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Research Article

MANAGEMENT OF OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURES: UNILATERAL AND BILATERAL PERCUTANEOUS KYPHOPLASTY, A COMPARATIVE ANALYSIS

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ABSTRACT

Back discomfort and a decline in quality of life are caused by osteoporotic vertebral compression fractures (OVCF), which are frequent in elderly people with weak bones. In order to treat patients with osteoporotic spinal compression fractures, this examination aims to determine the effectiveness and risk of kyphoplasty. 18 patients with single-segment OVCFs who had percutaneous kyphoplasty at the Department of Spine Surgery were included in this retrospective analysis. They had a mean age of 75 years (range, 61-90 years), with 13 (72%) females and 5(28%) males. In 10 instances, with 7 women and 3 men, unilateral PKP had a mean age range of 61 to 87 years. There were 8 instances with bilateral PKP, with a mean age of 73.2 years (64-89 years) and 6 women and 2 men.T10, T11, T12, L1, L2 and L3are the fracture locations. Regarding gender, age, and fracture site, there was no statistically significant difference between the two groups ($P > 0.05$). The volume of bone cement injected was 5.27±0.73 mL and 6.87±0.93 mL in the unilateral and bilateral puncture groups, respectively, with statistically significant differences between the two groups (P0.01). The operative time in the unilateral puncture group was 51.60±6.64 min which was significantly lower than that in the bilateral group (66.53±9.40min), which was statistically significant (P0.01). PKP is predicted to become a mainstream procedure for the treatment of OVCFs.

Keywords: - Osteoporotic Vertebral Compression Fractures, Unilateral, Bilateral Percutaneous Kyphoplasty.

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INTRODUCTION

Osteoporosis is the most common metabolic disorder of bone which is affecting approximately 100 million people worldwide. It is predictable that at least 61 million people suffer from osteoporosis and an additional 18 million people are at significant risk for development of the disorder in India. [1]

OVCFs (Osteoporotic vertebral compression fractures) due to osteoporosis are the most common type of osteoporotic fracture, with fractures of the thoracolumbar segment being the most common.2OVCFs commonly occur in women over the age of 60 and can lead to debilitating pain and spinal deformities, as well as a significant reduction in quality and quantity of life and a significant financial burden. OVCFs are also emerging as a growing public health problem with significant socio-economic implications due to the ageing population and the severe morbidity associated with these fractures. [3]. There has not been a definitive treatment course for patients suffering from OVCF.

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Overall, managing an acute OVCF includes pain control, activity modification, patient education, and treatment of the underlying osteoporosis. After vertebral fragility fractures, the risk of fracture collapse is high and preventive measures should be used. The best evidence for prevention of further collapse is currently kyphoplasty. [4]

It uses one or two small incisions and a probe placed in the vertebral space at the fracture site. The bone is drilled and a balloon is inserted on one or both sides. The balloons are inflated with contrast (to facilitate X-ray image orientation) and expanded to the desired height, and then removed. The spaces created by the balloons are filled with bone cement. The purpose of this evaluation is to estimate the benefit and risk of both types of kyphoplasty in the treatment of patients with osteoporotic vertebral compression fractures.

MATERIAL AND METHODS

This study was approved by Ethic Committee for Clinical Research of Bharath Medical college and Hospital, Chennai. Medical records and Magnetic Resonance (MR) imaging of patients received kyphoplasty from June 2020 to December 2022 were retrospectively studied.

Inclusion criteria:

(1) patients aged ≥ 60 years; (2) confirmed diagnosis of vertebral compression fracture of < 2 weeks duration; (3) MRI shows compression fractures of the thoracic and lumbar spine with bone marrow oedema (injured vertebra with low signal on T1-weighted images and high signal on T2-weighted images).

Exclusion criteria:

(1) secondary osteoporosis (corticosteroid, endocrine disorders, and inflammatory processes); (2) patients who cannot give informed consent or have difficulty with postoperative follow-up; (3) uncorrected coagulation disorders; (4) cachexia; (5) painless OVCFs; (6) secondary malignancy of the spine; (7) fracture resulting in neurological symptoms.

In this retrospective study, 18 patients with single-segment OVCFs treated with PKP **(**percutaneous Kyphoplasty**)** at the Department of Spine Surgery. Among them, 13 (72%) were female and 5 (28.%) were male, with a mean age of 75 years (range 61–90 years). Unilateral PKP in 10 cases, 7 women and 3 men, mean 70.73 years (61–87 years). There were 8 cases of bilateral PKP, 6 women and 2 men, with a mean of 73.2 years (64–89 years).Fracture sites: T10, T11, T12, L1, L2 and L3. There was no statistically significant difference between the two groups in terms of gender, age, and fracture site ($P > 0.05$).

Surgical technique

Both groups were performed by two senior surgeons (Dr. Santhana krishnan and Dr. Chinnadurai) from the same treatment group in our department study. All PKP operations were performed in the operating room with the ability to perform immediate decompression surgery. (1) Unilateral PKP group: The patient is placed in a prone position with 2 support pads placed under the chest and pelvis to reduce pressure on the abdomen. The C-arm was adjusted so that there was no bilateral shadowing of the fractured vertebrae and the shape of the vertebral arch was symmetrical and at the same distance from the spinous process.

The puncture needle is inserted on the side of the patient where the compression is more severe or where the patient's pain is more pronounced. If there is no significant difference in pain between the two sides of the patient and the degree of compression is similar on both sides, the side that is easier for the surgeon to operate on is chosen. The puncture point is chosen to be lateral to the arch on the injured side of the vertebra (10 o'clock on the left and 2 o'clock on the right) and orthogonal to the superior border of the "cat's eye sign" of the arch projection. The puncture needle is inserted through the puncture point at an angle of 10°-20° of decubitus. When the tip of the needle is located in the anterior and middle 1/3 of the vertebral body in the lateral image and close to or slightly above the midline of the injured vertebra in the AP image, the inner core is withdrawn and the guide needle is placed.

The working cannula is placed in sequence, step by step, to establish the working channel and balloon expansion system. The injection is stopped when the vertebral body is satisfactorily repositioned and/or the balloon is expanded to the upper and lower endplates of the vertebral body, and the balloon is removed. The cement is injected under fluoroscopy along the working channel with the front end of the cement injector located in the anterior 1/3 of the vertebral body at the start of the injection, with a fluoroscopic front and side view for every 0.5–0.75 mL of cement injected. If the bone cement leaks, adjust the anterior and posterior position of the cement injector in the vertebral body, generally backing off the cement injector by 1 cm and then continuing the injection. The injection is stopped when the bone cement reaches the posterior third of the vertebral body. After the bone cement has been adequately filled, the puncture needle is slowly withdrawn and the wound is sutured: Bilateral arch puncture is performed at the same time, and the rest of the procedure remains the same as unilateral.

Routine bed rest for 4–8h after surgery. All were taken out of bed on the second day after surgery with a lumbar back brace. calcitonin and vitamin D were used postoperatively to treat osteoporosis. X-ray films were routinely performed after surgery. And Follow-up were

carried out 1 day, 1 month, and 6 months after surgery (Record the patient's VAS score, ODI score and perform a spinal X-ray).

The duration of surgery and the amount of bone cement injected were routinely recorded for both groups. Two questionnaires, the visual analogue scales (VAS score) and the Oswestry Disability Index (ODI) were used to assess pain and function at different times before and after surgery. The patients' VAS and ODI were recorded preoperatively, 1 day postoperatively, and 6 months postoperatively, respectively. For reasons such as the age and lifestyle of the patients, the options related to sexuality in the ODI score were excluded from this study. The ODI questionnaire, therefore, consists of a total of 9 items out of 45. ODI score is calculated as follows: Total score = (score/45) x 100%.

Patients were also routinely X-rayed preoperatively, 1d postoperatively and at each follow-up visit to record changes in anterior vertebral body height (AH) and changes in Cobb's angle.

SPSS 26.0 software was used for statistical processing. The measurement data conforming to normal distribution were expressed as.The *t*-test of two independent samples was used for comparison between two groups, repeated measures ANOVA was used for comparison between different time points within groups, and LSD-*t*-test was used for multiple comparisons. Comparisons of the count data between the two groups were made using the $x2$ test. $P < 0.05$ was considered a statistically significant difference.

RESULTS

All 167 patients underwent successful surgery with good postoperative outcomes and all were given clinical follow-up. No deaths were reported in this study, and all patients had a one-stage surgery with no complications such as venous thrombosis, pressure sores, or pneumonia.

Patients in both groups were followed up for at least 6-8 months. There were no significant differences between the two groups in terms of age, gender, and fracture site ($P>0.05$), indicating that the two groups were comparable.

The operative time in the unilateral puncture group was (51.60 ± 6.64 min) significantly lower than that in the bilateral group (66.53 ± 9.40 min), which was statistically significant ($P<0.01$); the volume of bone cement injected was (5.27 ± 0.73 mL) and (6.87 ± 0.93 mL) in the unilateral and bilateral puncture groups respectively, with significant differences between the two groups ($P<0.01$).

Patients' postoperative pain and ODI indices were significantly reduced in both groups after surgical treatment with PKP. After unilateral puncture PKP treatment, patients' VAS scores decreased from 8.13 ± 2.06 preoperatively to 4.27 ± 1.80 postoperatively and to 2.27 ± 0.46 at 6 months postoperatively ($P<0.01$). Similarly, VAS scores for patients in the bilateral puncture group decreased from 9.07 ± 0.88 preoperatively to 5.67 ± 0.82 postoperatively and eventually became 1.13 ± 0.52 at 6-month postoperative follow-up ($P<0.01$).

No statistical difference was found between the two groups of patients for VAS scores at all follow-ups from preoperative to postoperative ($P>0.05$). Similar results were found in the ODI index, which decreased from 86.87 ± 5.02 preoperatively to 23.07±2.58 at 6 months postoperatively in the unilateral puncture group ($P<0.01$) and from 79.47 ± 6.08 to 23.27 ± 1.87 in the double puncture group ($P<0.01$). However, the ODI indices between the two groups were not statistically significant at 1 day postoperatively, 1 month postoperatively, and 6 months postoperatively ($P>0.05$).

Table 1 Characteristics of the Study Population.

	Unilateral Puncture Group	Bilateral Puncture Group	P value
No of patients	**10**	**8**	
Age	61–87 (70.73±6.61)	64–89 (73.27±6.94)	**0.314**
Gender			**0.687**
Female	**7**	**6**	
Male	**3**	**2**	
Fracture site			
T10	**1(10%)**	**0(0%)**	
T11	**1(10%)**	**2(25%)**	
T12	**2(20%)**	**2(25%)**	
L1	**3(30%)**	**3(37.5%)**	
L2	**2(10%)**	**1(12.5%)**	
L3	**1(10%)**	**0(0%)**	

Table 2 Intraoperative Comparison of Unilateral and Bilateral Punctures.

	Unilateral punctures	Bilateral Punctures	P-value
Operation time	51.60±6.64	66.53±9.40	<0.001
Dosage of cement injected	5.27±0.73	6.87±0.93	<0.001

DISCUSSION

PKP can provide rapid pain remedy and restore stability to the vertebral body. It can aid in fracture repositioning via balloon inflation, and the injection of bone cement can lessen the sensitivity of nerve endings within the vertebral frame, and the heat released can also cause necrosis of nociceptive nerve endings, thus achieving pain relief, etc. [5] At the same time, the stagnant blood in the injured vertebrae can be drained through the working channel, reducing the pressure in the injured vertebrae and thus reducing pain. [6]

The choice of unilateral or bilateral puncture is still controversial as which can more effectively achieve clinical outcomes, restore vertebral height, improve pain, and correct kyphotic deformity. This study found out that both unilateral puncture and bilateral puncture resulted in the same clinical outcomes which correlated with John et al study in the biomechanics of human cadavers, The average strength (1.40±0.38 kN) and average stiffness (0.4387±0.2095 kN/mm) of the body in the bilateral approach group showed no statistical difference from that in the unilateral approach group (1.57±0.55 kN) and average stiffness (0.6880±0.3179 kN/mm) (P>0.05). At the same time, there was no significant difference in vertebral height recovery (P>0.05). [7]

In the present study, the unilateral puncture approach could achieve the same clinical results as a bilateral puncture. However, unilateral PKP has a slight advantage in terms of operative time, and reducing operative time is important in older patients with more underlying diseases. This outcome is in comparison to Zhang et al [8] which also confirmed that unilateral PKP can reap equal effects as bilateral and unilateral puncture has the benefit of shorter operative time and less radiation dose.

Our study found that the unilateral group had essentially only 2/3 of the operative time of the bilateral group, significantly reducing the time spent in the prone position and the length of intraoperative pain stimulation, which may help to reduce the probability of intraoperative cardiovascular risk in patients.[9]

At the same time, the amount of bone cement injected turned out to be considerably less in the unilateral pkp group comparing the bilateral group (P <0.05). However, the two groups were identical in terms of postoperative vertebral height restoration, pain relief and correction of kyphosis, indicating that there was no correlation between the clinical outcome of PKP for OVCFs and the amount of bone cement used, which is consistent with the findings of Berlemann et al. [10]
This also indicates that further scientific studies must be carried out regarding the amount of cement to be injected. There are a few controversies concerning the amount of bone cement injected; it has been advised that the greater the amount of bone cement dispersed, the better the pain remedy; however, a larger quantity of bone cement injected is more likely to trigger the chance of bone cement leakage.[11]

Furthermore, bone cement leakage is a common postoperative hassle of PKP, which may additionally result in nerve compression, and further stimulate hypersensitive reaction which in turn can result in decreased blood pressure and dyspnoea.

CONCLUSION

In conclusion, our analysis revealed that both unilateral and bilateral PKP for OVCFs are equally effective and secure. Future multi-center clinical research will provide more evidence that unilateral PKP has advantages over bilateral PKP in terms of therapeutic utility and cost. Unilateral PKP puncture is anticipated to gain widespread use in the future for the treatment of OVCFs.

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