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Therapeutic effects of temporary retention one side of balloon kyphoplasty on vertebral compression fractures

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Abstract

The aim of this study was to evaluate the therapeutic effects of single-balloon percutaneous kyphoplasty (PKP) on elderly patients with vertebral compression fractures. Sixty-nine elderly patients with osteoporotic vertebral compression fractures were given single-balloon PKP. When a balloon was kept on one side of the vertebral body, methyl methacrylate was injected into the vertebral body on the other side. The anterior vertebral height change, sagittal Cobb angle change, injection amount of bone cement, visual analogue scale (VAS) score and Oswestry disability index (ODI) were determined. The average surgical time was (48.5 ± 12.4) min, blood loss was (23.1 ± 8.5) ml, pressure of balloon was 180-250 Psi and its volume was (3.6 ± 1.1) ml. The injection amount of bone cement was (8.2 ± 2.4) ml. The compression ratio of anterior vertebral height and Cobb angle after balloon expansion were significantly different from those after postural reduction or balloon release (P<0.05). The VAS score and ODI before surgery were significantly different from those two days after surgery or during follow-up (P<0.05). During follow-up, 5 new cases of vertebral compression fractures occurred, with 2 involving neighboring vertebrae. The average time from last fracture was 7.6 months. Single-balloon PKP had significant short-term therapeutic effects on elderly patients with vertebral compression fractures.

Key words: balloon expansion, percutaneous kyphoplasty, vertebral fracture

1. Introduction

Vertebral compression fracture is a spinal injury of elderly patients with osteoporosis. When the vertebra undergoes compressive fracture, the sagittal kyphosis angle of the spine increases, the center of gravity moves forward, and muscles at the spine back must elevate the contraction force to resist collapse of the anterior column and to rebalance the sagittal plane [1].

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However, the increase in contraction force also raises the load on the spine back. Muscles in the posterior part of the spine are under long-term high tension, and thus prone to spasm, chronic strain, muscle atrophy, flaccidity, weak contraction, and failure to balance the spine. As a result, the center of gravity slowly moves forward, which then increases the load on the anterior median column, i.e. the vertebra, causing chronic or acute compression. Since the gravity center of the trunk shifts forward, crutch or walking aid is usually in need to maintain balance. These changes may accelerate aging and increase the death risk.

Galibert et al. first successfully used percutaneous vertebroplasty (PVP) to treat second cervical vertebral hemangioma [2]. Afterwards, this method has been widely employed to treat osteoporotic vertebral compression fracture. Since PVP reinforces the vertebra that is compressed, local kyphotic deformity cannot be eliminated. Reiley et al. then improved vertebroplasty in 1994 by adding an expandable balloon to correct kyphotic deformity, and referred to this method as percutaneous kyphoplasty (PKP) [3]. This strategy was approved by the US Food and Drug Administration in 1998 to treat thoracolumbar vertebral compression fractures. This technique can expand the vertebra, stabilize fractures, relieve or eliminate pain, and prolong the survival time.

A balloon is inserted into a pre-made bone tunnel through a working channel, and then contrast agent is squeezed into the balloon through a connected pressure pump. As the pressure rises, the balloon extends to expand the compressed vertebra, which can reduce fractures and form a dense cavity around the vertebra. After removal of pressure, the balloon is withdrawn, and bone cement is injected at low pressure. Nevertheless, during balloon removal, the height of anterior vertebral edge and the kyphosis angle may be lost, thus attenuating the effects of balloon. Thereby motivated, we herein temporarily retained a single balloon to maximally maintain the original height.

2. Materials and procedures

Baseline clinical data

This study has been approved by the ethics committee of our hospital, and written consent has been obtained from all patients. Sixty-nine elderly patients with osteoporotic vertebral compression fractures enrolled in the Emergency Department of our hospital from January 2011 to December 2013 were selected. The fractures were confirmed by MRI. Inclusion criteria: 1) Disease course <1 month; 2) compression ratio of vertebral height >30%; 3) ≥65 years old; 4) Magerl A1 fracture; 5) new fracture injuring only one vertebra. Exclusion criteria: 1) <65 years old; 2) compression ratio of vertebral height >70%; 3) complication with spinal nerve injury; 4) new fracture injuring multiple vertebrae. There were 22 males and 47 females. The males were aged from 65 to 83 years old, with the average of (71.2 ± 7.3). The females were aged from 52 to 88 years old, (60.2 ± 15.8) on average. There were 5 cases of 11th thoracic vertebral fractures, 30 cases of 12th thoracic vertebral fractures, 25 cases of 1st lumbar vertebral fractures, 7 cases of 2nd lumbar vertebral fractures and 2 cases of 3rd lumbar vertebral fractures. The time from injury to surgery ranged from 16 h to 18 d, with the average of 5.4 d.

Surgical methods

All surgeries were performed under local anesthesia. With electrocardiogram monitoring, venous access was established, and the abdomen of patient in the prone position was suspended by raising the chest and iliac crest. This position not only eliminated kyphotic deformity to promote postural reduction and balloon expansion, but also reduced intraoperative blood loss by decreasing intraabdominal pressure and facilitating venous return. Lordosis was also allowed by adjusting the operating bed. Balloon expansion was not conducted if postural reduction recovered the height of injured vertebra to 85% of that of normal neighboring vertebra. Single-balloon expansion was carried out to reduce the hospitalization expenditure.

Under C-arm fluoroscopy, the horizontal surface projection of injured vertebral pedicle was localized and marked. On the lateral view, the endplate of injured vertebra was adjusted parallel to the X-ray projection direction. On the frontal view, the spinous process was located at the center of projections of bilateral vertebral pedicles. After sterilization, the skin 9.5-1.0 cm from the projection of vertebral pedicle was subjected to local infiltration anesthesia with 1% lidocaine, and multisite anesthesia was performed for predetermined osseous biopsy site.

A puncture needle was inserted into the area with most obvious bone marrow edema and withdrawn. Then a working cannula was inserted to approximately 5 mm from the posterior vertebral edge. Subsequently, a fine bone drill was slowly placed into the vertebra along the working cannula to about 5 mm from the anterior vertebral edge. A balloon was thereafter placed along the working cannula to 1/3 of the vertebra optimally. Afterwards, diluted contrast agent (5 ml of Omnipaque + 15 ml of normal saline) was slowly injected into the balloon for expansion and fracture reduction. Pressurization was stopped when the balloon pressure reached 200 Psi, the anterior vertebral height approached the posterior one or the balloon volume reached 5 ml. Then contrast agent in the balloon was slowly pumped out. The same procedure was conducted for the other vertebral pedicle. When the balloon was kept on one side of the vertebral body, methyl methacrylate was injected into the vertebral body on the other side.

Bone cement in the dough-like state was then slowly injected into the injured vertebra to observe whether leakage from the anterior or posterior edge occurred. The working cannula was removed when bone cement hardened. The temporarily retained balloon was taken out, followed by injection of methyl methacrylate on the same side. Finally, the surgical site was wiped with iodophor, anastomosed and covered by sterilized dressing.

Patients were allowed to ambulate 2 h after surgery. Waist-bending or weight-bearing should be prevented due to possible complicated low back muscle injury. Meanwhile, routine anti-osteoporotic therapy was conducted.

Imaging indices

Anterior vertebral height

The anterior heights of injured vertebra and normal vertebra (average of neighboring vertebrae) were measured to calculate the ratio as the compression ratio of anterior vertebral height (%). The postoperative ratio was the correction rate. The height obtained from intraoperative X-ray image was converted from preoperative measurement.

Sagittal Cobb angle

Sagittal Cobb angle represents the degree of anterior or posterior spinal curvature. Routine Cobb angle measurement was affected due to poor intraoperative X-ray images, especially those of T12 vertebra, which induced gas interference in the thoracic cavity. Therefore, sagittal Cobb angle was determined through measurement from the inferior endplate of the vertebra above and the superior endplate of the vertebra below the injury. Positive and negative numbers represent kyphosis and lordosis respectively.

Injection amount of bone cement

The injection amount of bone cement refers to the total amount injected through bilateral working cannulas into the injured vertebra.

Clinical indices

VAS score

In VAS, 0 point and 10 points represent painlessness and severe pain respectively. Patients were informed of all items of this scale and the pain degree represented by each score before test. Subsequently, they gave corresponding scores with the assistance of other medical staff who did not participate in surgery. Based on the responsiveness of patients themselves, VAS is more objective than other scales which are completed by doctors in charge of surgery [4].

Oswestry disability index (ODI)

ODI is the most widely used scoring system specific for low back pain. This system concerns intensity of pain, ability to care for oneself, lifting, ability to walk, ability to sit, ability to stand, sleep quality, sexual function, social life and ability to travel. Each topic is followed by 6 statements with different scores. The first statement is zero, and the last statement is scored 5 points, suggesting most severe disability [5].

Statistical analysis

All data were analyzed by SPSS16.0 and expressed as ($\bar{x}$ ± SD). The ratios of anterior and middle heights of injured vertebrae to those of neighboring vertebrae were subjected to the χ^2 test. The Cobb angle, VAS score and ODI were subjected to the paired t test. P<0.05 was considered statistically significant.

3. Results

Overall performance of surgery

During surgery, no patients suffered from bone cement injection-induced hypotensive shock, pulmonary embolism, spinal cord and nerve root damages, large blood vessel damage, deep vein thrombosis, puncture site infection or hematoma formation. The average surgical time was (48.5 ± 12.4) min, the blood loss was (23.1 ± 8.5) ml, the pressure of balloon was 180-250 Psi and its volume was (3.6 ± 1.1) ml. The injection amount of bone cement was (8.2 ± 2.4) ml. No patient had chief complaint of discomfort.

Vertebral height changes

The compression ratio of anterior vertebral height after balloon expansion ((85.14 ± 9.36)%) was significantly higher than that after postural reduction ((58.23 ± 12.55)%) or balloon release ((70.24 ± 8.12)%)(P<0.05). Such ratio after surgery ((82.46 ± 10.59)%) was also significantly higher than that after postural reduction (P<0.05), but similar to that after balloon expansion (P>0.05). During one year of follow-up, the percentage of anterior vertebral height to the mean of anterior heights of neighboring vertebrae was (78.59±9.37)%, and such height was similar to that after surgery (P>0.05) (Fig. 1).

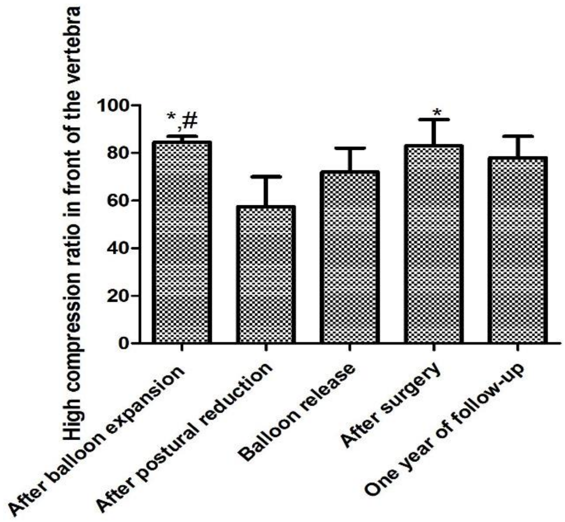

FIGURE 1. Vertebral height changes. *Compared with after postural reduction, P<0.05; #compared with balloon expansion, P<0.05.

Cobb angle changes

The Cobb angle after balloon expansion ((6.84 ± 2.57)°) was significantly lower than that after postural reduction ((18.65 ± 4.2)°) or balloon release ((10.21±3.41)°) (P<0.05). Such angle after surgery ((6.93 ± 2.26)°) was also significantly lower than that after postural reduction (P<0.05), whereas similar to that after balloon expansion (P>0.05). During follow-up, the angle ((7.06 ± 2.86)°) was similar to that after surgery (P>0.05) (Fig. 2).

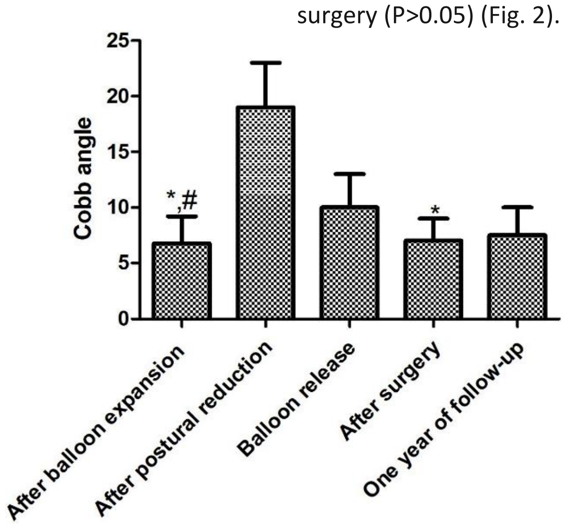

FIGURE 2. Cobb angle changes. *Compared with after postural reduction, P<0.05; #compared with balloon expansion, P<0.05.

Changes of VAS score and ODI

was significantly different from that two days after surgery ((The VAS score before surgery ((8.26 ± 1.17) points) 2.11 ± 0.36) points) or during follow-up ((1.83 ± 0.31) points) (P<0.05), but the latter two scores were similar (P>0.05) (Fig. 3).

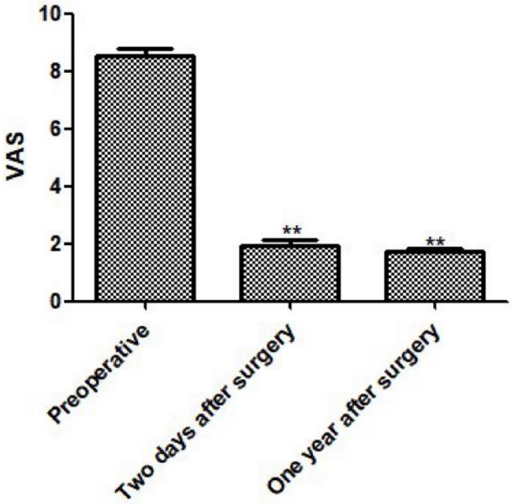

FIGURE 3. VAS scores before and at different time points after surgery. Compared with before surgery, *P<0.05, **P<0.001.

ODI before surgery ((88.35 ± 8.26) points) was significantly different from that two days after surgery ((23.56 ± 3.12) points) or during follow-up ((19.68 ± 2.81) points) (P<0.05), whereas the latter two values were similar (P>0.05) (Fig. 4).

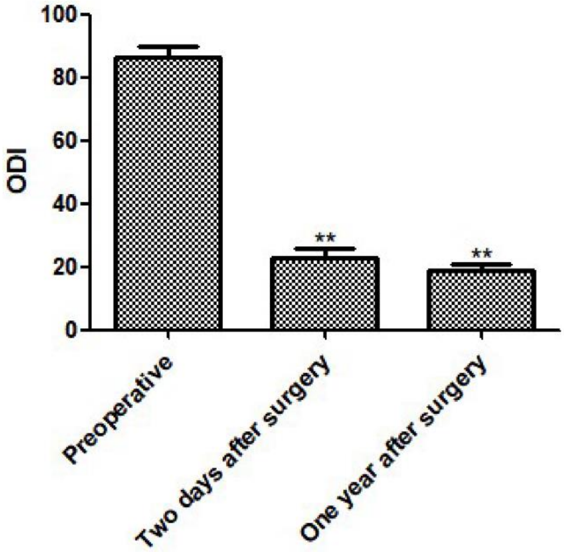

FIGURE 4. ODI values before and at different time points after surgery. Compared with before surgery, *P<0.05, **P<0.001.

4. Discussion

PVP has been in existence for more than three decades since 1984 when it was used for the treatment of cervical II vertebral invasive hemangioma. PVP can also restore the height of the compressed vertebral body through the positional reduction methods such as extreme overextension and traction of the spine and compression of spinous process. The postoperative patients can get out of bed early and do moderate activities, with rapid pain relief and high satisfaction [6]. Therefore, some researchers believe that PKP is unnecessary. However, a number of comparative studies have shown that compared with PVP, PKP can better restore the height of fracture vertebral body loss through air sac dilation, correct kyphosis, and significantly restore the height of postoperative anterior and central vertebral body [7-8]. PVP can recover 30% of the lost height, while PKP can restore the height of the injured vertebra to about 97% [9]. In the treatment of severe osteoporotic fractures, Boszczyk et al. found that percutaneous kyphoplasty with balloons expansion could achieve an average 5° kyphosis correction, but vertebroplasty did not take an effect of correction [10]. Lieberman et al.

reported 30 cases of 70 kyphoplasties with a height recovery of 35% (0–100%) and a corrected kyphosis angle of 6° [11] Crandall et al. obtained a better height correction rate, the reduction rate of fresh vertebral fractures was 86%, and the reduction rate of vertebral bodies with disease duration over 4 months was 79% [12]. The kyphosis correction angle is 7° for new fractures and 5° for chronic fractures. For patients with acute fractures fewer than 6 weeks with severe kyphosis, kyphoplasty can achieve more satisfactory results in restoring vertebral height. In general, if it is desired to open the collapsed endplate by balloon, PKP treatment is required in the acute phase of the fracture within 3 weeks after the injury. Balloon expansion can be used to raise the upper endplate and better correct deformity. In addition, PKP can also better increase the stability of the vertebral body. If the bone cement does not penetrate the gap in the vertebral body, the area becomes the site of compression fracture again. Balloon can compress and compact the already loose bones and increase the bone cement-filled cavity.

In addition to expansion of the compressed vertebral body and restoration of the vertebral body height, kyphoplasty can also largely eliminate kyphosis deformity of the spine, and significantly reduce the incidence of recurrent fracture. Hiwatashi et al. found that patients treated with PKP had a significantly lower incidence of new fractures during long-term follow-up than those treated with PVP [13] . In a comparative study of kyphoplasty and conservative treatment of thoracolumbar vertebral compression fractures, the incidence of vertebral fractures was significantly reduced 6 months after kyphoplasty. Ryu et al. found that PVP postoperative fractures are associated with poor correction of kyphosis or excessively large Cobb angle [14]. Movrin et al. reported a significant increase in the chance of recurrent fractures in patients with kyphosis more than 9° after vertebroplasty [15]. Although the correction of a single vertebral kyphosis does not seem to be important, many patients with osteoporosis suffer from multiple vertebral compression fractures in their lifetime, and the kyphosis deformities caused by each fracture form a serious kyphosis. Therefore, every vertebral fracture should be treated seriously.

To prevent the loss of height after reduction, it is necessary to have sufficient supporting force when injecting the bone cement to prevent the height loss until the bone cement hardens. In this study, we used a single balloon to complete the bilateral distraction. After the contrast agent in the balloon was extracted from both sides, the height of the vertebral body was lost to varying degrees. To solve this problem, we pre-retained the expanded balloon on one side and injected a sufficient amount of bone cement through the contralateral pedicle channel. After it was completely solidified, the contrast agent in the balloon was slowly withdrawn, and the balloon was removed. At this time, the anterior height and Cobb angle of the vertebral body did not change significantly. The bone cement was then injected through the vertebral pedicle channel of this side. The loss of vertebral height can be minimized by this technique of preserving the balloon support on one side.

The position of balloon in the vertebral body affects the safety of balloon. A common problem in this technique is the rupture of balloon during the injection of bone cement, which occurs as the bone cement flows onto the wall of the expanded balloon and damages it. Such damage includes chemical erosion and heat damage to the bone cement during solidification. To prevent such circumstances, the angle of puncture and the puncture point must be strictly designed. The main point is to separate the balloon positions on both sides as much as possible. In the area where the pedicle is projected, the abduction angle is controlled within 5°. During expansion, balloon pushes the cancellous bone on one side to the periphery, the midline in particular, which forms a bony barrier or a buffer zone between the cavities formed by the balloon on both sides, preventing the damage of the laterally injected bone cement to the balloon.

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