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Original Article

The clinical effect of percutaneous kyphoplasty for the treatment of multiple osteoporotic vertebral compression fractures and the prevention of new vertebral fractures

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Abstract: This study aimed to investigate the clinical effect of percutaneous kyphoplasty and the precautions against adjacent vertebral refractures in the treatment of multiple osteoporotic vertebral compression fractures. 54 cases (128 vertebrae) with multiple osteoporotic vertebral compression fractures from July 2007 to December 2013 treated with percutaneous kyphoplasty were retrospectively reviewed. 36 cases of them suffered from bi-segment vertebral fractures, 16 cases with tri-segment vertebral fractures and 2 cases with quadri-segment vertebral fractures. The operative effect was evaluated by visual analogue scale (VAS) score and oswestry disability index (ODI) score. Then the reasons for adjacent vertebral refractures were analyzed and the precautions were proposed. 54 cases (128 vertebrae) were admitted with percutaneous kyphoplasty successfully. No pulmonary embolism, spinal cord injury and other serious complications were found. The follow-up took 3-33 months with the average of 12 months. There was significant difference of VAS scores and ODI scores between pre-operation and post-operation ($P<0.05$). Bone cement leakage occurred in 23 vertebrae, and the incidence rate was 18.0%. 8 cases sustained adjacent vertebral refractures including 3 cases in the contiguous vertebral bodies and 5 cases in the interval vertebral bodies, and the incidence rate was 14.8%. 5 cases gained fracture healing after additional percutaneous kyphoplasty procedures while the other 3 cases were healed basically after conservative treatment for three months. In conclusion, percutaneous kyphoplasty is safe and effective to treat multiple osteoporotic vertebral compression fractures. However, the risk of new adjacent vertebral fractures in the multiple osteoporotic vertebral compression fractures is higher than that in the single osteoporotic vertebral compression fracture. Timely and proper treatment can reduce refractures.

Keywords: Percutaneous kyphoplasty, multiple osteoporotic vertebral compression fractures, new vertebral fractures

Introduction

With the degree of population aging worse off, osteoporotic vertebral compression fractures (OVCF) has been one of the leading factors in all osteoporosis-related deaths, which affects the quality of life of the elderly [1, 2]. The traditional conservative treatment methods include oral medications and immobilization. The latter will further aggravates osteoporosis, leading to various complications of pressure ulcers, pulmonary infection, decreased sleep quality, depression, as well as the increased risk of death in the elderly. This disease is prone to loss of vertebral height, local kyphosis deformity, chronic low back pain and other sequelae in the late stage. Due to the injury of open surgery, the elderly often can not be tolerated. And loosening, pull-out of the screws, bleeding, and infection, all these risks bring a challenge of treating elderly OVCF [3-5]. Percutaneous vertebroplasty (PVP) and Percutaneous kyphoplasty (PKP) are two kinds of minimally invasive spine operations in the treatment of OVCF, which can quickly relieve pain and help patients do early functional exercise. Both methods make it possible that surgery can be performed on the localized bone osteoporosis, and also provide time and opportunity for the subsequent medication on osteoporosis. PVP refers to percutaneous injection of bone cement into the vertebral body thus preventing vertebral collapse,

relieving pain and improving quality of patients' life. In 1984, French doctor Galibert firstly applied PVP for C2 vertebral hemangiomas [6]. After that, PVP was used to relieve the pain of OVCF caused by vertebral tumors and osteoporosis. Firstly applied in 1998, PKP is another minimally invasive technique based on PVP. Its working principle is to expand the collapsed vertebrae with balloons, and then to inject bone cement into the vertebral body in order to correct kyphosis deformity [7, 8]. Nowadays, PKP for the treatment of OVCF has been widely applied in clinic because of pain relief, improvement in kyphosis and low possibility of cement leakage [9].

Although PKP for elderly OVCF has been achieved satisfactory clinical efficacy, the spinal cord injury, pulmonary embolism, cement leakage, infection, and subsequent fracture and other complications can not be ignored. Due to the domestic and foreign researches focusing on single OVCF, there are a little related literature on clinical efficacy and complications of multiple OVCF. Compared with single OVCF, multiple OVCF patients have obvious loss of vertebral height and kyphosis deformity, so the requirements of its surgical procedures are higher [10]. Moreover, patients with multiple OVCF are particularly vulnerable to severe osteoporosis, so the postoperative risk of new adjacent vertebral fractures increases [11]. 330 cases with OVCF were treated with PKP recruited in our department from July 2007 to December 2013. Of which 54 cases were multiple OVCF, and their surgeries were relatively safe and effective, plus the postoperative pain relived significantly without serious complications. In this study, 54 cases (128 vertebrae) with multiple OVCF treated with PKP were retrospectively reviewed, and its clinical efficacy and complications were observed. Then the reasons for complications were analyzed and reasonable precautions were proposed.

Subjects and methods

Subjects

54 cases (128 vertebrae) with OVCF were treated with PKP received in our department from July 2007 to December 2013. The 54 patients were composed of 16 males and 38 females, and all of them were in the 60-88 age range with the average of 72.5 years old. The injured vertebrae were $T_5$1, $T_6$2, $T_7$3, $T_8$7, $T_9$4, T_{10}6, T_{11}12, T_{12}23, $L_1$32, $L_2$14, $L_3$16, $L_4$8. 36 cases of them suffered from bi-segment vertebral fractures, 16 cases with tri-segment vertebral fractures and 2 cases with quadri-segment vertebral fractures. Prior to surgery, low back pain was manifested in all patients with remission at supine position. Physical examination showed tenderness and percussion pain in the corresponding segment of spinous process without nerve injury. Preoperative X-ray, CT and MRI examination confirmed fresh fractures in all patients, the basic integrity of the inner and posterior wall of vertebral pedicle, and no significant compression in spinal cord and nerve root. This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of Tongji Hospital. Written informed consent was obtained from all participants.

Methods

General anesthesia was adopted in the surgery. Patients were placed at prone position with abdomen vacant, then were performed for postural reduction, and C-arm fluoroscopy was used to determine the fractured vertebrae. The transverse angle, the sagital angle, and the distance from the puncture point to the spinous process, all the key parameters were obtained based on the preoperative measurement of CT image. The puncture site was marked in the body surface with routine disinfection and draping. 0.5 cm skin was incised at puncture point with a sharp blade, and puncture was performed with puncture needles. When the end of the needle touched the bone structure behind the injured vertebra, the position of the needle end was determined via C-arm anteroposterior fluoroscopy. And it was ensured that its position was 9-11 o'clock in the left and 1-3 o'clock in the right of pedicle normotopia image. The needle continued deeply. When it reached the inner wall of the pedicle, the position of the needle was ensured to reach the posterior wall of the vertebral body via C-arm lateral fluoroscopy. After good position of the needle was determined via two-angle C-arm fluoroscopy, the needle was removed. Next the dilated cannula and working cannula were implanted along guide needle. A balloon was put into the vertebral cancellous bone along the working passage with slowly injection of contrast agent into the balloon under the C-arm close surveillance for balloon dilatation. The contrast agent was

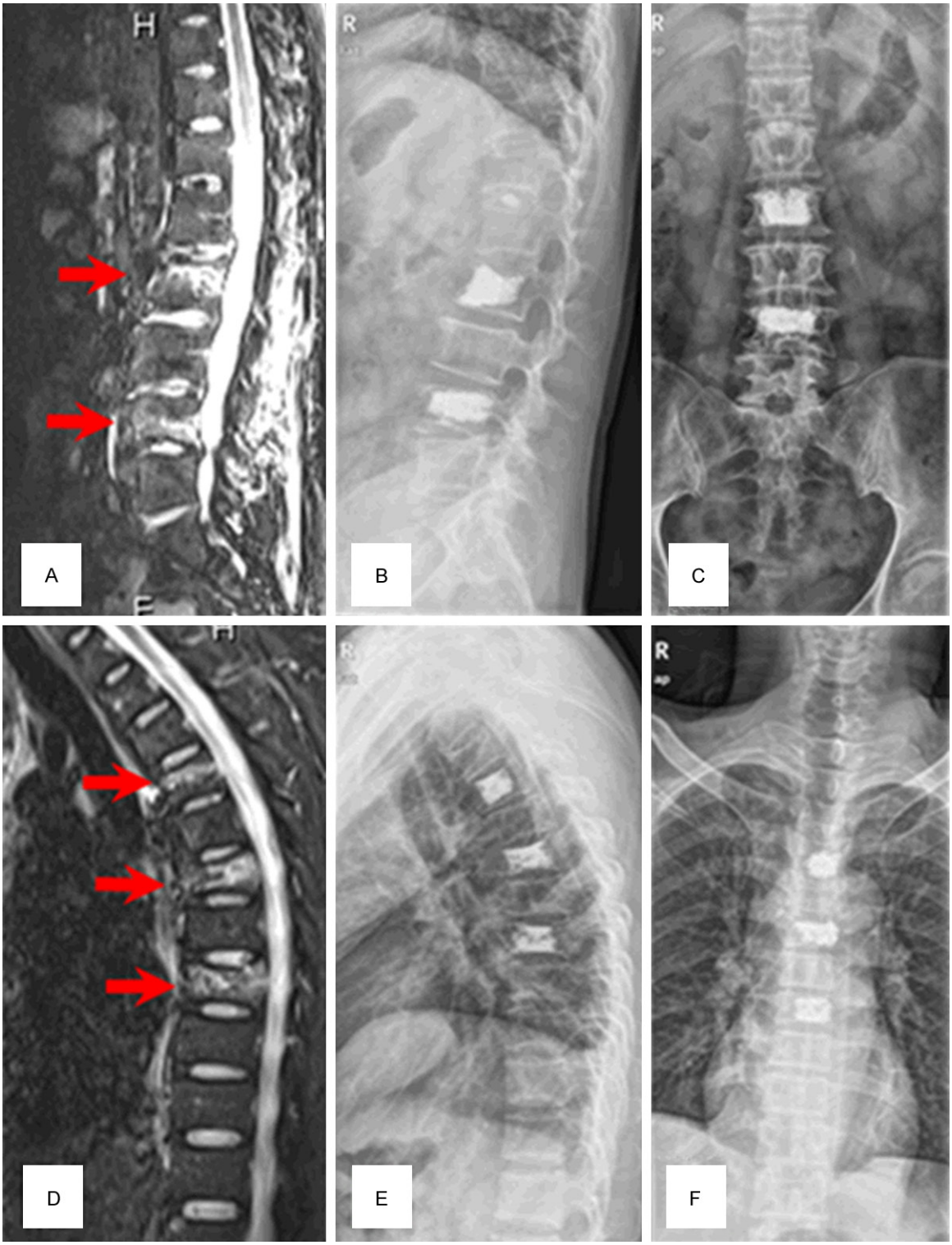

Figure 1. A: Lumbar MRI of a 61-year-old female patient with L_2 and L_4 being fractured; B, C: PKP postoperative X-ray; D: Thoracic MRI of a 51-year-old male with T_4, T_6 and T_8 being fractured; E, F: PKP postoperative X-ray.

extracted when vertebral height restored appropriately, and the balloon was taken out when it retracted to a vacuum. If multiple-level injured vertebrae were displayed in the same window, their operations could be carried out simultaneously. Otherwise, after the comple-

Table 1. Comparison of ODI score and VAS score at pre-operation, postoperative 2 days and the final follow-up

Items	Pre-operation	Postoperative 2 days	The final follow-up
ODI score	46.44 ± 1.74	18.56 ± 2.06*	12.57 ± 1.63*
VAS score	8.82 ± 0.58	1.94 ± 0.44*	1.70 ± 0.42*

Note: *refers to the statistical difference compared with pre-operation, P<0.05.

tion of single-level broken vertebral operation, the C-arm machine was moved to its tip or end with slightly adjustment of the projection angle, and the other vertebral operations were carried out with the same method. Poly methyl methacrylate (PMMA) (Tecres SPA, Sommacampagna, Italy) was injected at low pressure with C-arm fluoroscopy, and the injection was stopped unless good dispersion of cement. Once leakage, stop surgery. Cannulas were removed after cement hardening. C-arm fluoroscopy was needed to monitor all surgical procedures. All patients needed postoperative conventional anti-osteoporosis medicines (calcium, vitamin D, calcitonin).

54 cases with multiple OVCF were treated with PKP including 17 cases with bilateral approach and 37 cases with unilateral approach. The latter had good dispersion of cement with covering the vertebral midline. Disposable supplies for vertebroplasty and balloons were provided by Kaili Tai Medical Technology Co., Ltd., Shanghai, China.

Evaluation of surgical treatment

Visual analogue rating scale (VAS) and oswestry disability index (ODI) were measured at pre-operation, post-operation and the final follow-up respectively. And surgical treatment was evaluated.

Statistical analysis

All statistical analyses were performed using SPSS 17.0 (SPSS Inc, Chicago, IL, USA). Comparison of VAS score and ODI score data at different time points was analyzed using the paired t test between pre-operation and post-operation. The data was showed as the mean ± SD. P<0.05 was considered to indicate a statistically significant difference.

Results

54 cases (128 vertebrae) were admitted with percutaneous kyphoplasty successfully. The time of single-vertebral surgery was 15-35 min with the average of 20 ± 15 min, and 10-25 ml bleeding with the average of 17 ± 9 ml. The average injection volume of bone cement was 6.5 ± 4 ml. No serious complications of pulmonary embolism and spinal cord injury; no patients with paraspinal organ damage, death and conversion to open surgery (**Figure 1**).

The majority of patients with low back pain were relieved within postoperative 24 h. There was significant difference of VAS scores and ODI scores at pre-operation, postoperative 2 days and the last follow-up (P<0.05) (**Table 1**).

Cement leakage occurred in 23 vertebral bones, and the incidence rate was 18.0%, of which 2 vertebral bones with leakage into the spinal canal without any clinical symptoms, 3 leakage into the intervertebral disc, 8 leakage into the paraspinal soft tissues, 9 leakage into paravertebral vessels, 1 leakage into puncture channel.

During follow-up, 8 cases sustained new adjacent vertebral fractures including 3 cases in the contiguous vertebrae and 5 cases in the interval vertebrae, and the incidence rate was 14.8%, which was significantly higher than that of the single OVCF (3.6%, 10/276). The duration of subsequent fractures was 3-33 months after the first surgery with the average of 12 months. A total of 12 vertebrae were involved including 5 thoracic vertebrae and 7 thoracolumbar vertebrae, and they were $T_6$1, $T_7$2, $T_8$1, $T_9$1, T_{10}2, T_{11}2, T_{12}1, $L_1$1, $L_2$1. 5 cases gained fracture union after additional percutaneous kyphoplasty procedures the other 3 cases with union basically after conservative treatment for three months (**Figure 2**).

Discussion

It is still a controversial issue that how many vertebrae can be treated in one PKP or PVP operation. Barr et al. [12] showed that it was better to treat one vertebral body once while Singh et al. [13] revealed that there was no significant difference in clinical effect on treatment of multiple and single vertebra once. Mailli et al. [14] showed that PVP was a safe and effective treatment for OVCF, which had no significant correlation with the number of fractured vertebrae. In this study, 54 cases (128 vertebrae) with multiple OVCF were admitted with percutaneous kyphoplasty successfully. Moreover, their low back pain relived in postop-

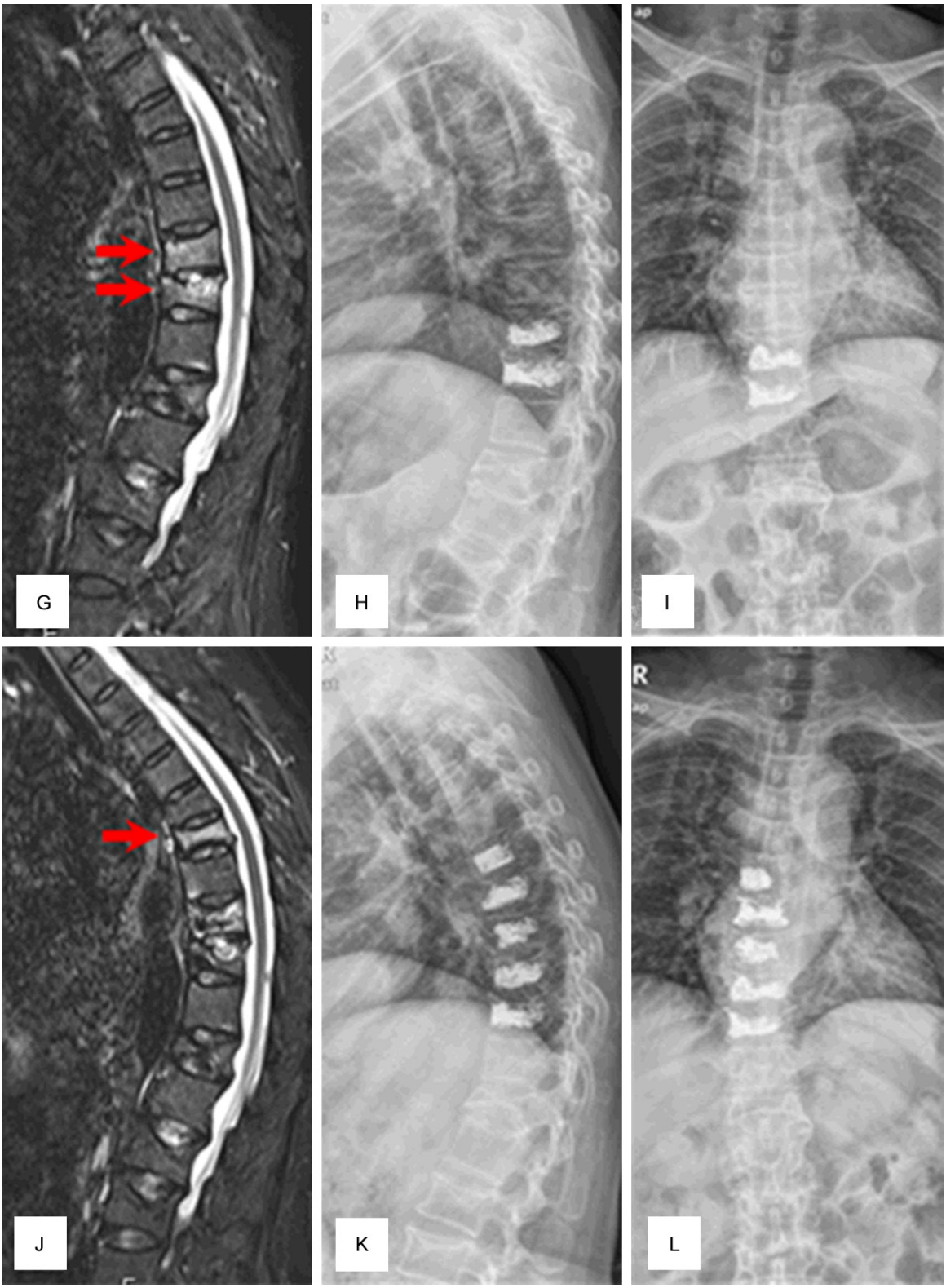

Figure 2. G: Thoracic MRI of a 65-years-old female patient with T_9 and T_{10} being fractured; H, I: PKP postoperative X-ray; J: Thoracic MRI of the patient with refracture in T_7 at postoperative 6 months or so (the second PKP surgery is needed); K, L: The second PKP postoperative X-ray (T_6 and T_8 undergo preventive vertebral augmentation duo to her poor bone mass).

erative 24 h with satisfaction clinical efficacy. Compared with PKP treatment of single OVCF, there was still the risk of cement leakage and new adjacent vertebrae fractures in this surgery on multiple OVCF. Bone cement leaked into the spinal canal through the crack in the fractured vertebra, the impaired pedicle wall and the nutrient vessels in the real of the vertebrae [15, 16], which could cause severe neurological dysfunction. In this study, cement leakage occurred in 23 vertebrae, and the incidence rate was 18.0%, which was basically consistent with the reported 11.5%-76.83% [17]. 8 cases sustained new adjacent vertebral fractures and the incidence rate was 14.8%, which was basically consistent with the reported 6.5%-26% [18-20]. It was significantly higher than that in PKP treatment of single OVCF (3.6%). What caused new adjacent vertebral fractures? What matters were needed to attend to in the second surgery for subsequent fractures? Both were the clinical problems to be solved.

At present, the degree of osteoporosis and vertebral compression, cement leakage into discs and fracture position, all these factors have been considered to associate with new adjacent vertebral fractures [21, 22]. Compared with single OVCF, multiple OVCF has its own peculiarities that it has obvious loss of vertebral height and kyphosis deformity with multiple vertebral fractures. Furthermore, requirement of great pressure to restore vertebral height with balloon may increase the tension of other vertebral soft tissues, which leads to new fractures because the load of adjacent vertebral increases [23, 24]. Meanwhile, loading stress is distributed unevenly because of the excessive stiffness in vertebral body after cement solidification, which will transfer to disc and adjacent vertebrae. This also increases the probability of new adjacent vertebral fractures [25]. Yoo et al. [21] showed that excessive correction to vertebral height increased the risk of distant vertebral fractures by dynamic hammer effect. In this study, 8 cases sustained new adjacent vertebral fractures including 3 cases in the contiguous vertebral bodies and 5 cases in the interval vertebral bodies, and the incidence rate was 14.8%, which was significantly higher than that of the single OVCF (3.6%, 10/276). Therefore, the number of fractured vertebrae was considered as a risk factor in adjacent vertebral refractures.

Lin et al. [26] showed that 58% of subsequent fractured vertebrae accompanied by cement leakage into the adjacent disc, while 12% did not, which indicated that the incidence of new fractures significantly increased because of cement leakage into the neighboring disc. Chen et al. [27] also showed that cement leakage into the adjacent disc could lead to new adjacent vertebral fractures, and it was related to the injection volume. However, based on retrospective analysis of PKP for the treatment of 358 patients with monosegment vertebral fracture, Wang et al. [28] showed that cement leakage to adjacent disc did not increase the risk of new fractures, which was mainly associated with age, the degree of osteoporosis and cement dispersion. In this study, there were 3 cases involved in cement leakage into disc, and all of them developed new fractures during follow-up. Therefore, cement leakage into neighboring disc could be another risk factor in new vertebral fractures. Moreover, the greater the number of intraoperative vertebrae in one surgery, the higher the risk of cement leakage. In the application of PKP for the treatment of multiple OVCF, the following points were needed to weigh to reduce the occurrence of cement leakage into disc: a) the puncture site being far away from the fractured endplate; b) appropriate balloon dilatation without the necessary of perfect fracture reduction; c) proper injection speed of cement for patients with fractured endplate.

Furthermore, it was still a controversial issue whether excessive injection of bone cement caused secondary adjacent vertebral fractures. Previous studies showed that the injection amount of bone cement was related to secondary vertebral fractures, because large amounts of bone cement increased the stress of the adjacent vertebral bodies, resulting in new fractures [29, 30]. But in recent years, an increasing number of clinical follow-up did not support this view, and many studies showed that there were not correlation of the amount of cement with secondary fractures [31, 32], but excessive injection increased the risk of cement leakage. Hulme et al. [33] showed that new adjacent vertebral fractures did not occur as long as bone cement did not reach the vertebral endplates. In this study, cement injection amount is 6.5 ± 4 ml, and no correlation between them was found because of the small

sample size. Bone cement being close to the upper and the lower endplates at lateral fluoroscopic image, and cement dispersion in both sides of vertebral midline at anteroposterior fluoroscopic image, both were considered to be the best filling condition of cement. Therefore, a sufficient amount of bone cement was injected with guarantee of no leakage during PKP surgery.

Rugger-jersey spine is another inevitable problem in PKP for the treatment of multiple OVCF, which refers to an intact vertebra of which the upper and the lower underwent PKP surgery, and the postoperative mechanical properties of adjacent vertebral bodies may alter in these patients, resulting in new adjacent vertebral fractures. Moreover, the risk of subsequent fractures after PKP in elderly patients with original vertebra fracture may increase significantly [34]. Lunt et al. [35] showed that the probability of new fractures in patients with 3 or above vertebral fractures was about 23.3 times that in patients without original fracture. Based on biomechanical study on cadaver samples, Berlemann et al. [29] showed that axial compression strength of the spinal motor unit was reduced after cement augmentation for one vertebra, which resulted in increasing the risk of adjacent vertebral fractures. But Harrop et al. [36] showed that PKP for the treatment of patients with primary osteoporosis fractures did not increase the probability of new vertebral fracture. So now it has been controversial whether preventive vertebral augmentation is needed for patients with rugger-jersey spine. Combined with clinical practices of rugger-jersey spine, preventive vertebral augmentation is not necessary for patients with good bone mass, while it dose for patients with poor bone mass (**Figure 2**).

Several points of PKP postoperative new fractures can mainly be summarized as follows: 1): standard anti-osteoporosis treatment. Osteoporosis is the underlying cause of OVCF, so long-term anti-osteoporosis treatment is necessary. After careful preoperative assessment of the general condition, kyphosis deformity patients, with high risk of postoperative re-fracture, should be actively treated with anti-osteoporosis. 2): appropriate activities under the protection of orthosis. After PKP operation, conventional orthosis for more than 3 months is needed for patients with minimize bending and weight-bearing activities. 3): preventive vertebral augmentation is recommended to avoid subsequent fractures for patients with rugger-jersey spine combined with severe osteoporosis, as well as for patients with apex vertebral fracture in kyphosis. 4): as for re-fracture patients, their conditions permitting, an additional surgery should be performed to reduce the time in bed and improve the quality of their life. If rugger-jersey spine occurs, patients with poor bone mass will be performed on preventive vertebral augmentation. 5): improve the surgical techniques and strictly control the injection of bone cement to reduce the leakage into disc.

In summary, it is safe and effective in PKP for the treatment of multiple OVCF, but the risk of new adjacent vertebral fractures is significantly higher than that in patients with single OVCF. Postoperative waist fastening protection and standard anti-osteoporosis treatment can reduce the incidence of new fractures. Re-fracture patients who undergo the second surgery achieved the satisfactory clinical efficacy. However, due to the small sample size of this study and short time for follow-up, it still needs further study on long-term effect of preventive vertebral augmentation on adjacent vertebrae in the second surgery and the reasons for the related complications.

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Disclosure of conflict of interest

None.

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