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Original Article

The efficacy of percutaneous kyphoplasty on osteoporotic vertebral compression fractures and its effects on the quality of life in the elderly

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Abstract: Objective: To investigate the efficacy of percutaneous kyphoplasty (PKP) on osteoporotic vertebral compression fractures (OVCF) and its effects on the quality of life (QOL) in the elderly. Methods: A prospective study was conducted on 126 elderly OVCF patients. They underwent surgery and were divided into an observation group (treated with percutaneous vertebroplasty, n=63) and a control group (treated with PKP, n=63). The two groups were given routine anti-osteoporosis treatment after admission. The Cobb angles of the injured vertebrae and the anterior height of the vertebral bodies before and after the operations were compared between the two groups. The Oswestry Disability Index and the Visual Analogue Scale scores before the operations, at three months after the operations, and at six months after the operations were compared between the two groups. The QOL scores before the operations and at six months after the operations were compared between the two groups. The postoperative complications were also compared between the two groups. Results: Compared with before the operations, the Oswestry Disability Index and Visual Analogue Scale scores in the two groups were significantly decreased at three and six months after the operations (all P<0.001), and the scores in the observation group were significantly lower than the scores in the control group (all P<0.05). Compared with before the operations, the Cobb angles of the injured vertebrae in the two groups were significantly reduced immediately after the operations, and the Cobb angles in the observation group were significantly smaller than they were in the control group (all P<0.001). There was an opposite trend in the anterior height of the vertebral body (all P<0.001). Six months after the operations, the two groups' QOL scores were significantly higher than they were before the operations, and the observation group's scores were significantly higher than the control group's (all P<0.001). The incidence of postoperative complications in the observation group was significantly lower than it was in the control group (3.17% vs. 15.87%, P<0.05). There were no severe complications such as lower-limb venous thrombosis or pulmonary embolism in the two groups. Conclusion: Compared with percutaneous vertebroplasty, PKP can significantly relieve pain, restore vertebral height, improve vertebral dysfunction and postoperative QOL in elderly OVCF patients, and it is very safe and worthy of clinical promotion.

Keywords: Osteoporotic vertebral compression fractures, percutaneous vertebroplasty, percutaneous kyphoplasty, quality of life, elderly patients

Introduction

Osteoporotic fractures are a serious complication of osteoporosis, in which thoracic and lumbar compression fractures are the most common types [1]. A study found that osteoporotic vertebral compression fractures (OVCF) account for about 50% of all osteoporotic fractures, and they are most often diagnosed in the elderly [2]. There are two types of treatment for elderly OVCF patents: surgical and non-surgical. Non-surgical treatment, such as anti-osteoporosis drugs, physiotherapy, and pain relief, can reduce the degree of pain in the process of fracture healing to a certain extent. However, long-term bedrest tends to cause severe complications such as lower-limb venous thrombosis and hypostatic pneumonia [3, 4]. Percutaneous vertebroplasty (PVP) is a minimally invasive surgery rapidly developed in recent years, which is mainly applied for the treatment of osteoporotic vertebral fractures. PVP mainly

involves the percutaneous injection of a certain amount of bone cement and other materials into the vertebral body under the mediation of an imaging system to increase vertebral body strength. It can effectively prevent collapse and relieve pain, but the improvement effect on the height of the vertebral body is insignificant and may cause bone cement leakage [5]. Percutaneous kyphoplasty (PKP) includes the creation of a safe and effective space in the fractured vertebra, the removal of the balloon tamp after venting, and then the injection of bone cement and other materials at low pressure. This surgical method can effectively promote the recovery of vertebral height and avoid bone cement leakage [6, 7]. This study mainly discusses the therapeutic effects of the two surgical methods on elderly OVCF patients and analyzes their effects on postoperative quality of life (QOL).

Materials and methods

General information

A total of 126 elderly OVCF patients who received surgical treatment in Jingzhou Central Hospital, The Second Clinical Medical College of Yangtze University from August 2018 to December 2019 were enrolled in this prospective study. The included patients were randomly divided into the observation and control groups, with 63 patients in each group. This study was approved by the Medical Ethics Committee of Jingzhou Central Hospital, The Second Clinical Medical College of Yangtze University, and all the patients signed an informed consent.

Patients were included if they were >60 years old, met the diagnostic criteria for osteoporosis, had a bone mineral density (T value) determined by dual-energy X-ray absorptiometry <-2.5 [8], met the OVCF diagnostic criteria, with the OVCF confirmed through MRI or CT imaging [9], had single segment OVCF, had no surgical contraindications, and were able to tolerate surgery.

Additionally, patients with a vertebrae bursting fracture, an incomplete vertebral posterior wall, incomplete pedicle, spinal deformity, a combined spinal nerve function injury, rheumatic diseases, or malignant tumors were excluded. Also, patients with a history of anti-osteoporosis treatment within three months of enrollment were excluded.

Methods

After admission, the patients in both groups were given routine anti-osteoporosis treatment, such as a calcium medicinal preparation, vitamin D, bisphosphonate, and other bone resorption inhibitors. The detailed drug regimen was as follows: Calcium carbonate D3 tablets (Hainan Selection Pharmaceutical Co., Ltd., China; each tablet contained 1.5 g calcium carbonate, equivalent to 600 mg of calcium) was taken orally, 600 mg/time, twice a day; vitamin D2 soft capsules (YaTai Dalian Aquatic Pharmaceutical Co., Ltd., China; 2400 IU) were taken orally, 2,400 IU/time, once a day; 5 mg of zoledronic acid injection (Yangtze River Pharmaceutical Group Sichuan Hairong Pharmaceutical Co., Ltd., China; 100 mL: 5 mg) was dissolved in 5% glucose and injected intravenously, once a day. After discharge, the calcium carbonate D3 tablets and vitamin D2 soft capsules were taken continuously.

PVP was performed on the control group. The patients were placed in a prone position, and the injured bilateral vertebral pedicles were located and marked on the cutaneous surface using a C-arm fluoroscopic machine (Dongguan RAYON Testing Equipment Co. Ltd., China; Rayon-RM150). After disinfection and towel laying, local anesthesia using lidocaine was administered after confirming the puncture site. A bilateral pedicle approach puncture was conducted under the guidance of the C-arm fluoroscopic machine to 1/3 of the anterior vertebral body. The sagittal plane of the vertebral body and the angle of the puncture needle were kept unchanged during the puncture process, and then the needle core was removed. High-viscosity bone cement (Stryker Company, USA; SN-00968) was injected into the vertebral body under the C-arm fluoroscopic machine, and the needle and trocar were removed after it was confirmed that the bone cement had good dispersion, the correct position, and no spillage in the vertebral body.

The observation group was treated with PKP. The puncture approach of the observation group was the same as that of the control group. The puncture was conducted to 1/3 of the anterior vertebral body. The balloon tamp

Table 1. Comparison of the general patient data ($\bar{x} \pm SD$, n)

	Observation group (n=63)	Control group (n=63)	χ^2/t	P
Gender			0.130	0.719
Male	26	28		
Female	37	35		
Age (years)	66.6±4.3	67.2±5.4	0.690	0.492
Cause of fracture			2.131	0.345
Fall injury	24	29		
Sprain	30	22		
Other	9	12		
Course of the disease	3.72±1.31	4.03±1.13	1.422	0.157
Fracture segment			2.560	0.310
T_{11}	18	15		
T_{12}	20	17		
L_1	14	17		
L_2	11	14		

was placed along the channel to the vertebral body, and about 3 mL of iopromide contrast agent was injected (Bayer Vital GmbH, Germany; 100 mL: 62.34 g). The balloon tamp was expanded to restore the height of the vertebral body. After removing the balloon tamp, high-viscosity bone cement was slowly injected into the vertebral body under low pressure until it diffused into the posterior margin of the vertebral body in a dark cloud shape. The bone cement then hardened.

Both groups were routinely given antibiotics to prevent infections after their operations and were given rehabilitation guidance.

Outcome measures

Primary outcome measures: (1) The Oswestry Disability Index (ODI) before the operations, at three months after the operations, and at six months after the operations were compared between the two groups. The scores were expressed as percentages, and higher scores (closer to 100%) represented more severe dysfunction [10]. (2) A proportional scale was used to measure the Cobb angles of the injured vertebrae and the anterior heights of the vertebral bodies before and immediately after the operations on plain, lateral x-ray plain [11]. (3) The Generic Quality of Life Inventory-74 (GQOLI-74) was used to assess the QOL of the two groups before the operations and at six months after the operations [12]. The questionnaire mainly included four aspects: physical function, social function, psychological function, and material life status. The material life status was scored from 16 to 80 and the others from 20 to 100. Higher scores in each aspect showed higher QOL.

Secondary outcome measures: (1) The Visual Analogue Scale (VAS) was used to assess the degree of pain in the two groups before the operations, at three months after the operations, and at six months after the operations [13]. A score of zero indicated no pain, and a score of ten indicated severe pain. (2) The postoperative complications were compared in the two groups, such as bone cement leakage, refracture around the vertebral body, neurospinal cord compression symptoms, lower-limb venous thrombosis, and pulmonary embolism.

Statistical analysis

The statistical analysis was conducted using SPSS 22.0 . The count data were expressed as n/%; chi-square tests and Fisher's exact probability test were used for the comparisons. The measurement data in line with a normal distribution were expressed as the mean ± standard deviation ($\bar{x} \pm SD$). Paired t tests were used for the intra-group comparisons, and independent t tests were used for the comparisons between groups. $P<0.05$ was considered statistically significant.

Results

General information

There were no statistically significant differences between the two groups in terms of their general clinical data, including gender, age, cause of fracture, course of the disease, or fracture segment (all $P>0.05$). See **Table 1**.

ODI and VAS scores

Before the operations, the two groups showed no statistically significant differences in their ODI and VAS scores (both $P>0.05$). Compared with before the operations, the two groups' ODI and VAS scores were significantly decreased at

Table 2. Comparison of the ODI scores ($\bar{x}$ ± SD, score)

	Observation group (n=63)	Control group (n=63)	t	P
Before the operations	66.50±7.58	65.98±6.09	0.424	0.672
3 months after the operations	30.50±4.44***	34.46±5.30***	4.546	<0.001
6 months after the operations	14.20±3.98***	16.06±4.29***	2.523	0.013

Note: Compared with before the operations, ***P<0.001. ODI: Oswestry Disability Index.

Table 3. Comparison of the VAS scores ($\bar{x}$ ± SD, score)

Group	Before the operations	3 months after the operations	6 months after the operations
Observation group (n=63)	7.60±1.66	4.38±1.05***	2.09±0.95***
Control group (n=63)	7.43±1.44	4.97±1.42***	2.47±0.87***
t	0.614	2.652	2.341
P	0.540	0.009	0.021

Note: Compared with before the operations, ***P<0.001. VAS: visual analogy score.

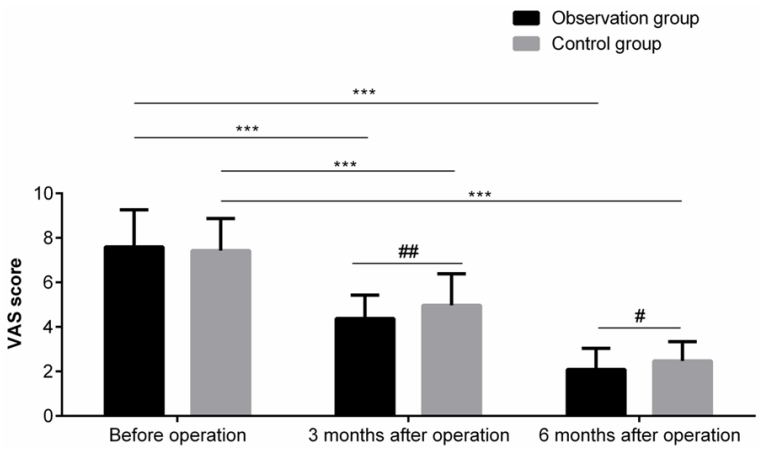

Figure 1. Comparison of the VAS scores. Compared with before the operations, ***P<0.001; compared with the control group at the same time, #P<0.05, ##P<0.01.

three and six months after the operations (all P<0.001), and the observation group's scores were significantly lower than the scores in the control group (all P<0.05). See **Tables 2**, **3** and **Figure 1**.

Cobb angles of the injured vertebrae and the anterior heights of the vertebral bodies

Before the operations, the two groups showed no statistically significant differences in the Cobb angles of the injured vertebrae or the anterior heights of the vertebral bodies (both P>0.05). Compared with before the operations, the Cobb angles of the injured vertebrae in the two groups were significantly reduced immediately after the operations, and of the angles in the observation group were significantly smaller than they were in the control group (all P<0.001). There was an opposite trend in the anterior height of the vertebral body (all P<0.001). See **Table 4**.

QOL

Before the operations, the two groups showed no statistically significant differences in terms of their GQOLI-74 scores (all P>0.05). Six months after the operations, the two groups' GQOLI-74 scores were significantly higher than they were before the operations, and the observation group's scores were significantly higher than the control group's scores (all P<0.001). See **Table 5**.

Postoperative complications

The incidence of postoperative complications in the observation group was significantly lower than it was in the control group (3.17% vs. 15.87%, P<0.05). There were no severe complications such as lower-limb venous thromboses or pulmonary embolisms in the two groups. See **Table 6**.

Discussion

OVCF is a common fracture type in osteoporosis patients. The patients have no significant trauma, but they have significant chest and waist pain, which is aggravated during their physical activities and seriously affects the patients' QOL [14]. PVP is a common operation for treating OVCF, for it can stabilize the fracture and prevent posterior process deformities of the injured vertebra through the injection of

Table 4. Comparison of the Cobb angles of the injured vertebrae and the anterior heights of the vertebral bodies ($\bar{x}$ ± SD)

Group	Cobb angle of the injured vertebrae (°)	Anterior height of the vertebral body (mm)
Observation group (n=63)		
Before the operations	32.38±4.30	14.87±2.88
Immediately after the operations	19.08±3.69***,###	23.20±3.27***,###
Control group (n=63)		
Before the operations	31.87±4.77	15.04±2.64
Immediately after the operations	27.30±4.03***	19.97±3.20***

Note: Compared with before the operation, ***P<0.001; compared with the control group immediately after the operations, ###P<0.001.

Table 5. Comparison of the QOL scores ($\bar{x}$ ± SD, score)

Group	Physical function	Social function	Psychological function	Material life state
Observation group (n=63)				
Before the operations	45.49±6.50	57.60±5.48	60.30±6.50	50.40±5.59
6 months after the operations	72.20±6.43***,###	80.50±6.56***,###	86.69±7.66***,###	69.98±6.60***,###
Control group (n=63)				
Before the operations	46.02±5.84	57.12±6.30	59.75±5.89	51.13±6.30
6 months after the operations	60.06±6.36***	64.48±7.50***	70.67±6.40***	61.50±6.44***

Note: Compared with before the operations, ***P<0.001; compared with the control group at six months after the operations, ###P<0.001. QOL, quality of life.

Table 6. Comparison of the postoperative complications (n (%))

Group	Bone cement leakage	Refracture around vertebral body	Symptoms of neurospinal cord compression	Total incidence rate
Observation group (n=63)	1 (1.59)	1 (1.59)	0 (0.00)	2 (3.17)
Control group (n=63)	6 (9.52)	2 (3.17)	2 (3.17)	10 (15.87)
χ^2	2.420	0.000	0.508	4.513
P	0.120	1.000	0.476	0.034

bone cement into the injured vertebra, but its long-term efficacy is poor [15].

PKP is a surgical method based on PVP. PKP involves the pressurization and compression of the surrounding osteoporotic bone with an inserted balloon tamp, and an injection of bone cement into the injured vertebra after the expansion. It can quickly restore the height of the vertebra and relieve its pain, with a lower risk of bone cement leakage [16]. In OVCF patients, the Cobb angles of the injured vertebrae are abnormally enlarged, and the fractures can cause wedge lesions in the vertebral body, leading to vertebral dysfunction [17]. The height of the vertebral body can be quickly restored, and the shape of the spine can be finally restored after surgery. PVP mainly relies on the pressure of bone cement itself to restore the vertebral height, so the recovery effect is limited [18]. However, the balloon tamps inserted in PKP can restore the vertebral height with the help of balloon pressure, so the recovery effect on the vertebral height is more substantial [19]. In this study, the Cobb angles of the injured vertebrae and the anterior height of the vertebral bodies in the two groups were significantly reduced and increased immediately after the operations. However, the reductions in the Cobb angles and the increases in the anterior heights of the vertebral bodies in the observation group were significantly better than they were in the control group. Compared with before the operations, the two groups' ODI

and VAS scores were significantly decreased at three and six months after the operations, and the reductions in the ODI and VAS scores in the observation group were significantly lower than they were in the control group, indicating that PKP is significantly better than PVP at alleviating pain, restoring vertebral height, and improving vertebral dysfunction in elderly OVCF patients.

Both PVP and PKP require the injection of bone cement into the injured vertebrae to stabilize the bone tissue, thus increasing the vertebrae's stability. Bone cement viscosity has a direct impact on the therapeutic effect [20]. Jian et al. reported that high-viscosity bone cement has a better effect at treating vertebral compression fractures [21]. However, there is no consensus on the optimal injection amount of bone cement. We believe that the standard should be a good diffusion of the bone cement in the vertebral body, because in vitro mechanical studies have confirmed that sufficient diffusion of bone cement between the upper and lower endplates of the vertebral body greatly helps to restore the anterior vertebral height during vertebroplasty for the treatment of vertebral compression fractures [22]. In terms of safety, Bernardo et al. posit that the safety of PKP is higher than that of PVP [23]. Similar results were also found in this study, as the observation group had a lower incidence of postoperative complications. This indicates that, compared with PVP, PKP is safer for the treatment of elderly OVCF. The injection of bone cement into the injured vertebrae may lead to bone cement leakage. Research has found that bone cement leakage is closely related to the injection amount of bone cement [24]. Therefore, an intraoperative amount of bone cement can help reduce the risk of bone cement leakage. In this study, the incidence of bone cement leakage in the observation group was 1.59%, which was lower than the rate in the control group (9.52%). However, no statistical significance was seen in the incidences of bone cement leakage between the two groups, which may be related to the small sample size and the surgical skills of the clinicians. In this study, a six-month follow-up was conducted, and the postoperative QOL was compared between the two groups. It was found that the physical function, social function, psychological function, and material life status scores in the observation group were significantly higher than the corresponding scores in the control group at six months after the operations. This suggests that compared with PVP, PKP is a more effective way to improve postoperative QOL among elderly OVCF patients.

However, limitations also exist in this study. This was a single-center study with a small sample size and a short follow-up time. Further studies should be conducted to confirm the effects of the two surgical methods on the patients' long-term QOL.

In conclusion, compared with PVP, PKP can significantly relieve pain, restore vertebral height, and improve vertebral dysfunction and postoperative QOL in elderly OVCF patients, and it is very safe and worthy of clinical promotion.

Disclosure of conflict of interest

None.

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