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Original Article

A comparative study of percutaneous kyphoplasty and conservative therapy on vertebral osteoporotic compression fractures in elderly patients

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Abstract: Objective: To compare the therapeutic efficacy of percutaneous kyphoplasty (PKP) with that of conservative treatment in elderly patients with osteoporotic vertebral compression fractures (OVCFs). Methods: A total of 80 elderly patients with osteoporotic vertebral compression fractures admitted to our hospital from January, 2013 to June, 2015 were randomly assigned by a random number table to receive PKP (the PKP Group, n=40) or conservative treatment (the CT Group, n=40). The two groups were compared in improvements in vertebral fracture restoration and symptom relief before and after treatment. Their improvements in vertebral height and Cobb angle of kyphosis before and after treatment were also measured. In addition, their pain relief and physical functions were assessed with the use of Visual analog scales (VAS) pain scores and Oswestry Disability Index (ODI) scores. Results: The postoperative vertebral height restoration (14.1 mm) of the patients in the PKP Group was significantly improved as compared with that before treatment, and the difference was statistically significant (P<0.05); but no significant improvements were found in the CT group; the decrease in Cobb angle was significantly greater in the PKP Group than in the CT group (P<0.05). Improvements in VAS pain scores and ODI scores at various time points postoperatively were also significantly greater in the PKP Group than in the CT group (P<0.05). Conclusion: The PKP treatment could provide immediate pain relief for the patients and takes the advantages of bringing more significant improvements in vertebral fracture restoration, better correction in kyphosis and weight-bearing capacity at an earlier stage. However, although conservative treatment might lead to smaller trauma, it cannot bring complete restoration in compressed vertebral height and in Cobb angle. Also, it was found to have a high incidence of complications. In such cases, the patients' quality of life warrants further improvement.

Keywords: Osteoporosis, compression fractures, PKP, case control trial

Introduction

Osteoporotic vertebral compression fractures (OVCFs) are common in the elderly, and are the most common clinical complications of osteoporosis, which seriously affect the life quality of elderly patients [1, 2]. With the increasing aging population in China, how to guarantee the subsistence and good life quality of the elderly has become an important part of social stability. Relevant epidemiological data show that fractures caused by osteoporosis affect about 13 to 16 million people every year in China. The incidence rate of fractures in the elderly is high up to 16.5% in the urban area of Shanghai, among which the incidence of vertebral fractures is the highest [3, 4]. Routine conservative treatment includes bed rest, medical therapy or physical therapy for 1-3 months with advantages of no need of surgery, thus no associated risks or postoperative complications. Long-term exercise intervention may result in certain improvements in fracture reduction, and the fractures can be cured if complemented with symptomatic medication [5]. However, due to long-term bed rest, the patients may have bedsores, hypostatic pneumonia, muscular atrophy, urinary tract infection or other complications.

Percutaneous kyphoplasty (PKP) is a medical spinal procedure in which an inflatable balloon bone tamp is advanced into the fractured vertebra and elevate the endplates, and then the balloon tamp is deflated and a cavity is produced, into which bone cement (usually polymethylmethacrylate, PMMA) can be injected. It

was originally developed by Wong and Reiley and was applied in clinical practice after approved by the FDA in 1998 [6]. This new minimally invasive surgery showed great superiority in the treatment of OVCFs [7, 8]. Later, it was introduced into China by Huilin Yang from First Teaching Hospital Attached to Suzhou University. Since then, it has been widely used in clinical practices [9, 10]. In this paper, a total of 80 elderly OVCF patients treated in our hospital from January 2013 to June 2015 were selected and assigned to undergo PKP therapy or conservative treatment. An analysis was made by comparing between PKP and conservative treatment in their therapeutic efficacy for OVCFs in the elderly regarding preoperative and postoperative symptoms and fracture restoration.

Materials and methods

Clinical data

A total of 80 elderly OVCF patients treated in our hospital from January, 2013 to June, 2015 were enrolled in our study, with an average age of 74 years. They were randomized into two groups in terms of treatment methods: the PKP Group and the CT group. Among them, 40 cases (30 male, 10 female) were in the PKP Group and 40 cases (26 male, 14 female) in the CT group. All the patients had only isolated VCFs, fracture sites being T10-L3. All of them presented such symptoms as typical disseminated lumbo-dorsa pain, accompanied by local tenderness or percussion pain. They all were preliminarily diagnosed as having OVCFs based on the results of X-ray lateral radiographs, CT or MRI scans.

American Society of Anesthesiologists (ASA) classification system: Grade I indicating the patient has no basic diseases and the functions of all organs are normal; Grade II indicating the patient has mild systemic diseases that result in no functional limitations; Grade III that the patient has systemic diseases and is restricted in strenuous activity, affecting the life; Grade IV that the patient has severe systemic diseases, and is unable to work and faced with constant threat to life. Grade V, a moribund condition in the patient who is not expected to survive with or without the operation; Grade VI, declared brain death in the patient whose organs are being harvested for transplantation.

The patients in this study fell into Grade I-III, 65% of them being in Grade I, 25% in Grade II and 10% in Grade III. There was no significantly statistic difference in distribution across the groups.

The vertebral fracture ratings was assessed as per Genant's classification (standard lateral radiographs): Grade 0 indicating that the shape and size of the vertebral body are normal; Grade I, fracture with less than 20% to 25% loss in vertebral height and less than 10%-20% loss in vertebral projection area; Grade II, fracture with 26% to 40% loss in vertebral height and 21%-40% loss in projection area; Grade III, fracture with more than 40% loss in vertebral height and in projection area [12].

Inclusion and exclusion criteria

Inclusion criteria: (1) 65 years of age or older; (2) the course of the disease lasting 2 hours to 2 weeks; (3) patients having imaging features consistent with clinical manifestations and confirmed as having thoraco-lumbar compression fractures; (4) those voluntarily provided the written informed consent.

Exclusion criteria: (1) patients with vertebral fractures or lumbo-dorsa pain that could not be ruled out the causes of other potential lesions; (2) patients with malignancy, severe cardiopulmonary disease, administration of long-term steroids or systemic infection; (3) patients with coagulopathy which could not be cured .

Methods

Preoperative preparations

After admission, the patients were required to have routine examination and bed rest. For patients associated with medical diseases in respiratory system or cardiovascular system, they should be first treated for their medical diseases. All patients underwent bone mineral density examination to confirm the possibility of osteoporosis. Their X-ray lateral radiographs, CT scans and magnetic resonance imaging (MRI) were taken to determine the locations of the fractures, and the degree of involvement, etc.

Selection of therapeutic methods

Percutaneous kyphoplasty (PKP): All of the 40 patients in the PKP Group underwent PKP. They

Table 1. General information of both groups

Items	Total	PKP group (n=40)	CT group (n=40)
Gender, n (%)			
Female	24 (30%)	10 (25%)	14 (35%)
Male	56 (70%)	30 (75%)	26 (65%)
Age (years)	74.03±6.21	74.32±7.02	74.36±7.40
BMI (kg/m^2)	21.86±2.12	21.79±3.10	22.14±2.80
ASA grading, n (%)			
1	52 (65%)	24 (60%)	28 (70%)
2	20 (25%)	12 (30%)	8 (20%)
3	8 (10%)	4 (10%)	4 (10%)
Affected sites			
T10	3 (3.75%)	1 (2.5%)	2 (5%)
T11	4 (5%)	2 (5%)	2 (5%)
T12	30 (37.5%)	16 (40%)	14 (35%)
L1	25 (31.35%)	12 (30%)	13 (32.5%)
L2	11 (13.75%)	6 (15%)	5 (12.5%)
L3	7 (8.75%)	3 (7.5%)	4 (10%)
Fracture ratings			
I	9 (11.25%)	4 (10%)	5 (12.5%)
II	30 (37.5%)	16 (40%)	14 (35%)
III	41 (51.25%)	20 (50%)	21 (52.5%)

Note: BMI, Body mass index; ASA, American Society of Anesthesiologists.

were placed in the prone position. After the targeted pedicles were localized under the guidance of the C-arm fluoroscopy, local anesthesia was administered to the compressed segments of the vertebral body and electrocardiographic (ECG) monitoring was performed as well. After a small incision, a needle was introduced into the vertebral body through the lateral parts of the superior border of the pedicle and stopped until its tip abutted the anterior three-fourths of the vertebral body. A balloon tamp was advanced into the fracture and then contrast agent was injected into the balloon tamp under the continuous fluoroscopic imaging guidance. The balloon tamp was slowly inflated, and it stopped till it abutted the superior and inferior endplates of the vertebral body. Contrast agents and the balloon were taken out and a cavity in the vertebral body was produced, into which bone cement (PMMA) was injected. Immediately after the cement solidification, the surgical incision was sutured, and then covered with an aseptic dressing. Thus, the surgery was completed.

Conservative treatment: All of the 40 patients in the CT Group received conservative treatment. They were confined to rests on the platform beds for 8-10 weeks. Bolsters could be gradually placed under the lumbo-dorsa fractures to facilitate the patients' vertebral restoration by stretching the spine backward. In the meanwhile, exercise interventions were also required. Then supplementation of antiosteoporosis drugs including vitamin D3 and calcium carbonate for symptomatic treatment and better nutrition and nursing can be effective in preventing related long-term bedridden complications.

Indexes for observation and evaluation

Vertebral height

Vertebral height was the height of the anterior wall of the affected vertebral body in the patients from the X-ray lateral radiographs.

Cobb angle

The Cobb angle is defined as the angle formed between a line drawn parallel to the superior endplate of one vertebra above the fracture and a line drawn parallel to the inferior endplate of the vertebra one level below the fracture. It is an index used for measuring the kyphosis angle [8, 13].

Visual analog scales

Analog scales Visual (VAS) is a clinically common pain scale for pain quantification [14]. Changes in pain intensity were measured and recorded using VAS ranging from "no pain" (0) to "the imaginable severe pain" (10). Based on their pain intensity, the patients made marks at the corresponding positions on the scale, the scores being the distance from the 'no pain' end to the marked positions (as shown in the following figure).

Oswestry disability assessment

The Oswestry Disability Index (ODI) is an index derived from the Oswestry Low Back Pain Questionnaire which contains ten topics concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. Each question is scored on a scale of 0-5 and the scores for all questions answered are summed, with the higher scores indicating more severe disability [15].

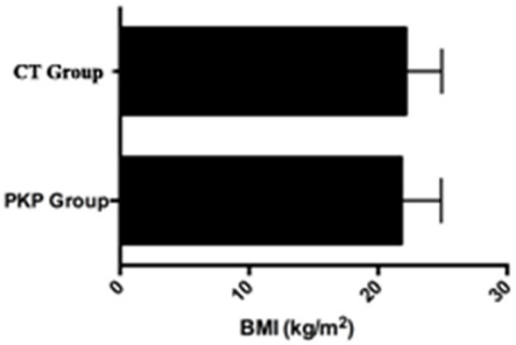

Figure 1. Comparison of Body Mass Index (BMI) between both groups.

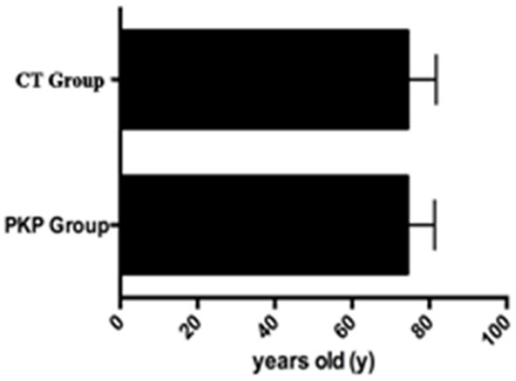

Figure 2. Comparison of age between both groups.

Statistical methods

Statistical analysis of all data was performed using SPSS 13.0. Comparison of vertebral height, Cobb angle, VAS scores and ODI between the two groups was made using the paired sample t-test. Results were considered significant at $P<0.05$ and the data were represented as $\bar{x} \pm S$.

Results

The treatment of the two groups went smoothly, and each index was recorded before the operation and at 3 days, one week, one month, three months and six months postoperatively, respectively. No complications such as spinal cord injuries were observed during the study.

Comparison of general information

Each group had 40 patients, and their age, gender, and preoperative BMI, ASA ratings, the injured sites and fracture classification are shown in **Table 1**. Their age ranged from 74 to 75 years, and there was no statistical difference between the groups ($P>0.05$, as shown in **Figure 1**). BMI of both groups varied between 21 and 23, and there was no statistically difference ($P>0.05$) between the groups, as seen in **Figure 2**.

Changes in anterior wall height of the compressed vertebra

Before the operation, the patients of the two groups showed no differences in the height restoration of the affected vertebra (range, 9-10 mm). At 1 week postoperatively, the compressed vertebral height was significantly higher in the PKP Group than in the CT group, and the difference was statistically significant ($P< 0.05$); but there were no significant improvements in vertebral height ($P>0.05$) in the CT Group during the period from pretreatment to 6 months after treatment (See **Table 2**).

Comparison of kyphosis angle (Cobb angle) reduction

Before treatment, there was no significant difference in the kyphosis angle reduction of the compressed vertebral body between the PKP Group and the CT Group ($P>0.05$). At 3 days after treatment, the Cobb angle of the PKP Group was reduced by 50%, as compared with that before treatment, indicating there was statistical difference ($P<0.05$), while outcomes revealed no significant difference in the CT Group ($P>0.05$). The Cobb angle of the CT Group was decreased from 26.2° before treatment to 16.9° at 1 week postoperatively, showing there was no statistically significant difference ($P>0.05$, see **Table 3**).

Comparison of changes in VAS scores

Comparison of changes in VAS scores at various time points before and after treatment between the two groups is shown in **Table 4**. Before treatment, there were no obvious difference in VAS scores between the PKP Group and the CT group. At 3 d after treatment, VAS scores were significantly lower in the PKP Group than in the CT group, indicating there was statistically significant difference ($P<0.05$). However, the VAS scores in the CT Group were significantly decreased at one month after treatment than before treatment, showing there was statistically significant difference ($P<0.05$); and at 6 months after treatment, the VAS scores in both groups were lower than 2.0.

Table 2. Comparison of preoperative and postoperative vertebral height between both groups ($\bar{x}$±S, mm)

Groups	Preoperatively	1 wk postoperatively	1 m postoperatively	3 m postoperatively	6 m postoperatively
PKP group	9.8±2.1	14.2±3.1$^{*,\Delta}$	14.5±4.2$^{*,\Delta}$	14.5±1.3$^{*,\Delta}$	14.1±2.6$^{*,\Delta}$
CT group	9.6±1.9	10.4 ±2.0$^{\#}$	10.5±3.2$^{\#}$	11.5±2.3$^{\#}$	11.2±2.7$^{\#}$

Note: $^{\#}$Compared with preoperative outcomes, P>0.05; *Compared with preoperative outcomes, P<0.05; $^{\Delta}$Compared with the CT Group, P<0.05.

Table 3. Cobb's angle between two groups (unit)

Groups	Pre-o	3 d post-o	1 week post-o	1 month post-o	3 months post-o	6 months post-o
PKP group	26.31±2.1	13.20±1.2$^{*,\Delta}$	13.45±1.24$^{*,\Delta}$	13.80±1.24$^{*,\Delta}$	14.31±1.63$^{*,\Delta}$	14.47±1.20$^{*,\Delta}$
CT group	26.24±2.4	25.63±1.27$^{\#}$	16.86±2.12$^{\#}$	17.62±1.29$^{\#}$	18.27±1.55$^{\#}$	18.97±1.46$^{\#}$

Note: Pre-o, Preoperatively; post-p, Postoperatively; $^{\#}$Compared with preoperative outcomes, P>0.05; *Compared with preoperative outcomes, P<0.05; $^{\Delta}$Compared with the CT Group, P<0.05.

Table 4. VAS pain scores at various time points before and after treatment in the two groups ($\bar{x}$±S, score)

Groups	Pre-o	3 d post-o	1 week post-o	1 month post-o	3 months post-o	6 months post-o
PKP group	8.60±0.46	2.10±0.28$^{*,\Delta}$	3.80±0.35$^{*,\Delta}$	2.64±0.22$^{*,\Delta}$	1.42±0.34$^{*,\Delta}$	1.02±0.24$^{*,\Delta}$
CT group	8.43±0.60	8.32±0.37$^{\#}$	7.20±0.38$^{\#}$	3.10±0.45*	2.38±0.52*	1.53±0.21*

Note: Pre-o, Preoperatively; post-p, Postoperatively; $^{\#}$Compared with preoperative outcomes, P>0.05; *Compared with preoperative outcomes, P<0.05; $^{\Delta}$Compared with the CT Group, P<0.05.

Table 5. Oswestry disability index scores (ODI, $\bar{x}$±S, score)

Groups	Pre-o	3 d post-o	1 week post-o	1 month post-o	3 months post-o
PKP group	42.3±6.7	20.2±5.4$^{*,\Delta}$	18.5±4.3$^{*,\Delta}$	15.1±3.6$^{*,\Delta}$	14.2±4.2$^{*,\Delta}$
CT group	41.3±6.2	36.5±5.1$^{\#}$	19.7±3.4*	18.7±5.3*	18.2±5.0*

Note: Pre-o, Preoperatively; post-p, Postoperatively; $^{\#}$Compared with preoperative outcomes, P>0.05; *Compared with preoperative outcomes, P<0.05; $^{\Delta}$Compared with the CT Group, P<0.05.

Comparison of disability assessment

The ODI scores of both groups varied between 41 and 43 before treatment, showing there was no statistically significant difference (P>0.05); improvements of ODI scores were significantly greater in the PKP Group at 1 week, and the ODI scores were obviously lower than those of the CT group, indicating there was statistically significant difference (P<0.05); and significant reductions in the ODI scores were also observed in the CT Group at 1 month after treatment (P<0.05). See **Table 5**.

Discussion

With the increasingly severe aging and a growing elderly population in China, the top priority of China is to ensure the subsistence and life quality of the elderly. The increase in age often goes with bone loss, so a high incidence rate of osteoporosis occurs in the elderly population [16]. As the bone mass of the patients with osteoporosis is reduced per unit of volume, the degradation of the bone structure may lead to the decrease of bone strength. With the increase in bone fragility, trauma, falls or collision is more likely to cause concurrent fractures, especially the OVCFs, which in turn may cause lumbo-dorsa pain or kyphosis, seriously affecting the quality of life of elderly patients [17, 18].

Currently, the conservative treatment and surgical treatment are the traditional lines of management of OVCFs in elderly patients. Conservative treatment mainly includes bed rest, drug therapy and physical therapy. The patients' long-term immobilization may aggravate bone

loss, and the risk of recurred fractures; a long-term confinement in bed may result in muscle atrophy or venous embolism and is also prone to cause bedsores, hypostatic pneumonia or other complications [19-21]. With the advances in medical technology and old people's requirement for higher quality of life, the development and application of PKP, a new minimally invasive surgery, are popular with many people [22]. Our present study demonstrated that at 1 week after treatment, no obvious improvements in the height of affected vertebras (mean, 9.6-10.4 mm), Cobb angle (mean, 26.2°-25.6°) and VAS scores (mean, 8.4 to 8.3) were noted in the CT group. At 6 months, the height of the affected vertebras was restored to 11.2 mm in the CT group, and the result was obviously lower than that of the PKP Group (mean, 14.1 mm). However, significant improvements in Cobb angle and VAS scores at 1 week after PKP were showed in the PKP Group. Thus, we may come to the conclusions that the PKP treatment is more effective than the conservative treatment for OVCFs in the elderly, and it can also provide immediate improvements in physical functioning. On the contrary, short-term conservative treatment could not provide significant improvements in vertebral fracture restoration nor symptom relief for the patients.

Conclusion

As far as conservative treatment is concerned, the trauma is small, but the vertebral body could not get complete recovery and it may cause more complications. So it is only suitable for elderly patients with mild compression symptoms or intolerable to surgery. In contrast, the PKP treatment, with more immediate pain relief, greater height restoration in affected vertebras and better correction in kyphosis, is an effective alternative for treatment of OVCFs in the elderly.

Disclosure of conflict of interest

None.

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