 1.2 (172/139, range, 1 to 2) and 1.2 (53/44, range, 1 to 2). All patients gave informed consent prior to participation. This study was conducted in accordance to the declaration of Helsinki and was approved by the Ethics Committee of our institution.

Operative procedure

The patients were placed prone on a radiolucent table, with both hands fixed on the lateral sides. Lateral and anteroposterior C-arm fluoroscopic images were obtained to confirm the land marks positions of the pedicles bilaterally at the affected level. The puncture points were marked; the puncture path and angle were determined. After sterilization, 1% lidocaine was used for local infiltration anesthesia. The needle point on the body surface was inserted 3 to 5 cm lateral to the midline. A transpedicular approach in the lumbar vertebra and through the intermediate part between the rib head and the pedicle in the thoracic vertebra, were used for penetration. The tip of the puncture needle (11G, Shanghai Kailitai Medical Technology Company, China) penetrated the bone × 2 to 3 mm laterally outside the 10 o'clock point (left pedicle) or the 2 o'clock point (right pedicle) of the pedicle projection. The puncture angle was 25° to 35° to the sagittal plane. The needle tip was located outside the inner wall of the pedicle on normotopia projection. The needle was inserted until it reached one-third of the anterior part into the vertebral body and into the intravertebral cleft in groups A and B, respectively. Kirschner wire was then inserted to the channel produced by the puncture needle and the working cannula was inserted along the Kirschner wire. Biopsy was taken through the working cannula by using pathological forceps. Liquid was drawn from the intravertebral cleft by using an injector if necessary.

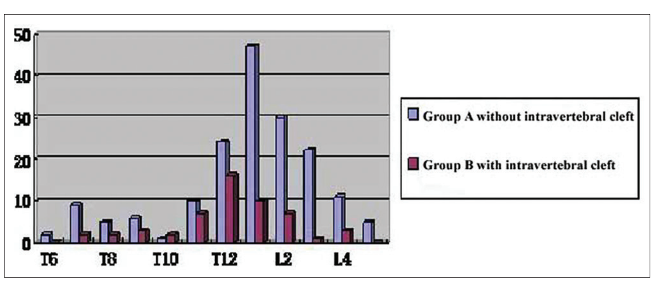

Figure 1: Frequency distribution of affected vertebral bodies

A balloon dilator was placed for dilatation after reaming. In group A, standard pasty PMMA bone cement (Tianjin Synthetic Materials Research Institute, China) was infused into the affected vertebral body using a bone cement injector (Shanghai Kailitai Medical Technology Company, Shanghai, China). In group B, 0.5 mL to 1.0 mL of sticky phase bone cement was infused into the anterior part of the cleft. A balloon dilator was placed again for dilatation. After the "eggshell" in the cleft was formed, the balloon dilator was withdrawn and the bone cement in the terminal sticky phase was gradually infused along the medial surface of the "eggshell." The vertebral body and cleft were diffusely filled with bone cement as confirmed by C-arm fluoroscopy and the surgical instruments were removed. The surgery was carried out based on a unilateral, bilateral, or para-pedicle approach. All of the operations were monitored under fluoroscopy. The patients were allowed to ambulate after 24 h of bed rest postoperatively. Waist belt was worn during the next three weeks to four weeks for protection. Vitamin D calcium chewable tablet (600 mg/d) and alendronate sodium (70 mg/w) were routinely administered to each patient to treat osteoporosis.

The following evaluation indices were used: (1) distribution of the intravertebral cleft in vertebral bodies; (2) operative time and blood loss; (3) volume of infused bone cement, bone cement leakage, leakage type and vertebral height; and (4) efficacy. Efficacy was evaluated by comparing the visual analog scale (VAS) scores and Oswestry Disability Index (ODI) scores before and 2 days after surgery. For imaging evaluation, X-ray was done 2 days postoperatively and compared with preoperative images. All the images were analyzed by three independent observers, two orthopedic surgeons and one radiologist, experienced in reading musculoskeletal images.

Statistical analysis

Statistical analysis was performed using SPSS 19.0 software. Independent *t*-test was performed to evaluate intergroup differences for continuous variables. Paired sample *t*-test was used to compare pre and postoperative differences for continuous variables in the same group. χ^2 test or Fisher's exact test was performed to compare the distributions of categorical variables. $P < 0.05$ was considered statistically significant.

Results

PKP was successfully performed on 225 vertebrae in 183 patients with an operative time of 36 min to 61 min (average, 43 min) and intraoperative blood loss of 6 to 11 mL (average, 8 mL). No significant difference was observed in the distribution of the affected vertebral body between the two groups ($P < 0.05$; Figure 1). In group A, L1 was the most commonly affected vertebra (27.2%) followed by the L2 vertebra (17.8%); in group B, commonly the fracture was observed at T12 vertebra (28.6%). The volumes of infused bone cement in groups A and B were 3.5 to 5.1 mL (average 4.3 mL) and 3.4 to 5.6 mL (average, 4.5 mL), respectively, indicating no significant difference ($P > 0.05$). In both groups, the bone cement leakage rate was similar ($P > 0.05$; Table 1), but the leakage types were significantly different ($P < 0.05$). The cement leaked along the blood vessels in OVCF without the intravertebral cleft (68.1%). In the presence of intravertebral cleft (79.2%), the cement leaked into the perivertebral soft tissues [Table 2].

In both the groups, the postoperative height of the affected vertebral body significantly improved ($P < 0.05$; Table 3). Restoration of the vertebral body height in group B was more evident than that in group A ($P < 0.05$; Table 4). The preoperative VAS and ODI scores in group B were significantly higher than those in group A; however, the postoperative scores were comparable in the two groups ($P > 0.05$; Table 5). The postoperative VAS and ODI scores were significantly better in both groups compared with the preoperative values ($P < 0.05$; Table 5). The improvement rates of VAS and ODI scores of the two groups was not significantly different ($P > 0.05$; Table 6).

Discussion

With the advancement of MRI, CT, and other advanced imaging modalities used to assess the vertebral status before PKP, numerous patients were diagnosed with OVCF complicated with the intravertebral cleft. The intravertebral cleft is considered as a manifestation of vertebral ischemic osteonecrosis.[3] This condition has a very clear mechanism of occurrence. However, the distribution as well as the clinical and radiological features of the intravertebral cleft in OVCF is rarely reported.[4-6]

In X-ray imaging, the intravertebral cleft is manifested as a thread-like or cyst-like transparent area[4] [Figure 2a], but the detection rate of the intravertebral cleft by an anteroposterior and lateral radiograph is low. Abnormal movement of the vertebral cleft caused by different body postures lead to corresponding changes in the affected vertebral body height. Under hyperextension and hyperflexion positions, the anterior affected vertebral body and the posterior zygapophyseal joint move and perform abnormal movement. This movement results in evident height variation in the anterior border of the vertebral

Table 1: Comparison of bone cement leakage between two groups

Group	Leakage	No leakage	Number of vertebral body
A	72	100	172
B	24	29	53
Statistical value	χ^2=0.194, *P*=0.751		

Table 2: Comparison of bone cement leakage type between two groups

Group	Leakage type				No. of vertebral body
	Intervertebral disc	Perivertebral soft tissues	Along blood vessel	Epidural	
A	13	8	49	2	72
B	3	19	2	0	24
Statistical value	χ^2=42.474, *P*=0.001				

Table 3: Preoperative and postoperative height of affected vertebral body in two groups ($\bar{X}\pm S$, mm)

	Group A			Group B		
	Anterior border of vertebral body	Center of vertebral body	Posterior border of vertebral body	Anterior border of vertebral body	Center of vertebral body	Posterior border of vertebral body
1st Preoperative day	21.44±4.68	18.03±3.56	28.07±2.71	15.08±4.33	14.08±3.08	26.24±2.67
2nd Postoperative day	22.90±4.34	22.64±3.23	29.51±2.83	18.40±4.45	17.81±3.31	27.41±3.18
T	18.184	-42.111	-37.518	-18.581	-83.613	-20.404
P	0.001	0.001	0.001	0.001	0.001	0.001

body (opening/closing syndrome) in the lateral projection on a plain radiograph. On the basis of this characteristic, the detection rates of the intravertebral cleft in the lateral projection at a supine position[5] are significantly higher than those in the upright and the upright extension position. Mckiernan *et al*.[6] studied patients with OVCF and found that the detection rates of the intravertebral cleft in the lateral projection in upright and supine positions are 14% and 64%, respectively. This result is similar to that in our study (56.8%, 25/44).

MRI is a sensitive and effective imaging method to treat OVCF and the intravertebral cleft, which represents a vertebral structural change after trauma.[7] In T1 weighted images, the intravertebral cleft is seen as a limited low signal area; in T2 weighted images, the intravertebral cleft is seen by a limited long and narrow high signal area (liquid; Figure 2b) or a low signal area (gas). The manifestation is determined by the nature of the contents.[8] The incidences

Table 4: Restoration values vertebral body height in two groups ($\bar{X}\pm S$)

Group	Anterior border of vertebral body	Center of vertebral body	Posterior border of vertebral body
A	1.46±0.97	4.61±0.96	1.43±0.56
B	3.32±1.31	4.32±1.03	1.16±0.62
T	-16.667	0.953	0.150
P	0.001	0.342	0.134

Note: Restoration value=postoperative vertebral body height- preoperative vertebral body height

Table 5: VAS and ODI score in two groups ($\bar{X}\pm S$)

	Group A		Group B		*t*		*P*	
	VAS	ODI	VAS	ODI	VAS	ODI	VAS	ODI
Preoperative	6.9±0.8	71.5±7.2	7.8±0.9	81.3±7.6	2.455	83.177	0.016	0.001
Postoperative	2.4±0.7	27.6±6.9	2.8±1.1	29.3±6.8	1.217	0.891	0.153	0.648
t	105.664	206.526	33.326	182.539	–			
P	0.001	0.001	0.001	0.001				

VAS=Visual analog scale, ODI=Oswestry disability index

Figure 2: (a) X-ray lumbosacral spine anteroposterior and lateral views showing thread like or cyst-like transparent areas for intravertebral cleft (black arrow). (b) MRI T1 and T2W showing low signal area (T1W) and long and narrow high signal area (liquid, T2W) for intravertebral cleft (black arrow). (c) MRI T1 and T2W showing affected vertebral body for OVCF without intravertebral cleft. (d) Low density image for intravertebral cleft in CT plain scanning with coronal and sagittal reconstruction (border, high density sclerotin)

of osteonecrosis and adjacent vertebral fracture in a gas phase in the intravertebral cleft are higher than those in a liquid phase.[9] For OVCF without the intravertebral cleft, T1W and T2W images exhibit diffused low and high signal areas, respectively[10] [Figure 2c]. According to the intravertebral cleft signal characteristics and contents, the manifestations of MRI are divided into four types: (1) liquid phase (14%): Low signal on T1, high signal on T2 and extensive bone necrosis; (2) granulomatous type (27%): Low signal on T1, medium signal on T2 and granulation tissue formation; (3) compression type (41%): Medium signal on T2, significant loss of anterior column height signal, bone necrosis, bone marrow fibrosis, granulation tissue formation and equal amount of reactive new bone proliferation; and (4) mixed type (18%): Low signal in all conventional sequences on bilateral borders (the same with hardening bone in CT). In this study, MRI detected 40 cases in 44 patients with intravertebral cleft. The detection rate was 90.9%, which is significantly higher than X-ray imaging.

Given the lack of spinal cord injury symptom for vertebral compression fracture, CT is seldom used to diagnose intravertebral cleft. CT was often used as a plain scan and its sensitivity and detection rate was lower than X-ray and MRI[11]. In this study, CT scan found typical intravertebral cleft with coronal and sagittal reconstructions [Figure 2d]. In 44 patients with intravertebral cleft, CT scan detected 31 cases, indicating a detection rate of 70.5%. Intravertebral cleft was not found in the remaining 139 patients. This result indicates that CT scan with coronal and sagittal reconstructions exhibited good application in diagnosing intravertebral cleft.

PKP is a minimally invasive technique to treat OVCF and benign or malignant vertebral tumors. In PKP, a balloon distraction is conducted to restore the compressed vertebral height for the correction of kyphosis.[12] PKP has been widely used in clinical practice and has shown good efficacy.[13] For patients with OVCF complicated with the intravertebral cleft, the surgery requirements are higher. The cleft area is the puncture target; an accurate entry to the cleft area is a key to a successful operation. Hyperextendible postural reduction was performed in some patients, which can better elevate the vertebral endplate, thus resulting in better restoration and easier balloon distraction.[14] Given the existence of the cleft, bone cement can be diffuse on both sides along the cleft to form a fracture pattern block with a smooth edge. Thus, good filling effect and supporting mechanical effect can be achieved.[15]

On the basis of distribution in the vertebral body after PKP,[15] bone cement can be divided into trabecular and fracture patterns. In this study, trabecular pattern bone cement is commonly found in OVCF without the intravertebral cleft. Bone cement filled the loose trabecular gap and presented a jagged block [Figure 3a]. The fractured pattern is commonly found in OVCF with the intravertebral cleft. Bone cement diffused in two sides along the cleft. This bone cement cannot further fill the trabecular gap because of the hardened sclerotin. Thus, a fracture pattern block with a smooth edge is formed [Figure 3b].

Bone cement leakage is one of the most common complication of PKP. [17,18] Most of these leakages are asymptomatic but a small portion of symptomatic leakages may cause serious consequences.[19] In group A, bone cement was infused under high pressure. Bone cement was further distributed along the trabecular gap and easily entered the vertebral body or paravertebral venous plexus. This condition resulted in leakage along the

Table 6: Improvement rates of VAS and ODI score in two groups ($\bar{X}\pm S$, %)

Group	VAS	ODI
A	66.2±16.8	62.3±10.2
B	63.2±18.1	63.4±9.4
t	1.288	−0.797
P	0.199	0.427

VAS=Visual analog scale, ODI=Oswestry disability index

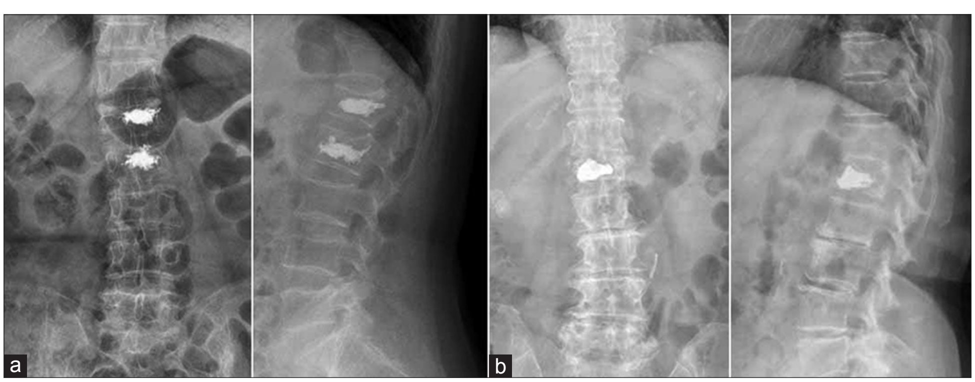

Figure 3: Postoperative x-ray dorsolumbar spine (anteroposterior and lateral views) showing (a) trabecular pattern of bone cement in PKP for OVCF without intravertebral cleft. (b) fracture pattern of bone cement in PKP for OVCF with intravertebral cleft

blood vessel (49/172, 28.5%) or leakage to the adjacent intervertebral disc by weak endplate breakage (13/172, 7.6%). The presence of the intravertebral cleft is a risk factor for bone cement leakage.[20] In group B, the bone cortex in the anterior border of the vertebral body was incomplete. Bone cement was uniformly distributed in the cleft, followed by leaking through the crevasse in the anterior border, resulting in the highest rate of bone cement leakage to the surrounding soft tissues (19/3, 35.8%). Therefore, no significant difference in the bone cement leakage rates was observed between the two groups. However, the presence of the intravertebral cleft governed the differences in leakage types in both groups. Preoperative MRI data can predict the trend and type of bone cement leakage.[21]

To avoid or reduce bone cement leakage, we should understand the preoperative fracture anatomy and position. The puncture needle should be placed in the cleft or in the upper or lower vertebral body to avoid the interosseous venous system. Bone cement should be infused in the sticky stage or terminal sticky stage. For the rupture on the peripheral vertebral wall, the "eggshell" technology can be applied;[22] after this procedure, bone cement filling can be performed. Some of the effective methods include intraoperative graded bone cement infusion and continuous monitoring by using a C arm. After operation, patients should stay in bed for more than 2.5 h to allow bone cement to solidify.

In PKP, balloon dilatation contributes to further restoration of the vertebral body height.[23] In this study, X-ray imaging determined the preoperative and postoperative heights of the anterior, central and posterior borders of the vertebral body [Figure 4]. The results showed that the postoperative height of the affected vertebral body in both groups was significantly improved; group B exhibited a more evident restoration of the vertebral body height than group A.

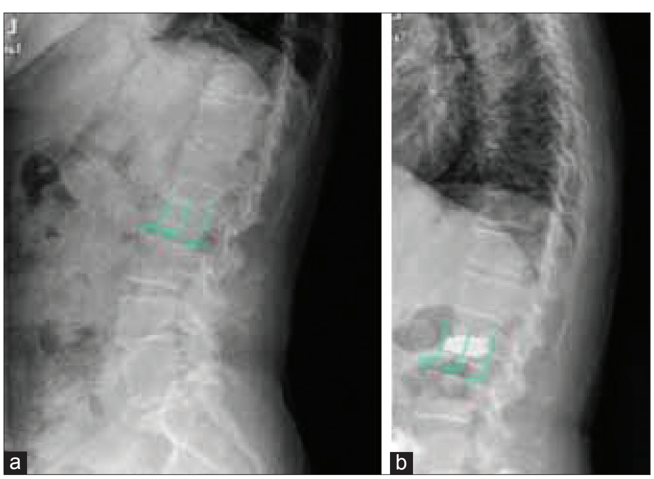

Figure 4: X-ray lateral view of lumbosacral spine showing measurement of anterior border, center, and posterior border of affected vertebral body before (a) and after (b) PKP

The intravertebral cleft is the result of evident vertebral collapse and bone necrosis in the late stage of OVCF.[24] In this stage, the fractured end can produce instability caused by a change in the body position, resulting in severe pain. Therefore, the preoperative pain degree in patients with intravertebral cleft is more severe than that in patients without intravertebral cleft. After PKP, both groups exhibited a stable vertebral body with reduced pain and improved daily activity function; no statistical differences were observed between the two groups. Further study is need to investigate the longterm effects of intravertebral cleft on the clinical outcomes.

To conclude, intravertebral cleft is a specific manifestation of OVCF, exhibiting unique clinical and imaging features. The minimally invasive PKP is an effective treatment of OVCF with intravertebral cleft. This technique can be performed to restore the affected vertebral body height, alleviate pain and improve the daily activity of patients.

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