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Analysis of Pre- and Postoperative Pain Variation in Osteoporotic Vertebral Compression Fracture Patients Undergoing Kyphoplasty

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

AB **Xin Mei***
CDE **Zhi-yong Sun***
EFG **Feng Zhou**
ADE **Zong-ping Luo**
BCE **Hui-lin Yang**

Department of Orthopaedic Surgery, The First Affiliated Hospital of Soochow University, Suzhou, Jiangsu, P.R. China

* These authors contributed equally to this work

Corresponding Authors: Zong-ping Luo, e-mail: luozp@suda.edu.cn and Hui-Lin Yang, e-mail: soochowspine@139.com

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Background: Balloon kyphoplasty (KP) has been widely applied in the treatment of elderly patients with osteoporosis vertebral compression fracture (OVCF), but there has been little research on the pain relief effect. Therefore, we performed this study of patients who received KP. The study included a set of fluoroscopy tests and follow-up evaluation, which aimed to verify the effectiveness of kyphoplasty in controlling back pain associated with OVCFs.

Material/Methods: Forty-three OVCF patients underwent kyphoplasty: 21 were allocated to an intervention group and 22 were allocated to a control group, and the 2 groups received treatment with different KP instruments. The variation of vertebral height was measured on X-ray and change of signal of MRI was recorded. The pain was assessed by VAS score and diagram, and physical function was evaluated by ODI. The complications after surgery were recorded and collated during 2 years of follow-up.

Results: The intervention group showed no significant difference on the VAS and ODI compared to the control group ($p>0.05$). There was no difference in the VAS with different degrees of radiological change ($p>0.05$). Signal change on MRI imaging was rare.

Conclusions: Kyphoplasty is a positive way to alleviate early-onset OVCF pain. The change of BME extent in the treated level is unrelated to the relief of back pain after KP.

MeSH Keywords: Kyphoplasty • Magnetic Resonance Imaging • Osteoporotic Fractures • Spinal Fractures

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Background

Kyphoplasty (KP) has been widely used in the treatment of vertebral compression fractures, which are commonly induced by osteoporosis in elderly people. Although this minimally invasive surgical method can alleviate back pain, as well as restore vertebral height and deformity, there are still problems to be solved.

The pain symptoms of patients with vertebral fractures underwent a series of changes from the onset of OVCF to the last follow-up. The pain was substantial with conservative treatment, and there was significant relief after kyphoplasty, but patients were somewhat uncomfortable at home. The restoration of OVCF consists of morphological change on imaging and evaluation of change in ability to perform activities of daily living.

The purpose of our study was to evaluate pain before and after the therapy procedure, including preoperative, postoperative, and follow-up intervals. Our research focused on the possible relationship of pain with factors such as vertebral height and bone edema.

Material and Methods

Patient selection

Between May 2010 and August 2012, 54 patients with painful osteoporotic vertebral compression fracture in our hospital were recruited, with older women accounting for over two-thirds. All had a wedged OVCF on X-ray film and severe BME on MRI film. Patients tolerated the back pain caused by OVCF for about 2 weeks to 3 months, and accepted conservative treatment including analgesics and bed rest for a while without satisfactory results. All patients agreed with the study and ethics protocols.

Procedure

Kyphoplasty (KP) was performed in accordance with the procedure described by Yang et al. [1]. Patients were sedated under general anaesthesia and kept in the prone position. Using a biplanar fluoroscopic C-arm, 2 small incisions were made over the bilateral transpedicular. After the incision, the guide wire was then penetrated to obtain bilateral transpedicular approach into the injured vertebra (at 10 O'clock and 2 O'clock). The punctured hole was gradually and carefully deepened using successively larger cannulas. The bone biopsy was obtained before introduction of bone cement. With the help of the C-arm machine, a balloon tamp was introduced slowly through the cannula and placed up to the anterior three-quarters of the vertebral body. The balloon tamp with the aid of contrast medium was then inflated slowly to restore the height of compressed bone, which then creates a void into which bone cement was injected. The inflation was stopped after reaching the optimum balloon pressure <250 psi to 300 psi (pounds per square inch) or if the balloon touched the endplates. Then, we deflated the balloon and released it. PMMA bone cement was injected slowly to fill the cavity. Once the surgery was completed, final radiographic images were taken to ensure the position of the bone cement. Finally, wound closure was performed with non-absorbable sutures, skin incision sites were sterilized, and tape was applied.

All patients were divided into 2 groups: in Group A we used a balloon manufactured by Kyphon (Sunnyvale, CA, USA), while in group B we used a balloon made by KMC (Kinetic, China). All of the surgeries of both groups were performed by the same medical team in the same medical center.

Imaging protocol

Standard AP and lateral X-ray on thoracolumbar spine segment were taken. MR imaging was performed on a 1.5T MR imaging scanner, consisting of sagittal T1-weighted, T2-weighted, and short τ inversion recovery (STIR) images.

Follow-up X-ray imaging was scheduled at 1 and 3 months and 3 years after KP. Follow-up MR imaging was taken at 3 months after KP. The extent of vertebral body height (Figure 1), according to Genant, was assessed as a percentage of the collapsed vertebral body, which is classified into normal (0–19%) minor (20–24%), moderate (25–40%), and severe (40–100%).

Assessment of relation between changes in BME and evolution of pain

Changes in BME extent after surgery were classified into less, the same, or more. To exclude possible other factors causing back pain, the relation between changes in BME in treated VCF and evolution of pain was only assessed in patients without new OVCF at 2-year follow-up. Two of these 43 patients developed new OVCF in 2 years, with 1 in each group.

Clinical follow-up

All of the patients received balloon kyphoplasty and completed 3-year consecutive follow-up after surgery. The entire procedure was approved by the local hospital's ethics committee.

Before KP and at every imaging follow-up visit, a visual analog scale (VAS) for pain was scored from 0 to 10, with 0 representing no pain and 10 representing the worst pain experienced in the patient's life. In addition, patients were asked to mark the pain point on a waist outline diagram to identify the pain

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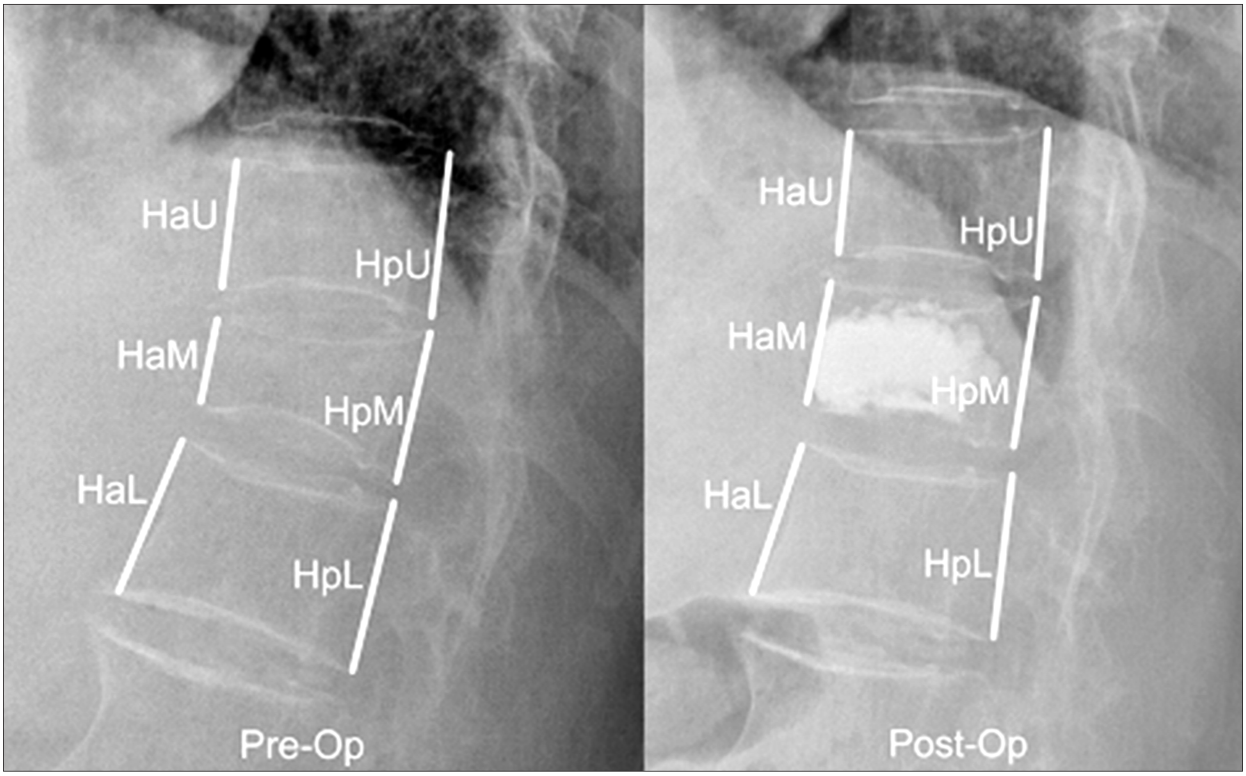

Figure 1. Methods of measurement of injured vertebral height and normal adjacent vertebral margins (anterior and posterior) prior to the BKP procedure includes: (1) HaM=[(HaU+HaL)/2]×100%, (2) HpM=[(HpU+HpL)/2]×100%. The calculated results are the average vertebral heights before the surgery, where "H" represents height, "a" represents anterior vertebral margin, "p" represents the posterior margin of vertebra, "M" represents fracture level, "U" represents upper level, and "L" represents lower level.

location (Figure 2). Changes in VAS were assessed by subtraction of scores at different follow-up intervals. Differences in location of pain at every follow-up period were coded as treated vertebral level, adjacent level, and paraspinal.

The pain symptom with its variation of each patient was analyzed at all time points. In the initial stage before surgery, all of the participants with OVCF were asked to describe their pain. First, the investigation of sensation problem in this study was confined to the back ache caused by recent OVCF, which excludes any other uncomfortable symptoms caused by degenerative spine disease. When OVCF back pain was confirmed, the detail of the pain symptom was further analyzed to include the extent of pain assessed by a visual analog scale (VAS), which was scored from 0 to 10, with 0 representing no pain and 10 representing the worst pain experienced in the patient's life.

Statistical analysis

Patient and imaging characteristics were evaluated in groups A and B. Patient characteristics in both groups were compared to evaluate other possible differences. All measurement data, including VAS score, ODI score, anterior, and middle and posterior vertebral heights, are expressed as mean ±SD. Preoperative, postoperative, and follow-up data were compared using a paired *t* test. We assessed the relationship between changes in vertebral height and evolution of pain. Patients with mild, moderate, and severe vertebral collapse extent of treated OVCF were compared with each other. The paired *t* test was used to compare changes in VAS, and the Wilcoxon paired sample test was used to compare type of vertebral height restoration used before and after KP. The relationship between changes in pain extent, sensation, and location was evaluated by linear regression analysis. Differences between characteristics in 2 groups were tested with the chi-square test (for categorical variables) or unpaired *t* test (for continuous variables).

Results

Forty-three patients fulfilled all of the study criteria, and 58 vertebrae of these 43 patients were diagnosed as OVCF. Of these 58 OVCF, 53 demonstrated BME on MRI and were subsequently treated with KP. All 53 treated vertebrae had intact posterior walls, pedicles, and posterior arches. In 9 patients, multiple VCF were treated: 8 patients with 2 VCF and 1 patient with

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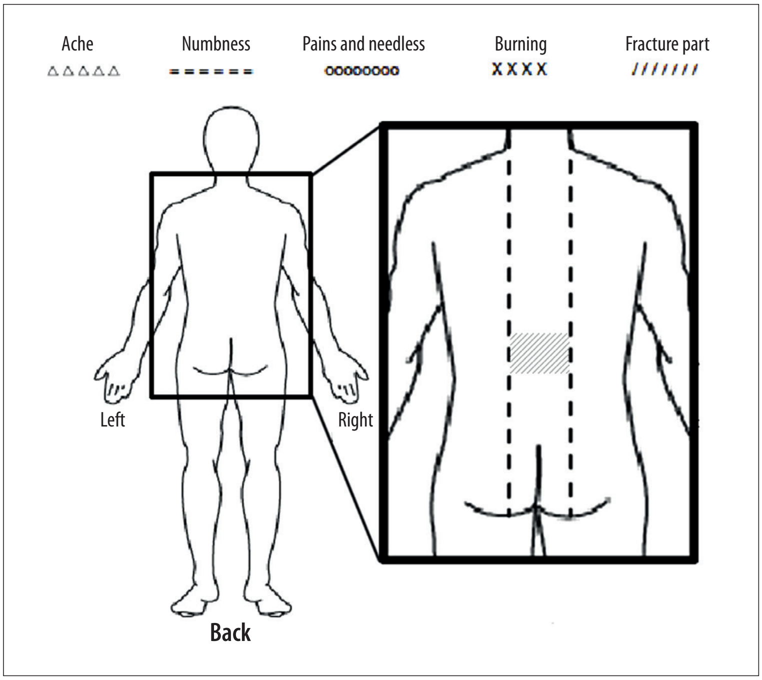

Figure 2. To determine the location of the back pain, the spine area was divided into thirds along the frontal axis. The thirds were defined as vertebral area in the middle, and paravertebral area on both sides along the painful level. Patients were asked to mark their pain points on a waist outline diagram to identify the pain location. After the back area was segmented into middle and both sides, the primary location of the pain relative to the delineated thirds was documented. In the event that the pain area occupied more than one-third, or extended beyond the delineated third, the segment with the greatest pain sensation was noted as the primary location.

Table 1. Patient demographics and medical information.

	All patients	Group A	Group B
Number	43	21	22
Age	67	67	69
Gender			
Male	7	4	3
Female	36	17	19
BMD value (T-score)	2.5±0.6	2.5±0.7	2.6±0.5
Hospital stay (day)	9.7±3.5	9.8±3.6	9.6±3.3
Number of treated vertebral fracture	53	25	28
Number of refracture	2	1	1

3 VCF. Vertebral levels treated by KP ranged from T5 through L5. No technical failures or procedural morbidity occurred.

Characteristics of the total study population and both subgroups are summarized in Table 1.

The mean preoperative VAS score was 7.6±1.4. After surgery, the mean VAS score decreased to 2.4±1.1, which means significant pain relief was achieved in all patients. The result of pain alleviation was steady at follow-up intervals. The average score changed slightly at 2-year follow-up. Similar effects were seen from the ODI scores. The ODI scores decreased from 74±13 before surgery to 34±9 after surgery, 30±9 at 3 months, and 31±8 at the last follow-up. Statistically significant differences were seen between the preoperative evaluation and each postoperative follow-up assessment (Table 2).

We also found significant improvement in the treated vertebral body height restoration between the preoperative and postoperative assessment. The mean postoperative vertebral body height (4.3±1.3 cm) increased compared with preoperative heights (5.0±1.4cm). There were no significant differences between the postoperative and follow-up data (Table 3).

Bone marrow edema evolution

Changes in BME in treated VCF in 43 patients at 3 months after KP were displayed by MRI. Preoperative MRI revealed moderate

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Table 2. Preoperative and follow-up evaluation in the 2 groups.

	Group A		Group B	
	VAS	ODI	VAS	ODI
Pre-op	7.3±1.6	72±13	7.8±1.1	76±13
1 mon	2.3±1.2	34±8	2.5±1.0	34±9
3 mon	2.4±1.4	29±8	2.2±1.1	32±9
3 year	2.5±1.2	31±8	2.2±1.1	31±8

Table 3. Vertebral height restoration according to Genant classification.

Compression degree	Pre-operation		Post-operation		3-year follow-up	
	No.	VAS	No.	VAS	No.	VAS
Mild	16	6.9±1.7	25	2.1±1.2	25	2.3±1.2
Moderate	15	7.8±1.4	11	1.4±1.2	11	1.2±0.8
Severe	12	8.1±1.5	7	2.8±0.9	7	2.4±0.7

and severe BME in most patients. There was no significant decrease in short-term BME. Only 1 case (Figure 3) had less BME at 3 months after kyphoplasty. Postprocedural MRI showed no severe BME. The bright rim sign surrounding the cement on STIR-weighted images represents a necrotic area as a result of heat-related local vertebral ischemia. In this study, bright rim sign was not found in any postoperative MRI.

Pain variation

After excluding any pain due to OVCFs, all 43 patients were analyzed. Back pain occurred in all fracture levels of the patients before the operation, with the middle spine area having the most significant pain. Eight patients stated they still had back pain on both sides at 1 month after surgery, without middle-area pain. This kind of pain was constant in some of the patients at follow-ups. At 3-month follow-up, 9 patients had back pain on both sides, of which 3 cases were new and 2 cases were relieved. At 3-year follow-up, there were still 13 patients with back pain on both sides (Table 4).

Complications

After the operation, none of the patients complained of any neurologic symptoms. The postoperative AP and lateral films were used to verify cement leakage. Anterior vertebral body leakage was found in 6 cases and intervertebral cement leakage was found in 2 cases. No cement leaked into the spinal canal. Two cases experienced subsequent fractures. One patient chose PKP again and the other chose conservative treatment.

Discussion

Postoperation VAS was significantly lower at all follow-up times compared with initial values (P<.001), and the VAS change became evident in the first 3 months after kyphoplasty. Then, the scores remained constant at further follow-up intervals. The VAS did not increase much at 3-month follow-up or at 3-year follow-up. There was no significant correlation between the extent of pain and the vertebral compression height ratio. The VAS score, despite bias resulting from subjective assessment, is a very valuable evaluation tool that is easy to use for researchers, easily understood by patients, and provides instant results for data analysis. Before the operation, the vertebral height can be divided according to the compression ratio, and diagnosis of new OVCF is based on BME signal on MRI. After surgery, the VAS score decreased simultaneously, regardless of inconsistency of the vertebral height restoration for different patients [1–6].

Magnetic resonance tomography is another way to verify the vertebral fracture, and it has some specific advantages. MRI is the most precise method to prove new vertebral fracture, with high sensitivity and specificity [7]. It is the best choice to determine if the wedged vertebra is caused by recent lesions, which include trauma, osteoporosis, or different kinds of tumors [8], and it is easy to detect if the intact vertebrae contain lesions. The typical example of fresh vertebral compression fracture, which include traumatic and pathological induced, on MRI is shown as a hypointense signal intensity on T1-weighted images and a hyperintense signal intensity on T2-weighted and STIR sequences in the vertebral body area. The specific characteristic of MRI is the BME signal, which can be detected sensitively in sagittal STIR imaging in acute vertebral

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Figure 3. Female patient, 58, L1 and L3 OVCF fracture, and received KP. One month after the operation, the MRI showed significantly less BME than before. (**A**) Preoperative, (**B**) 1-month postoperative.

Table 4. Primary pain location and pain extent investigation.

	Fracture level		Adjacent level		Para spine	
	Primary	VAS	Primary	VAS	Primary	VAS
Pre-op	43	7.6±1.4	–	–	–	–
1 mon	35	2.3±0.9	–	–	8	2.6±1.3
3 mon	34	2.4±1.2	–	–	9	2.8±1.4
3 year	28	2.5±1.0	2	2.6, 2.8	13	3.0±1.5

fractures [9–12]. Also, bone marrow pathologies can be detected in T1-weighted sequences, shown as a low signal [13].

In our study, the 3-month postoperative MRI scan showed no new bone edema in most of the patient, and no BME extent changes. Only 1 case showed less extent of BME after kyphoplasty. The patients with decreased BME extent in treated VCF compared with patients with no change in BME extent had no difference in mean decrease of VAS at each follow-up time interval after KP.

Little is known about the mechanism of variance of BME extent of untreated vertebral compression fractures. Compared with natural healing, we found that BME signals in treated OVCF remained for a much longer time: the average first follow-up time is 1 month after kyphoplasty, when the MRI was taken to evaluate the effect of the operation. All cases showed BME on MRI except for 1. The mechanism by which KP affects vertebral fracture healing and evolution of BME has received little research attention, and we had to find evidence from analogous vertebroplasty research. Accordingly, the BME decreased

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gradually and completely disappeared after 3 months in 35% of patients, at 6 months in 54%, and at 12 months in 71% [10,12]. Other studies using bone scintigraphy reported increased uptake in up to 41% of untreated VCF, persisting for as long as 1 year after the initial fracture.

BME signal in OVCF on MRI before the operation is considered to be related to the pain symptoms. Even so, the relationship between presence of BME in treated VCF after kyphoplasty and pain evolution in our study gave us a more confused result. Because of the cement augmentation intervention, it was impossible to determine the association.

There were obvious changes in sensation and location of back pain after KP. Previous studies [3,6,14–22] have assessed the effect of KP on pain relief. This effect is long-lasting unless a new OVCF occurs. Most research and comments about back pain after KP have focused on the relationship between refracture and pain, which mainly considers that pain after surgery is caused by adjacent vertebral fracture [23] or is just a same-level refracture. It should be noted that there is a slight difference between pain relief and pain disappearance after KP; the former is a real consequence in most investigations and the latter is just an ideal that is hard to achieve. Additionally, there was a slight pain increase at follow-up intervals compared to post-surgery in other research [24], although the difference was not statistically significant. This is explained by nerve distribution [25,26]. The pain result from OVCF is composed of at least 2 parts: the pain caused by the fracture site and the pain induced by soft-tissue injury (mostly by paraspinal muscles). KP immediately relieves fracture site pain, but it does not reduce soft-tissue pain. The tolerance of back muscles is altered by the change in vertebral body height and angle after surgery.

Conclusions

Kyphoplasty is an effective way to alleviate new-onset OVCF pain. The change in BME extent in the treated level is unrelated to the relief of back pain after KP. The remaining pain after KP is not caused by fractured vertebrae, but rather by paravertebral muscles.

Conflict of interest

None.

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