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Original Article

Prevention and treatment of bone cement-related complications in patients receiving percutaneous kyphoplasty

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Abstract: Objective: This study is to investigate the complications and preventive measures of bone cement in percutaneous kyphoplasty for the treatment of osteoporotic vertebral compression fractures. Methods: A retrospective analysis of 134 cases of osteoporotic vertebral compression fracture patients treated with percutaneous kyphoplasty, which involved 182 vertebral fractures, was performed. The bone cement-related complications, the reasons causing these complications, and the preventive measures were investigated. Results: Successful operation was performed in all patients. Operative bone cement toxic reaction occurred in 1 patient. Different degrees of leakage of bone cement were found in 21 patients with 25 fractures and 1 case needed operation treatment. During the long term follow-up, bone necrosis absorption and cement drifted away which needed operation treatment was found in 1 patient with vertebral fracture. Thirteen adjacent vertebral fractures were found in 11 patients and 10 patients underwent operation treatment again. Conclusions: With careful surgery, complications associated with bone cement could be greatly reduced.

Keywords: Osteoporosis, kyphoplasty, cement, complications

Introduction

Osteoporotic vertebral compression fractures (OVCFs) is one of the common causes of senile lumbar back pain. OVCFs can lead to disability and reduce quality of life. In recent years, with the development of minimally invasive treatment and interventional technique, percutaneous kyphoplasty (PKP) has become one of the effective methods to treat OVCFs [1-7]. PKP has been widely used in clinic and has obtained satisfactory curative effect. It is one of the main reliable methods for treatment of senile OVCFs. PKP can stable the fracture vertebral body and relieve back pain, thus, improving the quality of life [8, 9].

However, PKP has some complications [10, 11], especially bone cement-related complications, which can induce disastrous consequences in serious cases. The complications of PKP bone cement perfusion include leakage of bone cement, bone cement toxicity, vascular thrombosis, pulmonary embolism, and so on. Leakage of bone cement is the most common complication and bone cement may leak into the spinal canal, intervertebral foramen, intervertebral disc, paravertebral soft tissue, paravertebral veins and puncture needle tract. Small doses of bone cement leakage usually do not cause clinical symptoms [4, 12] and do not need treatment or only need symptomatic treatment. However, a large amount of bone cement leakage may cause serious complications. In this study, a retrospective analysis of OVCFs patients treated with PKP was carried out. Bone cement-related complications and the associated prevention measures were discussed.

Materials and methods

Patients' data

A total of 134 cases of OVCFs patients with 182 vertebral fractures were included in this study. The patients were admitted to our hospital from August 2009 to August 2013. They had complete clinical data (**Table 1**) and follow-up data.

Table 1. General data of the patients

Category	Data
Male/Female	33/101
Age	54-91, mean 66.5
Bone density (-)	2.54-4.21, mean 3.23
Operation time (min)	27-56, mean 38.4
Bleeding amounts (ml)	3-17, mean 8.2
Amount of bone cement (ml)	2.8-6.5, mean 4.45

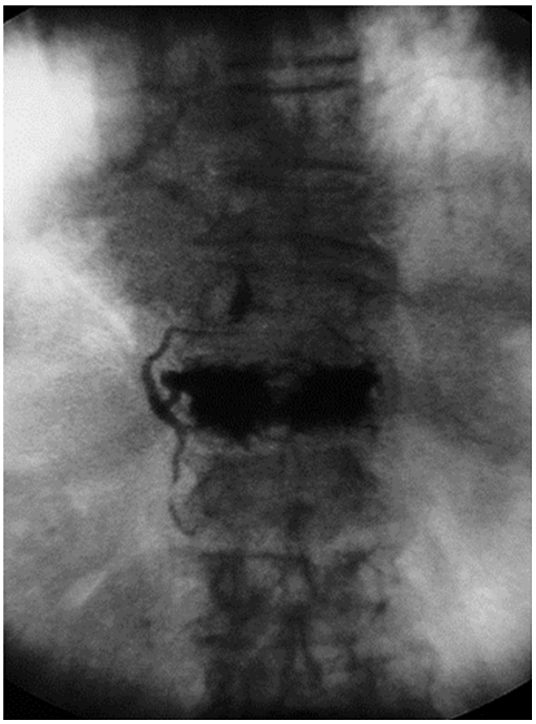

Figure 1. X-ray imaging of bone cement leakage of a 64 years old female OVCFs patient who had taken PKP treatment at T12. Bone cement leakage along the paravertebral vein was found during the operation. Because the patient did not feel any discomfort, no special treatment was taken.

Of the 134 cases, 33 were male and 101 were female with an average of 66.5 ± 7.6 years old. History of trauma caused by heavy lifting or lumbar sprain was found in 81 patients and no such history was found in the other 53 patients. There were 112 cases with single segment of vertebral fracture, 23 cases with double segments of vertebral fracture and 8 cases with three segments of vertebral fracture. Fracture involved segments were as follows: T7, 3 cases, T8, 5 cases, T9, 10 cases, T10, 15 cases, T11, 39 cases, T12, 42 cases, L1, 36 cases, L2, 19 cases, L3, 9 cases and L4, 4 cases. The time duration between the fracture and the operation treatment was from 1 day to 11 weeks. All patients were followed up for 11-33 months with an average of 18 months. The symptom of back pain was found in all the cases and in some cases, the pain radiated to the side part of chest and abdomen. Change position actions such as turn over aggravated pain and recumbent position could alleviate pain. Physical examination showed tenderness and percussion pain in the vertebral spinous process with fracture. No clinical manifestations of neural function damage such as lower limb numbness, pain or muscle weakness were found.

Prior written and informed consent were obtained from the patient and the study was approved by the ethics review board of the Shandong Provincial Qianfoshan Hospital.

PKP operation

After locally infiltrated with 2% lidocaine, transpedicular puncture was carried out with a needle under C arm fluoroscopy. When the tip reached the inner edge of the vertebral pedicle and the hind vertebral sides, the needle was pulled out, thus, a working channel was established. A balloon was implanted in the front 1/3 of the vertebral fracture, which could reset the collapsed vertebral bodies. Once the vertebral height recovered or the balloon contacted the edge of the cortical bone of vertebral body, the balloon was removed. Bone cement at the dough stage was injected into fracture of vertebral body under low-pressure via the working channel. Close monitoring of vital signs of the patients and their feeling of discomfort was performed during the operation. Attention was paid to the feeling and activity of double lower limbs. After staying in bed for 8 h postoperatively, recovery activities were carried with wearing a waist. Preventive application of antibiotics was used 24 h after operation and anti osteoporosis treatment was performed.

Preoperative examination and postoperative monitoring

Adverse clinical manifestation in the course of the surgery was recorded and the distribution and leakage of bone cement in the vertebra was closely monitored postoperatively. Imaging examinations including X ray, CT and MRI were performed before surgery, 3 days after surgery

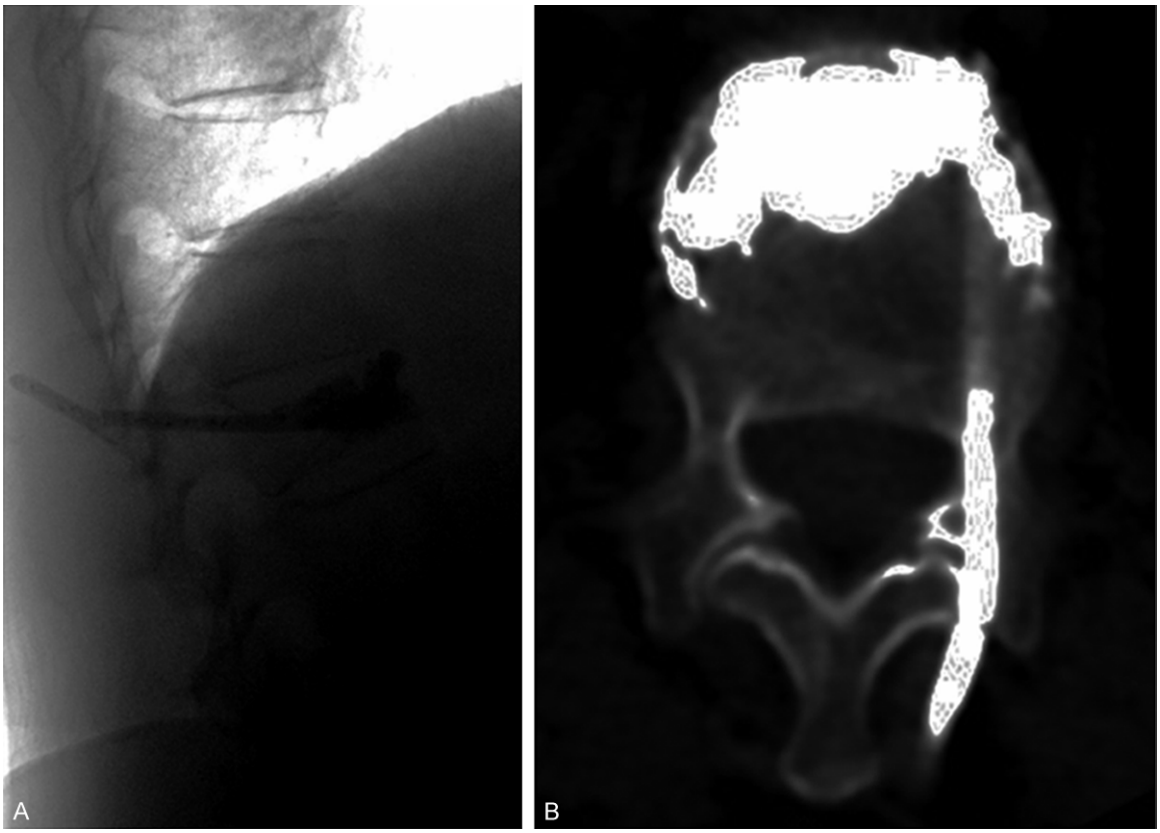

Figure 2. Imaging pictures of a 71 years old female OVCFs patient who had taken PKP treatment at L1. Bone cement residue was found in the paraspinal muscle intra-operatively and broke 7 years after operation, causing pain in the waist. The symptoms alleviated after removal of the residue. A. Radiograph lateral scan. B. CT base line scan.

and during the 11-33 months (18 months in average) follow-up period to evaluate the height of anterior and middle vertebral fracture, the location of bone cement and the fracture condition in adjacent segment.

Statistical analysis

All data were analyzed by SPSS19.0 software (SPSS Inc, Chicago, IL, USA). The data was expressed as $\bar{x} \pm s$. Differences within group were analyzed with one-way ANOVA and between groups were assessed with SNK method. $P < 0.05$ was considered as statistically significant.

Results

General condition after the surgery

In order to accurately evaluate the effect of operation, postoperative general conditions of the patients were recorded and analyzed. All the cases were successfully operated with no vascular injury, nerve injury or pulmonary embolism. Bone cement injection volume was 4.45 ± 1.24 ml and it dispersed in the vertebral body, both sides of the vertebral body or in the endplate, forming projections to anchor with vertebral bone. Operative bone cement toxic reaction occurred in 1 patient and the symptoms disappeared after fluid infusion and symptomatic treatment. Different degrees of leakage of bone cement were found in 21 patients with 25 sites of fractures (segment occurrence rate was 13.7%) and 1 cases needed operation treatment. Among the 25 sites of leakage, 11 sites were leakage along the paravertebral veins (**Figure 1**), 4 sites were leakage to the intervertebral disc, 6 sites were leakage to the side of the vertebra, 3 sites were leakage to vertebral canal and 1 site was leakage to the paraspinal muscles (**Figure 2**). The case with the paraspinal muscle leakage which caused back pain needed operation to remove bone cement. However, no pain, nerve injury or pulmonary embolism was found in other cases and thus no special treatment was carried.

Table 2. Comparison of relative vertebral height between preoperative, 3 day after cement augmentation and the time of last follow-up

	Preoperative	3 days postoperative	The last follow-up
Relative height of anterior vertebral body (%)	60.4 ± 8.4	85.6 ± 7.7*	84.7 ± 7.8*
Relative height of the middle part of the vertebral body (%)	66.3 ± 7.2	86.4 ± 8.1*	86.2 ± 8.1*

Note: *Compared with the preoperative group, $P < 0.05$.

Imaging results before and after the surgery

To diagnose the disease and to understand the postoperative condition of patients, a series of imaging examinations including X ray, CT and MRI were performed before and after the surgery. Dual-energy X-ray absorptiometry was used to detect the bone mineral density of L1-L4. The results showed that the bone mineral density T value of L1-L4 was 3.23 ± 0.41, which, indicated that the patients were with osteoporotic vertebral fractures. The X-ray findings showed that there was kyphosis of spine and osteoporosis of vertebral body. The vertebral body with fractures was collapsed and formed wedge - shaped, flat or concave change. The fracture line was observed in some of the diseased vertebra. CT showed that there was interruption of bone continuity in bone trabecular. MRI imaging observed similar features as X-ray. In acute stage, fractured vertebral body showed low signal in T1WI and high signal in T2WI and STIR. In the chronic phase, the low signal was seen in T1WI and high signal was seen in T2WI and STIR. High signal and vacuum phenomenon was seen in partial fractured vertebral body.

Preoperatively, the relative height of the anterior vertebra body was (60.4 ± 8.4)% and the relative height of the middle part of the vertebral body was (66.3 ± 7.2)%. At 3 days after surgery, the relative height of the anterior vertebra body was (85.6 ± 7.7)% and the relative height of the middle part of the vertebral body was (86.4 ± 8.1)%. Compared with the preoperative value, the difference was statistically significant ($P < 0.05$). At the time of the latest follow-up, the relative height of the anterior vertebral body was (84.7 ± 7.8)% and that of the middle part of the vertebral body was (86.2 ± 8.1)%. Compared with the preoperative value, the difference was statistically significant ($P < 0.05$) (**Table 2**). The imaging results showed that after the operation, good curative effect was found in most of the patients and bone cement leakage mainly occurred in paravertebral veins, adjacent intervertebral disc or paravertebral soft tissue.

The condition during the follow-up

To obtain the long-term curative effect of operation, a long time follow-up was carried. During the long term follow-up, a total of 11 cases with 13 adjacent vertebral compression fractures (segment incidence rate of 7.1%) were found and 10 patients underwent operation treatment again. One case had bone necrosis absorption and cement drift away, causing lumbar pain and weakness of lower limbs. This patient also underwent further operation (**Figure 3**).

Discussion

Bone cement-related complications are caused by perfusion of bone cement leakage during operation and long-term complications of bone cement are caused by bone cement shift and adjacent vertebral fractures and so on. Bone cement leakage occurred in 13.7% of the patients in our study. However, it was less likely to cause adverse clinical manifestations. The incidence of adjacent vertebral fracture was relatively (7.1%) but most of cases with adjacent vertebral fracture required PKP treatment once again. Bone cement caused vertebral bone necrosis absorption was extremely rare, however, because of the serious consequences, operation treatment was needed.

Complications of bone cement after PKP operation are mainly adjacent vertebral new fractures [9, 13], fracture of vertebral body[14], aseptic necrosis of local bone resorption [15] and bone cement shift [4, 16]. With the total occurrence rate of 10%-25%, the complications are especially easy to occur in the patients with old VCFs. We suppose that the reasons causing such complications might be as follows. Firstly, once the vertebra is strengthened with the bone cement, local segmental stiffness increases. Secondly, with multi segment VCFs, kyphosis enables concentration of local stress.

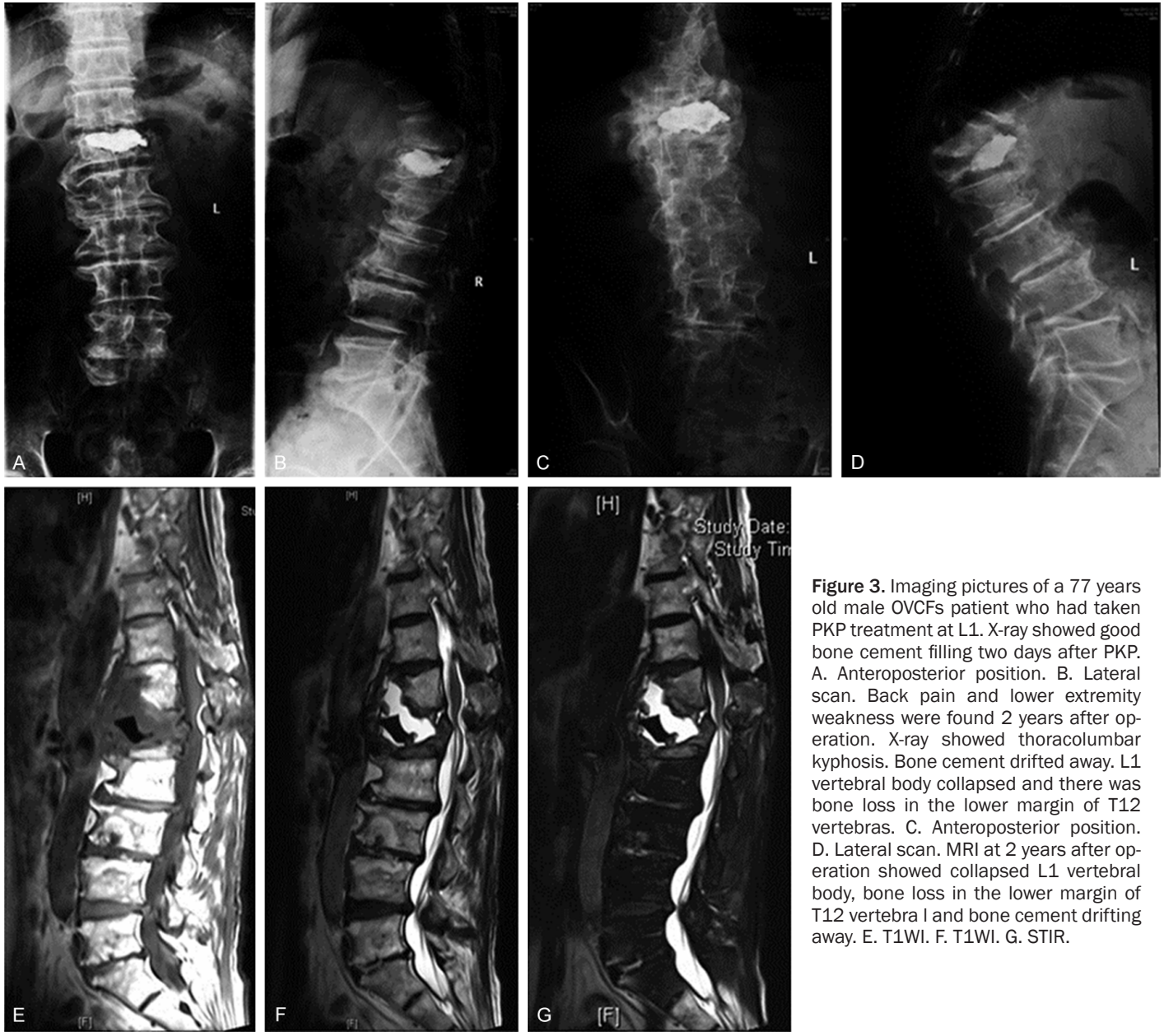

Figure 3. Imaging pictures of a 77 years old male OVCFs patient who had taken PKP treatment at L1. X-ray showed good bone cement filling two days after PKP. A. Anteroposterior position. B. Lateral scan. Back pain and lower extremity weakness were found 2 years after operation. X-ray showed thoracolumbar kyphosis. Bone cement drifted away. L1 vertebral body collapsed and there was bone loss in the lower margin of T12 vertebras. C. Anteroposterior position. D. Lateral scan. MRI at 2 years after operation showed collapsed L1 vertebral body, bone loss in the lower margin of T12 vertebra l and bone cement drifting away. E. T1WI. F. T1WI. G. STIR.

And, together with the poor strength of the non enhanced vertebral body, it is easy to lead to fracture. Thirdly, because of the heat reaction of bone cement, bone and blood supply of local vertebral body is damaged, which further causes necrosis. However, there is different opinion about bone cement thermal damage. Braunstein et al [17] found that 3.5 years after bone cement vertebroplasty, a lot of new bone callus appeared locally, suggesting that there was still local osteogenic ability after PKP. In the postoperative pain relief period, if the pain occurs again, high attention should be paid to new fracture. In our study, adjacent segment fracture was found in 8.2% of the patients. In addition to a rare case of vertebral fracture and necrosis with bone cement drifted away needed operation treatment. The other seven cases did not take second operation.

We consider that in the PKP operation process, various measures should be taken in order to reduce or avoid the complications associated with bone cement. Preoperative CT or MRI routine examination is necessary so as to understand the general condition of the vertebral pedicle and to determine whether the posterior wall of the vertebral body is complete. Medical staff should improve skills for accurate positioning to ensure a successful puncture and to avoid damage caused by repeated puncture. During the balloon dilatation process, more attention should be paid to the pressure and the expansion direction. Expansion should be stopped just for the treatment in case of vertebral cortical bone defect caused by excessive expansion. Penetration through the inner wall of the vertebral pedicle is better to be avoided. Reduce the number of puncture as much as possible. When perfusion of bone cement after unilateral pedicle puncture crosses over the middle part of the vertebral body, contralateral pedicle puncture perfusion is not needed. Bone cement work time window should be well handled. Bone cement should be implanted in vertebral body in the sticky stage at low-pressure. Good radiographic monitoring is the key to the success of PKP. The whole process of PKP operation should be in perspective. Once leakage occurs, the operation should be stop or wait until the bone cement viscosity increased enough for the injection. The powder liquid ratio of bone cement can be properly adjusted to reduce thermal reaction release of bone cement monomer [18], meanwhile, the bone cement to be injected can be frozen in sterile brine ice bath. Bone cement with biological activity should be used. Large amount injection of bone cement will induce toxic effects on the body. During one operation, the number of vertebral injection should not be more than 3. During operation in our study, we noticed the aforementioned points, which achieved the desired effect. Altogether, bone cement-related complications are common in the process of PKP treatment. However, it rarely causes clinical symptoms. Intraoperative careful operation can reduce the complications associated with bone cement.

Acknowledgements

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Disclosure of conflict of interest

None.

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