Outcomes of Vertebroplasty versus Kyphoplasty in Management of Osteoporotic Vertebral Fractures: A Single Center Experience

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ABSTRACT

Objective: To compare the clinical and radiological parameters of vertebroplasty versus kyphoplasty in the treatment of osteoporotic vertebral compression fractures.

Method: A retrospective analysis was conducted among 68 patients who underwent percutaneous vertebroplasty (PVP) or percutaneous kyphoplasty (PKP) for treatment of osteoporotic vertebral compression fractures (OVCFs) at the Royal Rehabilitation Center between January 2018 and August 2022. Clinical outcomes were measured using a numeric rating scale (NRS) for pain intensity, and radiographic outcomes included local kyphosis angle, anterior and middle vertebral body height, and the wedging index.

Results: There were 36 patients who underwent PKP (6 males and 30 females; mean age: 69.58±7.82 years) and 32 patients who had PVP (13 males and 19 females; mean age: 72.75±7.75 years). There were no significant differences between the groups with regard to improvement in the NRS score (P>0.05). Both treatment groups achieved marked vertebral height restoration, kyphotic angle reduction, and wedging index improvement, but the radiographic parameters were significantly better in the PKP group ($P < 0.05$). No serious complications were found. Fracture of the adjacent vertebra was found in 3 patients (1 in the PKP group and 2 in the PVP group), and cement leakage occurred in 5 patients (2 in the PKP group and 3 in the PVP group).

Conclusion: PKP and PVP are both effective and relatively safe treatments for OVCFs.

Keywords: osteoporotic vertebral compression fractures, efficacy, kyphoplasty, vertebroplasty, outcomes

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INTRODUCTION

In the elderly population, osteoporotic vertebral compression fractures (OVCFs) are rather prevalent and vary according to age and sex (1-3). Height loss, kyphosis, and an increased risk of nonvertebral fractures are some of the adverse consequences of this condition (4,5), which is also associated with pain, high mortality, and high morbidity (6-8). In clinical practice, three approaches are employed to treat patients with OVCFs: conservative care, standard surgical procedures, and minimally invasive techniques (9). Minimally invasive approach have better treatment outcomes in terms of shorter treatment duration, less blood loss, less pain, faster recovery, and a shorter hospitalization than the other two approaches (9-13).

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Inadequate bone quality in such patients results in a high rate of implant failures after surgical intervention (14,15), and open surgery has greater morbidity and mortality concerns among the elderly (16). However, it is considered as an option in cases of a neurological deficit and significant painful kyphosis (15). Therefore, many minimally invasive procedures have been developed and are widely used. Percutaneous techniques, including vertebroplasty (PVP) and kyphoplasty (PKP), have gained significant popularity. Patients with OVCFs may greatly benefit from these two methods because they enhance stability and decrease pain (17,18). In this retrospective study, we compared the outcomes of PVP versus PKP in the treatment of OVCFs.

Methods

Patients and setting

A retrospective analysis was conducted to examine patients with OVCFs who were treated at the Royal Rehabilitation Center between January 2018 and August 2022. A patient who had an osteoporotic vertebral fracture that occurred during the three months before the study period was excluded. Patients were also excluded if they had more than two vertebral body fractures or fractures due to malignancy. A diagnosis of an osteoporotic origin of the fracture was made by excluding high-force trauma before the beginning of back pain. Other exclusion criteria were found in the following: a history of spinal surgery, an infection of the spine, scoliosis, and patients' electronic medical files missing required data. Patients' demographic and clinical data were evaluated, including age, sex, fracture classification, number of levels affected, and follow-up time. Fractures were classified according to the AO thoracolumbar fracture classification system (19).

Study outcomes

The effectiveness of the surgical approach was measured using the following outcomes: Clinical parameters included a numeric rating scale (NRS) to measure pain before and after surgery. The NRS was measured and recorded in the patients' medical files on a daily basis by nurses according to the nursing policy at the Royal Rehabilitation Center. NRSs are the simplest and most commonly used scales. They most commonly range from 0 to 10, with 0 meaning "no pain" and 10 meaning "the worst pain imaginable."

Radiological parameters included the local kyphosis angle, wedging index, and vertebral body heights measured before and after surgery. In lateral X-ray images, we assessed the kyphosis angle (KA) of the fractured spine segment, which is the angle created by lines drawn parallel to the posterior wall of the vertebral bodies below and above the implicated disc. The wedge angle was defined as the angle between the superior endplate line and the inferior endplate line of the fractured vertebral body.

The vertebral height ratios were calculated according to the McKiernan, Faciszewski, and Jensen equation as follows (20):

$$(\text{Fractured vertebral height})/(\text{mean adjacent control vertebral height}) \times 100\%.$$

Post-operative complications included extravasation of cement, venous embolism, and fracture of the adjacent vertebra. Operational parameters were also compared between the groups, including the operation time and the amount of cement applied.

SURGICAL TECHNIQUES

All surgeries were performed under guidance using C-arm fluoroscopic imaging. Patients were positioned in a prone position, and kyphoplasty began with the placement of a cannula into the vertebral body, followed by the placement of an inflating balloon. Within the body of the vertebrae, the balloon is made to expand. When the balloon is inflated it creates a gap within the core of the vertebral body, which raises the end plate fractures. Afterwards, polymethylmethacrylate (PMMA) cement is injected with low pressure into the cavity created by the balloon.

The inflation of the balloon during the procedure can also lead to an increase in the vertebral body height and, consequently, to correction of the abnormal configuration of the vertebral body induced by the fracture. For vertebroplasty, a channel was inserted in the pedicle, and bone cement was injected directly into the cancellous bone of a vertebral body without using a balloon as in the kyphoplasty technique. All the materials, including kyphoplasty kits, cement, fillers, and balloons, are manufactured by Stryker Company.

ETHICAL CONSIDERATION

All patient data was handled with strict confidentiality, and data was analyzed anonymously by patient ID number. No contact was made with patients or their relatives. This study was approved by the Ethics Review Board at Royal Medical Services (Approval No: 17/2022-14)

Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 25.0. The sample characteristics were described in descriptive terms. An independent t test was used to compare the baseline clinical and radiological continuous parameters between groups. A chi-squared test and Fisher's exact test were used to compare post-operative complications between the groups as appropriate besides to investigate proportion differences of between categorical data at baseline. Furthermore, the multivariate analysis of covariance (MANCOVA) was utilized to investigate the estimated marginal mean of clinical and radiological continuous parameters between groups after controlling the baseline data as a covariate. Partial eta-squared (η_p^2) was used to measure the effect size (magnitude of differences) and P-values less than 0.05 were considered statistically significant.

RESULTS

Patient demographics and baseline data

Overall, this study included 68 patients with OVCFs, who consisted of 19 males (27.9%) and 49 females (72.1%) with a mean age 71.07±7.89 years. A total of 36 patients (52.9%) underwent PKP, and 32 patients (47.1%) underwent PVP. The mean follow-up time was 10.64±3.61 months. Most patients had one-level fractures (86.8%), and fracture type A1 was the most common type (51.5%). The PKP and PVP groups significantly differed in terms of sex ($p < 0.05$) with significantly more female patients in the PKP group (83.3%) than in the PVP group (59.4%). No significant difference was found between the groups regarding other baseline data ($p > 0.05$). Baseline data for the study groups is presented in Table 1.

Table 1. Comparison of baseline data between the groups

Parameters	Total	PKP (n=36)	PVP (n=32)		t/x^2	P
Age (years)	71.07±7.89	69.58±7.82	72.75±7.75		1.67	0.099
Sex						
Male	19 (27.9)	6 (16.7)	13 (40.6)		4.83	0.028
Female	49 (72.1)	30 (83.3)	19 (59.4)			
Number of levels affected						
One level	59 (86.8)	31 (86.1)	28 (87.5)			0.978
Two level	9 (13.2)	5 (13.9)	4 (12.5)			
Fracture classification						
A1	35 (51.5)	21 (58.3)	14 (43.8)		1.55	0.493
A2	21 (30.9)	10 (27.8)	11 (34.4)			
A3	12 (17.6)	5 (13.9)	7 (21.8)			
Mean follow-up time (months)	10.64±3.61	11.16±3.41	10.06±3.80		1.26	0.212

PKP: percutaneous kyphoplasty; PVP: percutaneous vertebroplasty; t: independent t test; X^2: chi-squared or Fisher's exact test.

INTRAOPERATIVE PARAMETERS

The mean operation time was 49.55±10.91minutes, and the mean volume of bone cement injected during surgery was 5.13±0.84 ml. The mean length of stay in the hospital was 3.95±2.10 days. Patients in the PKP group received a higher volume of cement (5.50±0.84 ml) during surgery than the PVP group (4.71±.63 ml) ($p \leq 0.001$). No significant difference was found between the groups regarding other intraoperative parameters ($p > 0.05$). Intraoperative parameters are presented in Table 2.

Table 2. Comparison of intraoperative parameters between groups

Parameters	Total	PKP (n=36)	PVP (n=32)		t	P
Operation time (min)	49.55±10.91	51.80±12.82	47.03±7.71		1.83	0.072
Volume of bone cement injected (mL)	5.13±0.84	5.50±0.84	4.71±.63		4.26	0.001
Length of hospital stay (days)	3.95±2.10	4.13±2.53	3.75±1.50		.758	0.451

PKP: percutaneous kyphoplasty; PVP: percutaneous vertebroplasty; t: independent t test

Surgery complications

During surgery there were no serious complications such as acute pulmonary embolism, nerve injury, or spinal cord compression. Fracture of the adjacent vertebra occurred in 3 patients (4.4%), and cement leakage occurred in 5 patients (7.4%). No significant difference was found between the groups with regard to surgery complications ($p > 0.05$). Surgery complications are presented in Table 3.

Table 3. Incidence of complications in both groups

Parameters	Total	PKP (n=36)	PVP (n=32)	P
Adjacent vertebra fracture	3 (4.4)	1 (1.5)	2 (6.3)	0.619
Incidence of cement leakage	5 (7.4)	2 (2.9)	3 (9.4)	

PKP: percutaneous kyphoplasty; PVP: percutaneous vertebroplasty

CLINICAL AND RADIOLOGICAL EVALUATION

The MANCOVA statistical analysis test was utilized to investigate if there is a statistically significant mean difference of the clinical and radiological parameters on post-operative time after considering the baseline parameters as covariates for control. The results in table (4) have revealed that those operated with PKP significantly reported lower local kyphosis angle adjusted mean than who operated with PVP (13.66° vs. 15.91°), p<.001 respectively, with large effect size η_p^2=.404 or in other words about 40.4% of kyphosis angle variance was explained by surgery factor.
In the same context, the anterior and middle vertebral height were found to be significantly higher among PKP patients' group than PVP patients' group (52.07mm vs. 48.20mm, with large effect size η_p^2.312, p<001) and (54.86mm vs. 51.38mm, with large effect size η_p^2= .163, p<001) respectively
Furthermore, the wedging index was found to be significantly higher among PKP patients' group than PVP patients' group (66.98 vs. 60.99 mm, large effect size η_p^2= .229, p<001) while no significant difference was found between the two groups with regard to the mean difference in pain intensity (P > 0.05).

Table 4.Post-operative mean differences of the clinical and radiological parameters

Parameters	Groups	Adjusted mean	Std. Error	Mean square	F-value	Partial eta^2 (η_p^2)	p-value
NRS	PKP PVP	2.30 2.53	.145 .154	.906	1.194	.018	.279
Local kyphosis angle (°)	PKP PVP	13.66 15.91	.231 .245	83.913	44.053	.404	<.001
Anterior vertebral Height (mm)	PKP PVP	52.07 48.20	.488 .518	252.01	29.443	.312	<.001
Middle vertebral height (mm)	PKP PVP	54.86 51.38	.656 .696	202.24	13.136	.163	.001
Wedging index	PKP PVP	66.98 60.99	.591	602.94	48.169	.229	<.001

PKP: percutaneous kyphoplasty; PVP: percutaneous vertebroplasty,η_p^2=>.14 large effect size)

DISCUSSION

Analgesic regimens may not always relieve the pain associated with vertebral fractures, which can have a serious impact on quality of life. Therefore, PKP and PVP are reasonable options in such challenging conditions. Multiple factors, including the extent of body height compression, the size of the pedicles, the integrity of the posterior cortical wall, and the associated cost, were taken into consideration while deciding whether to treat OVCFs with vertebroplasty or kyphoplasty.

This study showed that PKP and PVP provided immediate and significant pain relief following surgical procedures, and there was no significant difference between procedures regarding pain reduction. Our results are in accordance with the findings of a recent meta-analysis that examined 15 randomized control studies, which also reported good pain relief and decreased need for painkiller medications after vertebral augmentation (12). In contrast, two randomized control studies compared a PVP group with a placebo control group, and no significant pain reduction was observed between them (21,22). This may have been due to the low mean volume of cement injected in the vertebrae, which was around 2.8 ml.

According to Nieuwenhuijse et al. (2012), the amount of cement injected (measured as the mean cemented vertebral body fraction) appears to be a key factor in achieving pain alleviation (23). In the present study, the mean amounts of cement injected in each vertebra in the PKP and PVP groups were 5.50±0.84 ml and 4.71±.63 ml, respectively. The nerve terminals in the fractured vertebral body can be destroyed with PMMA cement, which may reduce pain (24). Furthermore, it has been claimed that pain tends to improve on its own throughout the acute phase (25).

In addition to the favorable clinical outcomes, both PKP and PVP achieved considerable improvement in postoperative radiological parameters. The kyphosis angle was reduced by both methods but to a higher extent with PKP ($P<0.01$). This finding is in line with previous studies (12,26). The mean changes in kyphotic angle in the PKP and PVP groups were 8.72±2.13° and 5.90±2.79°, respectively. Yan et al. reported the best angle-based finding with a mean change was in the kyphotic angle of 11.7° (27).

An essential metric for evaluating the clinical efficacy of these minimally invasive procedures is the restoration of vertebral height after surgery since incomplete restoration of the vertebral body height after a fracture increases the risk of further fractures (28,29). The present results show that both PKP and PVP achieved considerable vertebral height restoration in postoperative radiological parameters. The vertebral height (anterior and middle vertebral height) was increased by both methods but to a higher extent with PKP ($P<0.01$). Most previous studies indicated that both PKP and PVP methods are effective treatments for OVCFs and suggested that PKP may be favored for vertebral height restoration (30).

Regarding the wedging index, both PKP and PVP achieved considerable improvement postoperatively. However, the index was increased to a greater extent with PKP ($P<0.01$). This result is in line with those of Chen et al. (17).

In terms of surgery complications, it is well known that PVP and PKP treatments can have complications such as bone cement leakage into the intervertebral disc space and spinal canal. In extreme cases, leaking bone cement might cause paraplegia (31) and pulmonary embolism (32, 33). In our study, cement leakage was observed in two patients in the PKP group (2.9%) and three patients in the PVP group (9.4%). None of the cement leaks in this investigation resulted in clinical consequences. Similar results were reported by Chen et al. (17).

Previous meta-analyses and systematic reviews suggest that the rate of cement leakage is significantly lower with PKP than PVP (30,34). PKP may result in less cement leakage because it creates a cavity into which more viscous cement may be injected at a lower injection pressure (35). The important complications of these interventions include fractures of the adjacent vertebrae, of which one occurred in the PKP group (1.5%) and two occurred in the PVP group (6.3%). All of these fractures occurred within six months after surgery. During the course of follow-up with these patients, we did not detect any increased risk of further fractures.

According to Lindsay et al., among patients who have one OVCF for the first time in baseline imaging, around 19.2% of them will develop a new fracture within a year. If there are two or more OVCFs present, the incidence rises to 24% (36). Based on previous studies, new fractures in adjacent vertebrae have been hypothesized to be caused by the biomechanical effect of the injected PMMA cement. The number of vertebral body fractures upon presentation (37) and bone cement distribution during surgery (38) were determined as risk factors for fractures of the adjacent vertebrae. An analysis of 247 patients who received PVP or PKP for OVCFs found that 18 patients in the PVP group and 5 patients in the PKP group experienced adjacent vertebral fractures (39).

From our perspective, the decision of whether to proceed with conservative treatment or vertebral augmentation, as well as whether to utilize kyphoplasty or vertebroplasty, is a crucial matter that will significantly impact the management of future complications. In addition, the fracture must remain unhealed in order for the intervention to be deemed necessary; thus, referral and treatment must be initiated within a restricted time period. Consequently, lengthy waiting lists for outpatient evaluation and subsequent treatment may prevent some patients from obtaining potentially beneficial care.

There are some limitations to this study. Firstly, it was a retrospective study without random sampling. The potential for selection bias and confounding in studies with a nonrandomized design cannot be ruled out. Secondly, the sample size was compromised by the low number of patients who were actually followed up. The number of patients who can be monitored closely is limited by the higher rates of morbidity and mortality among elderly people. Nonetheless, our study's strength stems from the fact that we evaluated both radiological and clinical outcomes. The study had a limited sample size, but the sample was relatively homogeneous. Considering the relative similarity in clinical efficacy between the two procedures, cost may be a useful way to choose the better option. Nevertheless, there is a need for additional investigation into the relative cost-effectiveness of PKP and PVP techniques.

CONCLUSION

Our findings support the conclusion that PKP and PVP are effective and relatively safe treatments for OVCFs. They may restore vertebral body height loss and improve the kyphosis angle and wedging index, but greater improvements are achieved with PKP. Both treatments show benefits for pain reduction without a considerable difference.

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