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Is it Beneficial to Reuse the Balloon in Percutaneous Kyphoplasty for the Treatment of Non-Neoplastic Vertebral Compression Fractures?

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Background: Percutaneous kyphoplasty (PKP) has been widely used to treat vertebral compression fractures (VCFs). Bilateral percutaneous punctures are always performed to access the fractured vertebrae. However, the procedure has expensive clinical costs, especially the cost for the device, which creates a heavy financial burden for patients.





Material/Methods: Data from 49 patients who have single-level non-neoplastic vertebral compression fracture (VCF) were collected for 12 months after treated by PKP, including 21 cases that used bilateral puncture with single balloon (S group) and 28 cases that used bilateral puncture with double balloon (D group). We assessed the clinical (visual analogue scale, VAS) and radiological (vertebral height and kyphotic angle, KA) outcomes. Cost data (gross medical cost, cost for the device and cost for drugs) were obtained from the medical bill of each patient.

Results: Baseline patient variables were similar between the two groups except the compensation (S group <D group). No severe cement leakage and only one adjacent-level fracture were observed during the follow-ups. Each group showed significant improvements in the VAS, anterior height (AH) of vertebral body and KA after PKP, while no significant differences were observed when the VAS, vertebral height, and KA at the same time were compared between the S group and the D group. Costs in the S group were significantly lower than those in the D group.

Conclusions: Both single balloon and double balloon bilateral puncture PKP are relatively safe and efficient in non-neoplastic VCFs. However, reuse of the balloon in PKP can decrease the costs.

MeSH Keywords: **Cost of Illness • Kyphoplasty • Spinal Fractures**

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Background

Vertebral compression fractures (VCFs), which always cause chronic pain, insomnia, depression, and even loss of ability to perform daily activities, are seen increasingly in clinics all around the world [1]. What is more, VCFs are always associated with an increasing rate of painful VCF, vertebral height loss, and kyphosis [2]. Recently, percutaneous kyphoplasty (PKP) has been routinely used in the treatment of VCFs due to its smaller incision, less pain, less blood loss, shorter operative time, faster recovery, and fewer hospital stays compared with traditional treatment [3]. During the PKP process, bilateral percutaneous punctures are always performed to access the fractured vertebrae [4]. After anaesthetized, two balloons are inserted into the fractured vertebral body percutaneously, respectively from both sides, and then inflated, deflated, and withdrawn to create a cavity and restore the fractured vertebral height before bone cement is injected [5,6]. It is theoretically feasible to reuse the balloon in the PKP process to lessen the medical costs. But, to the best of our knowledge, seldom clinical trial including comprehensive comparison between single balloon and double balloon bilateral puncture PKP has been reported.

The aim of our research was to compare the clinical and radiological results and medical costs between single balloon and double balloon bilateral puncture PKP in the treatment of patients with non-neoplastic VCFs.

Material and Methods

This research was approved by the Ethics Committees of Dalian Medical University. Before operation, informed consent was obtained from each patient after a careful and comprehensive explanation of the therapy plan.

Patient population

We retrospectively reviewed patients who underwent PKP for non-neoplastic VCFs at the Department of Spine Surgery of the Second Affiliated Hospital of Dalian Medical University between January 2014 and January 2016. We used four inclusion criteria [4]. First, the collapse was 5% or more of the vertebral height. Second, the severe back pain caused by single-level VCF was refractory to analgesic medication for not less than seven days. Third, the pain was over 5, measured on a VAS, and there was percussion tenderness on the spinal process of the affected vertebral body. Fourth, in magnetic resonance imaging (MRI), the fractured vertebral body showed a hypointense signal on T1-weighted images and a hyperintense signal on T2-weighted stir fat-suppressed images. There were exclusion criteria [4]. First, there was secondary osteoporosis caused by corticosteroids, endocrine disorders, and inflammation. Second,

there was no informed consent. Third, there was uncorrected coagulopathy. Fourth, the patient was in a terrible physical state. Fifth, the fracture caused no pain. Sixth, there was a spinal metastatic cancer. Seventh, there was a neurologic deficit. In total, 49 patients were included. Of these, 21 patients who wanted to undergo single balloon bilateral puncture PKP and who were offered informed consent forms including the limited evidence on the benefit and related complications to reuse the balloon were assigned to the S group. As a control group, 28 patients who decided to perform double balloon bilateral puncture PKP were assigned to the D group.

The baseline of the two groups was defined as the day before PKP. In both groups, the baseline data, including age, sex, body mass index (BMI), smoking, injury mechanism, compensation, fracture level, and operator, were obtained from medical records.

Outcome measures

All outcomes were measured according to a previous study [4]. Clinical outcome was monitored by VAS from 0 to 10 the day before the operation, immediately after the operation and one year after the operation. A zero score meant no pain. A 10 score indicated a maximal imaginable pain. The investigations were performed by an investigator not involved in clinical care. Anteroposterior and lateral radiographs were collected pre- and post-operatively. By gauging these, the vertebral height and KA of each patient was obtained. The posterior height (PH) of the caudal vertebrae adjacent to the fractured vertebrae was measured as 100%. Then, referring to this, the anterior height (AH) and PH of the fractured vertebrae were collected in the same way. The KA was gauged around the fractured vertebral body by a widely recognized method [4]. It was defined as an acute angle composed by superior endplate of upper vertebral body and inferior endplate of lower vertebral body.

Costs

Direct healthcare cost data, including gross medical cost, cost for device, and cost for drugs, were obtained from the medical bills of all patients. The costs of medication prescribed and procedures performed outside of our hospital were not involved because all patients denied medications and procedures outside of our hospital during our follow-ups. All healthcare costs were obtained one year after the operation. All costs were measured as RMB (Renminbi, Chinese currency) at their value during January 2016.

Statistical analysis

SPSS software, version 12 (SPSS Inc., Chicago, IL, USA), was used for data analysis. Categorical variables were analyzed

Table 1. Characteristics of the study population.

Characteristics	S group (N=21)	D group (N=28)	p	Statistical method
Age	72.52±8.594	74.57±8.557	0.448	Mann-Whitney test
Male	6 (28.6)	4 (14.3)	0.2906	Fisher's exact test
Body mass index (kg/m ²)	22.09±1.902	23.29±2.450	0.0614	Mann-Whitney test
Smoking	4 (19)	4 (14.3)	0.7155	Fisher's exact test
Injury mechanism			0.1424	Chi-square
Fall	13	17		
Traffic or sports injury	5	2		
Others	3	9		
Compensation	12	25	0.0172	Fisher's exact test
Fracture level			0.3942	Chi-square
T	7	13		
L	14	15		
Operator			0.8714	Chi-square
Feng Nan	5	5		
Zhengwei Li	6	6		
Zhi Zhao	4	5		
Liang Yuan	4	7		
Guangcan Li	2	5		
Operation time	60.95±32.85	58.39±20.28	0.7141	Mann-Whitney test
Cement leakage	0	0		
Adjacent-level fracture	0	1		

Data are presented as mean ±standard deviation and number (percentage values).

using chi-square test and Fisher's exact test. They were showed as number and percentage values. Continuous variables were compared by Mann-Whitney test, paired *t*-test and unpaired *t*-test with Welch's correction and presented as mean and standard deviation. All statistical methods are listed in the charts in this article with *p*<0.05 indicating statistical significance.

Results

Subject characteristics

Table 1 shows the baseline characteristics of both cohorts. There were no significant differences in the baseline characteristics of the two groups (all *p*>0.05) except the compensation (S group <D group).

Clinical results

The VAS pain scores are showed in Figure 1 and Table 2. Every patient had significantly less pain after operation. In both groups, the pain scores decreased significantly immediately

after operation and one year after operation compared with those before operation (*p*<0.05). No significant difference was found when comparing the VAS between the S group and the D group at the same period (*p*>0.05).

Radiological results

Radiological data, including AH, PH, and KA, were collected before and after the operation. These data are compared in Figures 2 and 3 and presented in Tables 3 and 4. After the operations, AH increased significantly in both groups compared with those before the operations (*p*<0.05), however, the difference between pre-operative and post-operative PH was not significant (*p*>0.05). There was no significant difference in AH and PH between the two groups at the same time (*p*>0.05). What is more, both the S group and the D group had significant declines in KA post-operation compared with pre-operative KA (*p*<0.05), however, there was no significant difference between pre-operative and post-operative KA or change in KA found between the two groups (*p*>0.05).

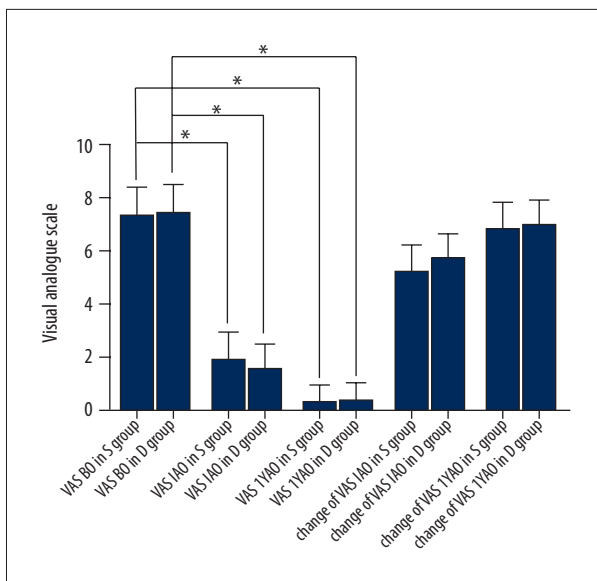


Figure 1. Comparison of VAS pain scores and changes of VAS at different time points in the S group and the D group. Error bars represent ± 1 SD from the mean. VAS – visual analogue scale; BO – before operation; IAO – immediately after operation; 1YAO – 1 year after operation; * indicates statistical significance ($p < 0.05$).

Costs

The costs of the S group and the D group are shown in Table 5 and Figures 4 and 5. In the S group, the gross medical cost, cost for device, cost for drugs, and device/gross cost were less than those in the D group, significantly ($p < 0.05$); however, medical/gross cost was not significant difference between the two groups ($p > 0.05$).

Table 2A. Comparison of VAS pain scores before, immediately after and one year after operation in the S group and the D group.

VAS pain score	VAS BO in S group	VAS IAO in S group	VAS 1YAO in S group	VAS BO in D group	VAS IAO in D group	VAS 1YAO in D group	Score
VAS BO in S group		Mann-Whitney test	Mann-Whitney test	Mann-Whitney test			7.429 \pm 0.9783
VAS IAO in S group	$p < 0.0001$				Mann-Whitney test		2.048 \pm 0.9735
VAS 1YAO in S group	$p < 0.0001$					Mann-Whitney test	0.4762 \pm 0.5118
VAS BO in D group	$p = 0.5979$				Mann-Whitney test	Mann-Whitney test	7.571 \pm 0.9974
VAS IAO in D group		$p = 0.1633$		$p < 0.0001$			1.679 \pm 0.8630
VAS 1YAO in D group			$p = 0.8433$	$p < 0.0001$			0.4643 \pm 0.5762

Data are presented as mean \pm standard deviation. VAS – visual analogue scale; BO – before operation; IAO – immediately after operation; 1YAO – one year after operation.

Table 2B. Comparison of changes of VAS immediately and one year after operation in the S group and the D group.

Change of VAS IAO in S group	Change of VAS 1YAO in S group	Change of VAS IAO in D group	Change of VAS 1YAO in D group	Score
Change of VAS IAO in S group		Mann-Whitney test		5.381 \pm 0.8646
Change of VAS 1YAO in S group			Mann-Whitney test	6.952 \pm 0.9207
Change of VAS IAO in D group	$p = 0.0596$			5.893 \pm 0.8317
Change of VAS 1YAO in D group		$p = 0.5161$		7.107 \pm 0.8751

Data are presented as mean \pm standard deviation. VAS – visual analogue scale; BO – before operation; IAO – immediately after operation; 1YAO – one year after operation.

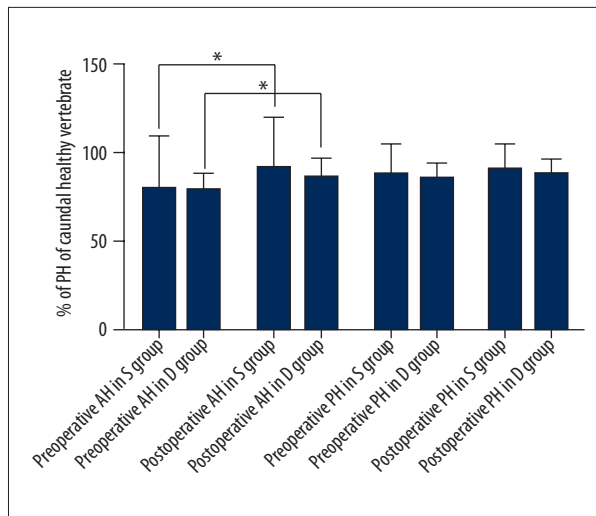


Figure 2. Comparison of anterior and posterior heights pre- and post-operation in the S group and the D group. Error bars represent ± 1 SD from the mean. AH – anterior height; PH – posterior height; * indicates statistical significance ($p < 0.05$).

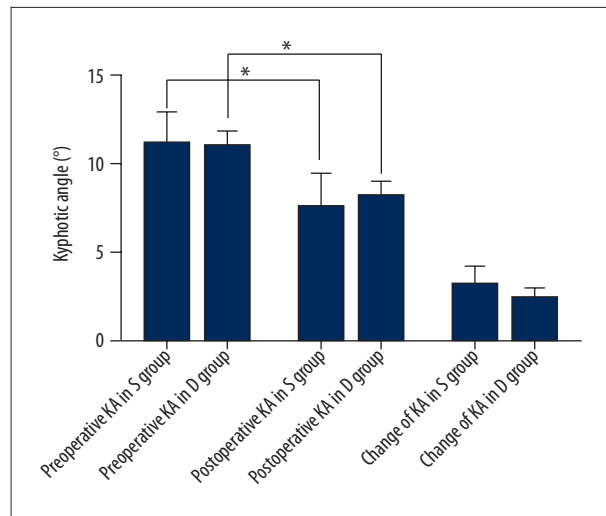


Figure 3. Comparison of kyphotic angles pre- and post-operation in the S group and the D group. Error bars represent ± 1 SD from the mean. KA – kyphotic angle; * indicates statistical significance ($p < 0.05$).

Table 3. Comparison of anterior and posterior heights pre- and post-operation in the S group and the D group.

Vertebral body height	Pre AH in S group	Pre AH in D group	Pre PH in S group	Pre PH in D group	Post AH in S group	Post AH in D group	Post PH in S group	Post PH in D group	% of PH of caudal healthy vertebrae
Pre AH in S group		Mann-Whitney test			Paired t-test				81.42±28.60
Pre AH in D group	$p=0.1148$					Paired t-test			80.34±8.053
Pre PH in S group			Mann-Whitney test				Paired t-test		90.04±15.45
Pre PH in D group			$p=0.9436$					Paired t-test	87.50±6.950
Post AH in S group	$p < 0.0001$				Mann-Whitney test				93.56±27.11
Post AH in D group		$p < 0.0001$			$p=0.3027$				88.48±8.154
Post PH in S group			$p=0.1343$				Mann-Whitney test		92.23±12.62
Post PH in D group				$p=0.1051$			$p=0.8006$		89.88±6.651

Data are presented as mean \pm standard deviation. Pre – preoperative; post – postoperative; AH – anterior height; PH – posterior height.

Discussion

An ideal method for treating vertebral compression fractures (VCF) is supposed to provide a fast and durable relief of pain and a lasting correction of deformity [7–12]. Percutaneous

vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) are two common alternatives to the modern treatment concepts, offering a fast and durable pain relief, a lasting kyphotic correction and a significant improvement of life quality [13–18]. Some comparative studies reported that PVP and PKP result

Table 4. Comparison of kyphotic angles pre- and post-operation in the S group and the D group.

Kyphotic angle	Pre KA in S group	Pre KA in D group	Post KA in S group	Post KA in D group	Change of KA in S group	Change of KA in D group	Kyphotic angle (°)
Pre KA in S group		Mann-Whitney test	Mann-Whitney test				11.33±6.993
Pre KA in D group	<i>p</i> =0.8364				Mann-Whitney test		11.24±3.295
Post KA in S group	<i>p</i>=0.0439			Unpaired t-test with Welch's correction			7.868±7.555
Post KA in D group			<i>p</i> =0.7174				8.500±2.709
Change of KA in S group		<i>p</i> =0.0021				Mann-Whitney test	3.459±3.752
Change of KA in D group					<i>p</i> =0.4086		2.740±1.522

Data are presented as mean ± standard deviation. Pre – preoperative; post – postoperative; KA – kyphotic angle.

in similar pain control and improvement of physical function [19–22]. On the contrary, a meta-analysis conducted by Eck et al. [23] comparing all studies of PVP and PKP in VCFs showed that there was less cement leakage, fewer new compression fractures, and fewer pulmonary embolisms in PKP compared with PVP.

Traditional bilateral PKP was shown to be safe and effective for the treatment of VCFs [24,25]. The latest meta-analysis [26], which demonstrated that there was no clinically important differences between unilateral and bilateral PKP, concluded that both methods appear to be safe and effective for treating VCFs, thus suggesting that a unilateral PKP is advantageous owing to theoretical speed, safety, and less expense. However, higher-level operation skills are needed while performing unilateral PKP, which to some extent hinders its development and popularity. Theoretically, reusing the balloon in bilateral PKP process can address the difficulty for the operator and reduce the medical cost for patients. As for as we know there is seldom clinical trial including comprehensive comparison between single balloon and double balloon bilateral puncture PKP. Thus, in this study, clinical and cost data of single balloon and double balloon bilateral puncture PKP were obtained, compared, and analyzed.

As a previous study [4] demonstrated, the inclusion criteria should be collapse of 15% or more of the vertebral height and severe back pain related to a single-level VCF refractory to analgesic medication for at least two weeks. But collapse over 15% and two weeks' suffering of severe back pain may be too hard to bear. For rapid relief of pain, patients always ask for the operation as soon as possible. In fact, in real clinic treatment, patients tend to be more active in seeking to receive

the operation. Thus, the indication should be revised on the basis of 15% and two weeks. We adjusted the inclusion criteria to be over 5% loss of height and at least one week's analgesic medication.

During our follow-ups, no patient had serious post-operative adverse events including cement extravasation, puncture mistake, and false selection of indications [27]. There was only one patient in the D group who suffered from adjacent-level fracture. Our data about clinical and radiological outcomes indicated that single balloon can benefit patients of VCFs as effective as double balloon in PKP. Although, theoretically speaking, the vertebral endplate may be stressed more uniformly by simultaneous bilateral dilatation with double balloon compared to successive bilateral dilatation with single balloon, Yang et al. [28] and Sun et al. [29] demonstrated that there was no difference between the two methods in terms of vertebral height restoration and KA improvement; these conclusion were similar to ours. However, a study about single-level VCF by Wang et al. [30] demonstrated that double balloon bilateral PKP had advantages in terms of the improvement of vertebral height and KA. Moreover, Wang et al. [30] and Theocharopoulos et al. [31] reported that single balloon bilateral PKP may increase the operation time and occupational exposure to x-ray. But the operation time in our study showed no significant difference (*p*>0.05) between the S group (60.95±32.85 minutes) and the D group (58.39±20.28 minutes). A meta-analysis incorporating these data will be conducted in our following studies.

Data of medical costs were obtained from patients' medical bills from our institute during the follow-ups, which showed that reusing the balloon can reduce the gross medical cost

Table 5. Comparison of medical costs in S and D groups.

Medical cost	S group (N=21)	D group (N=28)	P	Statistical method
Gross medical cost (RMB)	32290±4084	52920±7089	<0.0001	Mann-Whitney test
Cost for device (RMB)	25440±4356	45820±7169	<0.0001	Mann-Whitney test
Cost for drugs (RMB)	1024±1404	1325±1195	0.0331	Mann-Whitney test
Device/gross cost	0.792±0.1479	0.8623±0.05327	0.0348	Mann-Whitney test
Drugs/gross cost	0.02944±0.0354	0.02649±0.03112	0.7696	Mann-Whitney test

Data are presented as mean ± standard deviation.

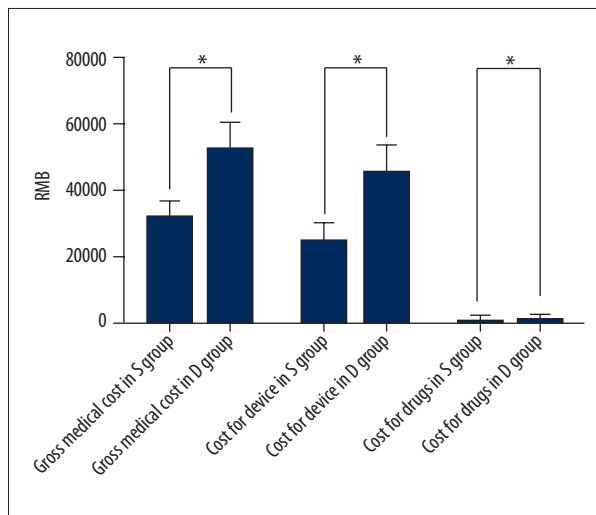


Figure 4. Comparison of gross medical cost, cost for device, and cost for drugs between the S group and the D group. Error bars represent ±1 SD from the mean; * indicates statistical significance ($p < 0.05$).

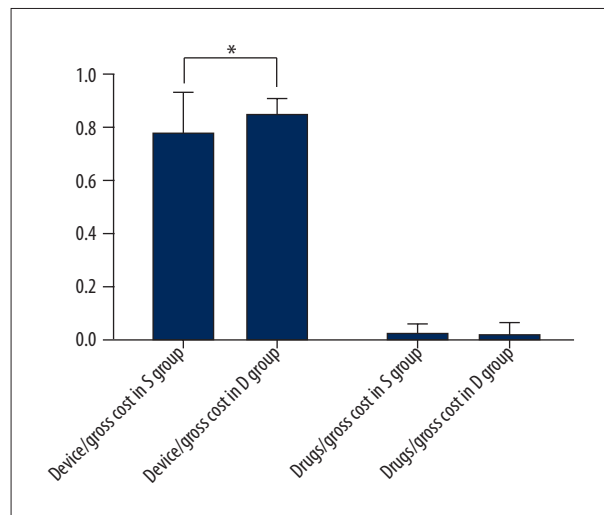


Figure 5. Comparison of device/gross and drugs/gross costs between the S group and the D group. Error bars represent ±1 SD from the mean; * indicates statistical significance ($p < 0.05$).

of each patient mainly by decreasing the proportion of device cost (Table 5, Figures 4, 5). There should be no difficulty in understand how reusing the balloon can decrease the cost for device and the gross medical cost. But it is interesting to discuss why decreasing a balloon cost can lessen the cost for drugs. As noted in our methods description, the type of operation was chosen by each patient after a careful and comprehensive explanation of the therapy plan. So, people without healthcare compensation may tend to choose to reuse the balloon to save money, though limited evidence is available to support this theory. The proportion of patients without compensation in the S group was higher than in the D group (Table 1). Patients without compensation may also tend to use cheaper drugs. That might be why the cost for drugs in the S group was less than that in the D group. Figure 5 shows that there was significant difference in device/gross costs between the S group and the D group, while there was no difference in drugs/gross costs between the two groups, which supports the aforementioned speculation.

Cost can be divided into micro-costing and macro-costing [32,33]. Macro-costing involves all expenses during a specific period. It is relatively simple to perform, although specific components composing the cost cannot be identified. However, micro-costing is done by analyzing the costs after listing all the resources and matching the unit cost of each part. The medical bills of all patients in our study were checked for micro-costing. According to the perspective of sociology, direct healthcare cost, direct non-healthcare cost, and productivity cost should be included in cost [34]. As data on length of absenteeism and cost for caregiver and transportation could not be obtained from medical records in our study, we collected only direct healthcare costs. According to the relative guidelines from the UK, The Netherland and South Korea, cost utility analysis can be used without indirect costs (non-healthcare and productivity costs) [35,36].

On the basis of a previous study [37], recommendation for deciding the adoption and proper utilization of medical procedures

could be classified from A to E. A grade A technology is less costly and as effective as or more effective than the existing one, with strong evidence for adoption and proper utilization. A grade E technology tends to be rejected because it is of less or equal effective and more costly. Grades B, C, and D indicate more effective, costlier, or less effective and less costly, respectively. According to the results of our study, single balloon bilateral puncture PKP, which is as effective as double balloon bilateral puncture PKP while less costly, should be a grade A. Therefore, it is recommended to reuse the balloon in bilateral puncture PKP in the treatment of VCFs.

There are some points and limitations to our study to be considered. First, as a retrospective study, some inherent limitations cannot be avoided. A future prospective study would better validate these findings. Second, the data of bone attenuation on bone densitometry were not obtained. Although the medical history indicated that most patients might have osteoporosis, we did not give the diagnosis as osteoporotic VCF. Third, the sample size in our research may be relatively small. Large, long-term clinical trials are needed to generalize these results. Fourth, the operation method was decided based on patient's choice. Patient compensation in the S group was lower than in the D group, which may affect the choices made, because patients without compensation are more likely to be able to afford more cost for a device by themselves. Lastly, VAS was

the only index we got to assess the clinical outcomes. A further study including SF-36 scores, quality-adjusted life years, and cost utility analysis should be performed [37].

Conclusions

This study concluded that both single balloon and double balloon bilateral puncture PKP are relatively safe and efficient treatment for patients with non-neoplastic VCFs. During the follow-ups, VAS, AH, and KA in both groups improved significantly while single balloon bilateral puncture PKP costs less, especially as it reduces the cost for devices. According to the existing evidence in this article, it is reasonable to recommend the single balloon bilateral puncture PKP for the treatment of non-neoplastic VCFs.

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Conflict of interest

None.

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