

Comparison of percutaneous balloon dilation kyphoplasty and percutaneous vertebroplasty in treatment for thoracolumbar vertebral compression fractures

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Abstract. – **OBJECTIVE:** Osteoporotic vertebral compression fractures (OVCFs) are common diseases in elderly patients and can cause serious thoracolumbar compression fractures. For patients with such fractures, conservative treatment, nail-stick fixation, percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) can be selected as treatment methods. In this study, we aimed to compare the clinical efficacy of PKP and PVP in the treatment of osteoporotic thoracolumbar vertebral compression fractures.

PATIENTS AND METHODS: One hundred and sixty-one patients with single-stage osteoporotic vertebral compression fracture in thoracolumbar were enrolled and divided into two groups, percutaneous balloon kyphoplasty (PKP group) and percutaneous vertebroplasty (PVP group). The subjects were selected from patients who were once treated in our hospital from January 2012 to December 2015. There were 91 cases in PKP group and 70 cases in PVP group. The hospitalization time, operation-related index (including blood loss, bone cement injection, surgical time and number of intraoperative fluoroscopy), bedrest time, visual analog pain score (VAS), Cobb's angle, vertebral anterior height, Oswestry Disability Index (ODI) dysfunction index and quality of life score were compared to evaluate the clinical effects of the two treatment methods.

RESULTS: There were significant differences in hospitalization time, operation-related index (including blood loss, bone cement injection, operation time, number of intraoperative fluoroscopies) and bed rest time between the two groups. Compared with the patients in PVP group, patients of PKP group had less hospital stay ($p<0.001$), less time in bed ($p<0.05$) and less intraoperative blood loss ($p<0.05$). In addition, the number of times we used intraoperative fluoroscopy was significantly different between the two groups ($p<0.001$). However, the operation time of PKP group was longer than that of PVP group, and the amount of intraoperative cement injection was more than that of PVP

group ($p<0.05$). After treatment, VAS scores in both groups were dramatically decreased, of which the scores in PKP group were markedly lower than that in PVP group and the difference was statistically significant ($p<0.05$). The changes of Cobb's angle, the height of anterior vertebral body and ODI scores in PKP group were noticeably better than PVP group ($p<0.05$). There were 5 cases occurring intraoperative cement leakage in PKP group and 12 cases in PVP group, indicating that the former is relatively better ($p<0.001$). However, no significant difference was found between the two groups in the occurrence of secondary vertebral fractures at 1 month, 3 months, 6 months and 12 months after treatment ($p>0.05$).

CONCLUSIONS: The clinical effects of both PKP and PVP in the treatment of osteoporotic vertebral compression fractures are good, of which the reductive and analgesic effect of PKP is superior to that of PVP and the former has less leakage of cement, higher safety and fewer complications.

Key Words

Osteoporosis, Vertebral compression fractures, Percutaneous balloon kyphoplasty, PKP, Percutaneous vertebroplasty, PVP.

Introduction

Osteoporotic vertebral compression fractures (OVCFs) are common diseases in elderly patients, and can lead to thoracolumbar compression fractures in the cases of serious trauma, cough or mild concussion, which were common type of injury in spinal fractures¹. The occurrence of OVCFs in thoracolumbar in the elderly over 70 years old can reach 20%^{2,3}, and about 1.4 million people suffer from OVCFs every year¹.

For patients with such fractures, conservative treatment, nail-stick fixation, percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) can be performed to treat them clinically^{4,5}. However, it takes a long bed rest time for patients who choose conservative treatment, which may lead to complications such as pulmonary infection, pulmonary embolism and venous thrombosis, seriously affecting the quality of life of patients, and even endanger their lives^{6,7}. Surgery is currently the main treatment way for the disease. PKP and PVP are two minimally invasive procedures with advantages of simple, safe, stable and few complications, thus become two common surgical procedures for treatment of thoracolumbar vertebral compression fractures^{8,9}. However, there are some complications such as secondary OVCFs, infection, nerve root injury, pulmonary embolism and bone cement leakage after the operation. In addition, which one has a better therapeutic effect between the two procedures remains controversial.

In this study, the aim was to compare the clinical efficacy of PKP and PVP in the treatment of osteoporotic thoracolumbar vertebral compression fractures.

Patients and Methods

General Information

We selected patients with single-stage thoracolumbar osteoporotic compression fractures as our research subjects. All of them were admitted in our hospital from January 2012 to December 2015. A total of 161 patients were effectively followed up, of which there were 91 patients in PKP group, including 38 males and 53 females, and 79 patients in PVP group, including 24 males and 46 females. Bone mineral density, X-ray, vertebral Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) examination were performed on all the subjects. As a result, each of them was found to have different degrees of osteoporosis and vertebral compression fractures without spinal nerve injury. This study was approved by the Ethics Committee of Weifang People's Hospital. Signed written informed consents were obtained from all participants before the study.

Treatment of PKP

PKP operation was performed under general anesthesia by using prone position. C-arm of

x-ray machine was used in PKP group to determine the location of injured vertebrae. Cannulae placed percutaneously into the vertebral body allowed the insertion of two inflatable bone tamps. The balloons compacted the surrounding trabecular bone and created an enclosed cavity during inflation, which was filled with bone cement under low manual pressure after removal of the balloons. By percutaneous insertion of a needle through the pedicles into the vertebral body and the injection of bone cement into the cancellous bone, this surgery could alleviate pain, stabilize the fracture and prevent progression of kyphotic deformity or further loss of vertebral body height.

Treatment of PVP

The cement followed the path of least resistance and the procedure was monitored directly by fluoroscopy. Conventional preparation was performed following the same procedure as the PKP group. When the tip was located in the 1/3 height of anterior vertebral and the needle monitored through fluoroscopy was near the median line of the limb, the core was removed and the bone cement was injected into the spine.

Efficacy Evaluation Index

The following indexes of patients in PVP and PKP group were recorded: the duration of hospital stay, operation-related indexes (including amount of blood loss and bone cement injection, operation time, intraoperative fluoroscopy times), postoperative bed rest time, visual analog pain score (VAS) before and after surgery, Cobb's angle, vertebral height, Oswestry Disability Index (ODI) and quality of life index. The VAS¹⁰ and ODI¹¹ were recorded preoperatively and 1 day, 3 days, 1 week, 1 month, 3 months, 6 months, and 12 months after surgery, while Cobb's angle, anterior height of vertebral body and quality of life scores were recorded preoperatively and 12 months after treatment.

Statistical Analysis

Statistical product and service solutions (SPSS) 21.0 software (IBM, Armonk, NY, USA) package was used to analyze the data. All the measurement data were presented as mean \pm standard deviation ($\bar{x} \pm s$). *t*-test was used to analyze measurement data and χ^2 -test was performed to evaluate count data. $p < 0.05$ indicated the difference was statistically significant.

Results

General Information Comparison

In this study, a total of 161 patients who suffered from single-stage thoracolumbar osteoporotic compression fractures were enrolled in our study. All of them were admitted to our hospital from January 2012 to December 2015. The follow-up time was ranged from 1 to 3 years with an average of 2.1 years. There were 91 patients in the PKP group, aged 55-83 years, with an average of (70.55 ± 9.30) years and 79 patients in the PVP group, aged 56-85 years, with an average of (71.38 ± 8.53) years. Gender, age, vertebral injury sites and other general information of patients in the two groups showed no significant statistical difference ($p > 0.05$), which made them comparable (Table I).

Hospitalization and Surgery Status Compared

To investigate the hospitalization and surgical status of the two groups of patients, we compared their information and found that PKP effectively shortened the duration of hospitalization (mean reduction, 2.16 days, $p < 0.001$) and bed rest time (mean reduction, 0.34 days, $p < 0.05$). At the same time, the amount of intraoperative blood loss and intraoperative fluoroscopy times in PKP group were especially less than those in PVP group. In addition, PKP significantly increased the space to accommodate cement by balloon dilatation to achieve adequate bone cement injection, which was conducive to the recovery of vertebral height and early self-care ability (Figure 1).

Table I. The General data of the two group.

Clinical features	Number of cases	PKP	PVP	<i>p</i> -value
<i>Age (years)</i>				
≥ 65	134	75	59	0.75312193
< 65	27	16	11	
<i>Sex</i>				
Male	62	38	24	0.33408914
Female	99	53	46	
<i>Fractural vertebrae</i>				
T12	53	32	21	0.77957474
L1	92	50	42	
Others	16	9	7	

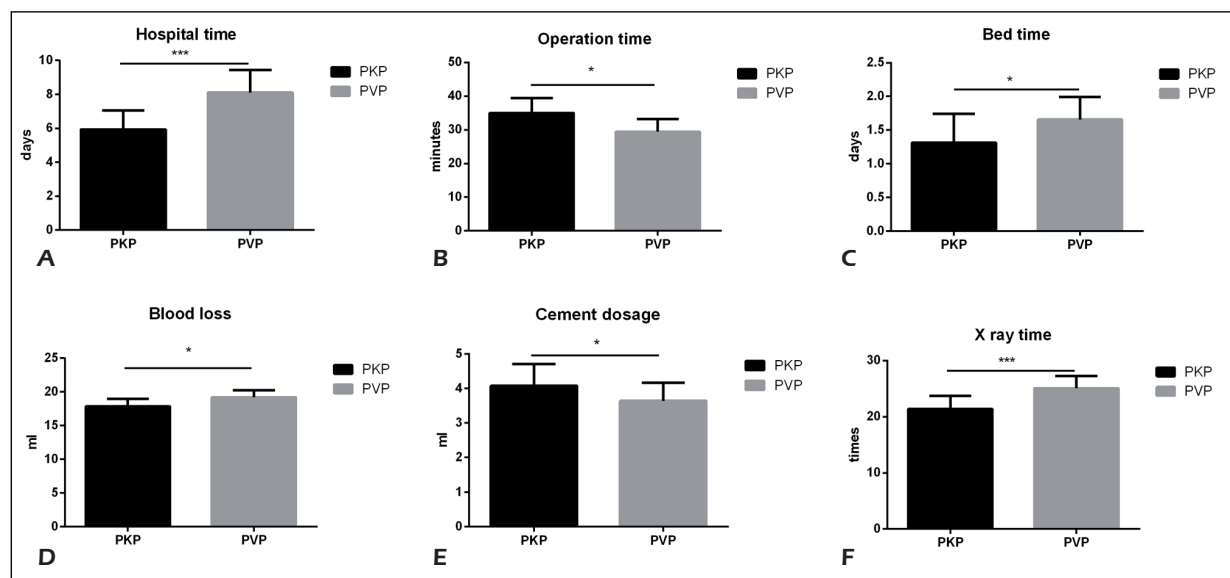


Figure 1. Two groups of patients' hospitalization, surgery and postoperative bed time comparison. **A**, Patients in the PKP group had shorter hospital stays than those in the PVP group. **B**, Patients in the PKP group had longer operation time than patients in the PVP group. **C**, Patients in the PKP group had shorter bedtime than those in the PVP group. **D**, Patients in the PKP group had less blood loss during surgery than those in the PVP group. **E**, Patients in the PKP group had higher intraoperative cement usage than patients in the PVP group. **F**, PKP group of patients with less X-ray projection than PVP patients

Comparison of the Treatment Effect of Two Groups of Patients

The postoperative VAS score, ODI dysfunction index, Cobb's angle, vertebral anterior height and quality of life in both groups were dramatically improved ($p < 0.05$). There was no significant difference between the two groups before treatment ($p > 0.05$), which made them comparable. VAS scores in PKP group were obviously better than that in PVP group ($t = 2.41, 2.44, 2.26, p < 0.05$) on the 1st day, the 7th day and 1 month after operation. The index of ODI dysfunction in PKP group was significantly lower than that in PVP group on the first day, the seventh day, the first month and the third month after treatment ($t = 2.49, 2.58, 3.32, 3.20, p < 0.05$). What's more, there was a significant difference between the two groups in postoperative vertebral height and Cobb's angle. ($t = 7.26, 16.26, p < 0.001$). Meanwhile, the quality of life scores of patients in PKP group was higher than those in PVP group ($t = 5.87, p < 0.05$) (Figure 2 and Figure 3).

Comparison of Complications of the two Group Patients

Bone cement leakage occurred during operation in both the two groups, of which 5 cases in PKP group and 12 cases in PVP group, indicating a higher leakage occurrence in PVP group ($p < 0.001$). There was no statistically significant difference in the occurrence of secondary vertebral fractures at 1 month, 3 months, 6 months, and 12 months after treatment ($p > 0.05$) (Table II).

Patients with cement leakage did not occur significant clinical symptoms.

Discussion

At present, PVP and PKP are widely used in the treatment of OVCFs worldwide. Both of the two surgical procedures can increase the strength of vertebral body and the stability of spine, relieving patients' pain quickly. Meanwhile, PKP can better restore the compressed vertebral body height as well as correct kyphosis of the spine so as to enable patients to walk early as soon as possible^{12,13}. With the efficiency up to 90%¹⁴, a satisfactory clinical effect can be achieved by PKP. The main purpose of this two surgery is to relieve postoperative pain and restore self-care ability of the patients. PKP and PVP surgery ameliorate pain of patients mainly through the following ways. (1) Injection of bone cement can fix the vertebral of patients, strengthen their bone and ameliorate pain through reducing the stimulus of movement to nerve. (2) The thermal energy released by the cement polymerization can cause damage to the nerve endings so as to relieve pain¹⁵. VAS scores one day after surgery of the 161 patients were significantly lower than preoperative, indicating that the effect of surgery was obvious and the pain was effectively alleviated. The VASs of patients in PKP group were lower than those in PVP group at 1 day, 1 week and 1 month after operation, indicating that the short-term efficacy

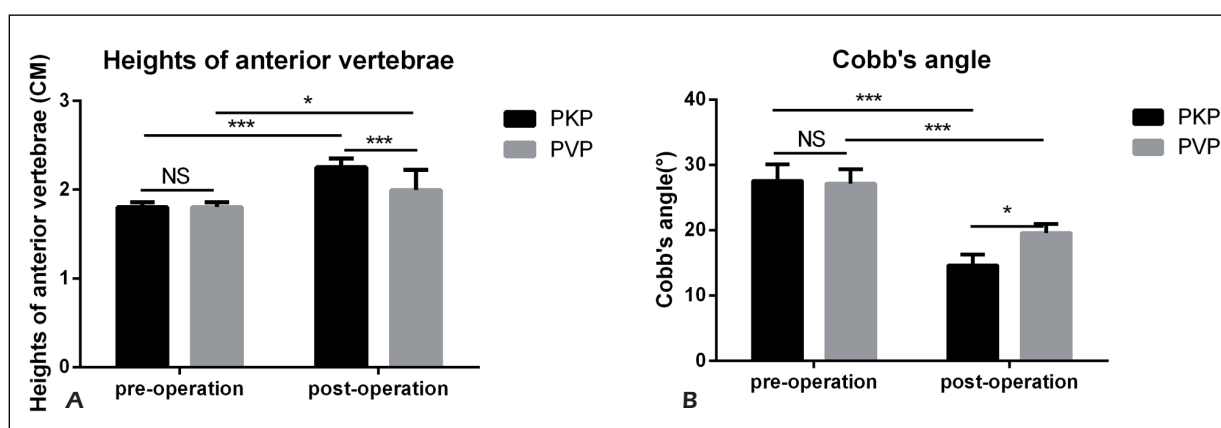


Figure 2. Vertebral body height recovery and Cobb's angle changes in both groups. **A**, There was a significant difference in the recovery of the anterior vertebral height before and after the operation between the two groups. There was no difference between the two groups before operation, but the height of the anterior vertebral body in PKP group was significantly higher than that in PVP group. **B**, The Cobb's angle of vertebral body in the two groups was significantly different before and after operation, there was no difference between the two groups before operation, but difference of Cobb's angle after operation between the two groups appeared.

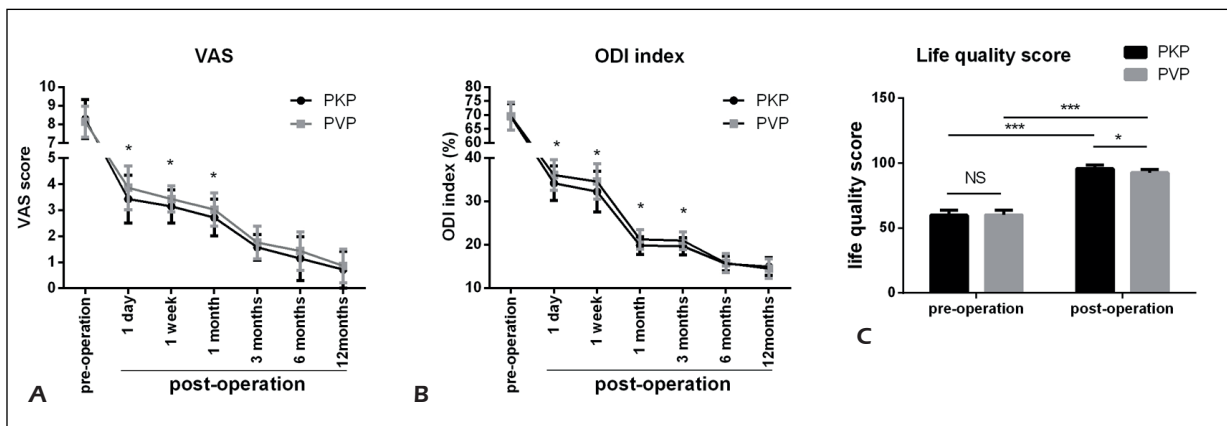


Figure 3. VAS score, ODI index and quality of life score of two groups before and after operation. **A**, There was no difference in VAS score between the two groups before and after operation. The VAS scores of the two groups had no significant difference before operation, and the VAS scores at 1 day, 1 week and 1 month after operation were significantly different. **B**, There was no significant difference in ODI index between before and after operation in group B and before operation, there was a significant difference in ODI index at 1 day, 1 week, 1 month and 3 months after operation. **C**, There was significant difference between the two groups in preoperative and postoperative groups, there was no significant difference between the two groups before operation, and the postoperative quality of life score of patients in PKP group was higher than that of patients in PVP group.

of PKP on pain relief was better than that of PVP, which could help the patients restore normal life as soon as possible. At the same time, the postoperative ODI index in PKP group was significantly lower than that in PVP group, while the quality of life scores were higher, indicating that PKP was superior to PVP in alleviating pain and restoring self-care ability of patients.

In this paper, patients in PKP group had less postoperative bed rest time than those in PVP group, which could effectively prevent and reduce complications such as pressure sores and hypostatic pneumonia caused by long time bed rest. And the amount of intraoperative blood loss and intraoperative fluoroscopy times in PKP group were less than those in PVP group, which could effectively reduce the patient's injury and operation risk as well as protect the medical staff from the excessive radiation damage. Biomechanical studies have confirmed that the restoration of vertebral body strength requires 4-6 mL of bone cement. Therefore, on the premise of ensuring no leakage of cement, adequate bone cement should be injected into the spine of patients in PKP or PVP surgery¹⁶. As a result of the application of a balloon to create a cavity in the vertebral body prior to injection of cement, a low-pressure injection environment is created in PKP. Therefore compared to the high-pressure environment in PVP, it is possible to inject a more sufficient amount of bone cement and reduce the rate of bone cement leakage in PKP. In addition, the expansion of the

balloon in vertebral body can squeeze the cancellous bone to make it denser, thereby sealing the bone fissures and venous access to reduce leakage of bone cement.

PKP and PVP can not only relieve pain and improve function, but also restore vertebral height and reduce kyphosis. PKP uses balloon dilatation and sufficient amount of bone cement to restore the height of the vertebral body, while some scholars think PVP can only reinforce the vertebral body without restoring the vertebral height⁹. However, in recent years, studies have indicated that PVP still have a certain degree of effect on the restoration of vertebral height and correction of kyphosis, especially in fresh thoracolumbar compression fractures¹⁷. The results of our study showed that the average height of vertebral body restored by PKP was 4.5 mm and the average Cobb's angle corrected by PKP was 12.92°, while the two index was 1.9 mm and 7.51° in PVP group, indicating that PKP could restore vertebral height and correct the kyphosis more effectively than PVP did. In this study, patients in PKP group showed a better recovery of vertebral body height and correction of kyphosis than those in PVP group, which is consistent with the literature reported¹⁸.

Bone cement leakage is the most common complication of bone cement vertebroplasty. The reported occurrence of cement leakage of PVP is about 30%, while that of PKP is 1.0%-2.0%^{19,20}. In this paper, there were 17 cases occurred intraop-

erative leakage of cement among 161 cases with the occurrence rate of 10.56%. Among the 17 cases, there were 5 cases in PKP group, significantly less than 12 cases in PVP group. Taylor et al²¹ also found that the occurrence rate of complications such as bone cement leakage in PKP surgery was significantly lower than that in PVP operation. In our study, bone cement leakage occurred mainly in the intervertebral space and paravertebral soft tissue, without occurring in the spinal canal. In addition, patients who occurred cement leakage showed no obvious clinical symptoms.

In summary, both PKP and PVP in the treatment of elderly patients with osteoporotic vertebral compression fractures have good efficacy, allowing patients to early get out of bed to reduce the complications caused by long-term bed rest after fracture. Compared with PVP, PKP, with lower bone cement leakage rate, higher safety and fewer complications, has obvious advantages in vertebral height restoration and improvement of Cobb's angle and can ameliorate pain more effectively, thus improving the clinical curative effects. However, the selection of treatment method should still be associated with the specific patient's condition in order to ensure the effectiveness of clinical treatment.

Conclusions

The clinical efficacy of both PKP and PVP in the treatment of osteoporotic vertebral compression fractures was compared. Compared with PVP, PKP achieves superior fracture reduction and analgesic effects with less leakage of cement, higher safety and fewer complications.

Conflict of Interest:

The authors declared no conflict of interest.

References

- 1) JOHNELL O, KANIS JA. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. *Osteoporos Int* 2006; 17: 1726-1733.
- 2) DAVIES KM, STEGMAN MR, HEANEY RP, RECKER RR. Prevalence and severity of vertebral fracture: the saunders county bone quality study. *Osteoporos Int* 1996; 6: 160-165.
- 3) RIGGS BL, MELTON LR. The worldwide problem of osteoporosis: insights afforded by epidemiology. *Bone* 1995; 17: 505S-511S.
- 4) XU JC, WU GH, ZHOU LL, YANG XJ, LIU JT. Two unilateral punctation comparative analyses of multiple-level fresh osteoporotic vertebral body compression fractures treated with percutaneous vertebroplasty guided by C-arm fluoroscopy or in senile patients. *Eur Rev Med Pharmacol Sci* 2017; 21: 1456-1461.
- 5) WARDLAW D, CUMMINGS SR, VAN MEIRHAEGHE J, BASTIAN L, TILLMAN JB, RANSTAM J, EASTELL R, SHABE P, TALMADGE K, BOONEN S. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet* 2009; 373: 1016-1024.
- 6) HIDE IG, GANGI A. Percutaneous vertebroplasty: History, technique and current perspectives. *Clin Radiol* 2004; 59: 461-467.
- 7) LIEBERMAN IH, DUDENEY S, REINHARDT MK, BELL G. Initial outcome and efficacy of "kyphoplasty" in the treatment of painful osteoporotic vertebral compression fractures. *Spine (Phila Pa 1976)* 2001; 26: 1631-1638.
- 8) DE NEGRI P, TIRRI T, PATERNOSTER G, MODANO P. Treatment of painful osteoporotic or traumatic vertebral compression fractures by percutaneous vertebral augmentation procedures: a nonrandomized comparison between vertebroplasty and kyphoplasty. *Clin J Pain* 2007; 23: 425-430.
- 9) GARFIN SR, YUAN HA, REILEY MA. New technologies in spine: kyphoplasty and vertebroplasty for the treatment of painful osteoporotic compression fractures. *Spine (Phila Pa 1976)* 2001; 26: 1511-1515.
- 10) STERLING M, CHADWICK BJ. Psychologic processes in daily life with chronic whiplash: relations of post-traumatic stress symptoms and fear-of-pain to hourly pain and uptime. *Clin J Pain* 2010; 26: 573-582.
- 11) FAIRBANK JC. Oswestry disability index. *J Neurosurg Spine* 2014; 20: 239-241.
- 12) BOONEN S, WAHL DA, NAUROY L, BRANDI ML, BOUXSEIN ML, GOLDHAHN J, LEWIECKI EM, LYRITIS GP, MARSH D, OBRANT K, SILVERMAN S, SIRIS E, AKESSON K. Balloon kyphoplasty and vertebroplasty in the management of vertebral compression fractures. *Osteoporos Int* 2011; 22: 2915-2934.
- 13) SURESH SP, WHITEHOUSE RW. Vertebroplasty and kyphoplasty. *J Br Menopause Soc* 2005; 11: 28-32.
- 14) YEN CH, TENG MM, YUAN WH, SUN YC, CHANG CY. Preventive vertebroplasty for adjacent vertebral bodies: a good solution to reduce adjacent vertebral fracture after percutaneous vertebroplasty. *AJNR Am J Neuroradiol* 2012; 33: 826-832.
- 15) DIAMOND TH, BRYANT C, BROWNE L, CLARK WA. Clinical outcomes after acute osteoporotic vertebral fractures: a 2-year non-randomised trial comparing percutaneous vertebroplasty with conservative therapy. *Med J Aust* 2006; 184: 113-117.
- 16) PAPANASTASSIOU ID, PHILLIPS FM, VAN MEIRHAEGHE J, BERENSON JR, ANDERSSON GB, CHUNG G, SMALL BJ, AGHAYEV K, VRIONIS FD. Comparing effects of kyphoplasty, vertebroplasty, and non-surgical management in a systematic review of randomized and non-randomized controlled studies. *Eur Spine J* 2012; 21: 1826-1843.

- 17) LIU JT, LIAO WJ, TAN WC, LEE JK, LIU CH, CHEN YH, LIN TB. Balloon kyphoplasty versus vertebroplasty for treatment of osteoporotic vertebral compression fracture: a prospective, comparative, and randomized clinical study. *Osteoporos Int* 2010; 21: 359-364.
- 18) HULME PA, KREBS J, FERGUSON SJ, BERLEMANN U. Vertebroplasty and kyphoplasty: a systematic review of 69 clinical studies. *Spine (Phila Pa 1976)* 2006; 31: 1983-2001.
- 19) BOUZA C, LOPEZ T, MAGRO A, NAVALPOTRO L, AMATE JM. Efficacy and safety of balloon kyphoplasty in the treatment of vertebral compression fractures: a systematic review. *Eur Spine J* 2006; 15: 1050-1067.
- 20) MOVRIIN I, VENGUST R, KOMADINA R. Adjacent vertebral fractures after percutaneous vertebral augmentation of osteoporotic vertebral compression fracture: a comparison of balloon kyphoplasty and vertebroplasty. *Arch Orthop Trauma Surg* 2010; 130: 1157-1166.
- 21) TAYLOR RS, TAYLOR RJ, FRITZELL P. Balloon kyphoplasty and vertebroplasty for vertebral compression fractures: a comparative systematic review of efficacy and safety. *Spine (Phila Pa 1976)* 2006; 31: 2747-2755.