Randomized Control Trial

Local Anesthetic and Steroid Injection to Relieve the Distal Lumbosacral Pain in Osteoporotic Vertebral Compression Fractures of Patients Treated with Kyphoplasty

Fanguo Lin, MD, Yuye Zhang, MD, Tao Wu, Yanping Niu, MD, Peng Su, MD, Jun Hua, MD, and Yongming Sun, PhD*

From: Department of Orthopedics, The Second Affiliated Hospital of Soochow University, Suzhou, China

Address Correspondence: Yongming Sun, PhD Department of Orthopedics, The Second Affiliated Hospital of Soochow University No. 1055, Sanxiang Road Suzhou, 215000, China E-mail: sunyongmingdo1@163.com

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Background: Percutaneous kyphoplasty (PKP) is widely used in osteoporotic vertebral compression fractures (OVCF). But in some patients, distal lumbosacral pain (DLP) persists even after treatment and affects their quality of life.

Objective: To investigate the effectiveness of local anesthetic and steroid injection in improving DLP after PKP.

Study Design: A prospective, randomized, and controlled clinical trial.

Setting: The study was carried out in a university hospital.

Methods: A total of 150 patients were included in this study and randomly divided into 2 groups of 75 patients each. Patients in the control group (PKP) underwent PKP, and those in the observation group (PKP + LAI) received an injection of lidocaine + triamcinolone acetonide suspensions during the surgery. The visual analog scale (VAS) of the fracture site, Oswestry disability index (ODI), and the rate of patients with lower back pain were compared between the 2 groups at 1 day, 3 days, 1 week, 1 month, and 3 months after the surgery.

Results: One hundred thirty-nine patients completed the entire postoperative follow-up schedule, with 70 patients in the PKP group and 69 cases in the PKP + LAI group. The VAS and ODI in the PKP + LAI group were significantly lower than those in the PKP group 1 day, 3 days, 1 week, and 1 month after the surgery; there was no significant difference 3 months after the operation. The rate of patients with lower back pain in the PKP + LAI group 1 day, 3 days, and 1 week after the operation was significantly lower than that in the control group; there was no significant difference 1 month and 3 months after the operation.

Limitations: The number of cases was small, and the follow-up time was short.

Conclusion: Local anesthetic and steroid injection improved the short-term clinical outcome of PKP for OVCF, which will enhance the confidence of patients in performing out-of-bed activities and functional exercises early after the operation.

Key words: Local anesthetic and steroid injection, distal lumbosacral pain, osteoporotic vertebral compression fractures, kyphoplasty

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Osteoporotic vertebral compression fractures are common in clinic (1,2). Percutaneous kyphoplasty or percutaneous vertebroplasty (PVP) is often used to treat osteoporotic vertebral compression fractures (OVCF) (3,4). Surgery can reconstruct spinal stability and immediately reduce lumbar pain (5,6). However, it has been observed that in some cases the pain caused by OVCF is not limited to

the level of the vertebral fracture but refers to areas away from the injured vertebrae, such as the back, peri iliac crest, or hip. This pain is called distal lumbosacral pain (DLP) (7-9). PKP or PVP can quickly relieve local pain and most DLP. But some patients still experience postoperative residual lumbar pain, which can hamper their quality of life.

Local anesthetic injections are widely used to treat chronic strain diseases and can significantly relieve the pain associated with tendon attachment points (10,11). It is also widely used in the treatment of osteoarthritis (12,13). A limited number of studies have shown that local anesthetic injections can improve distal pain associated with OVCF (14-18). However, to the best of our knowledge, no studies have used local anesthetic and steroid injection to the attachment point of interspinous ligaments in treating DLP with OVCF. The purpose of this study was to explore whether this mixture of steroid with local anesthetic injected into the vertebral interspinous attachments from L3- sacrum can alleviate DLP faster than kyphoplasty alone and improve early patient function.

Methods

Patient Population

This study was approved by the Ethics Committee of the university hospital. Patients with OVCF in our hospital from January 2020 to April 2021 were enrolled in this study. All patients underwent anteroposterior and lateral x-ray examination, CT 3-dimensional reconstruction examination, and MRI examination prior to the surgery. Inclusion criteria for this study were as follows: ① x-ray showed single thoracic or single lumbar fracture; ② T value of -2.5 or less on dual-energy x-ray imaging; ③ back pain because of injury caused by minimal trauma such as falling to the ground, sprain, or lifting heavy objects in one week; ④ provision of informed written consent. Exclusion criteria were: ① pathological fractures; ② presence of nerve injury; ③ visual analog scale (VAS) score < 5. A total of 150 patients were enrolled in this study. All patients were given oral nonsteroidal anti-inflammatory drugs (NSAIDs) therapy after admission. The patients were randomly allocated to 2 groups with 75 cases in each group (PKP group and PKP + LAI group). The group allocations were concealed in sealed opaque envelopes that were opened only after the patients were enrolled. In the sealed opaque envelopes, computer random numbers were included. Patients did not know which group they were assigned to.

Surgical Techniques

PKP group

After successful general anesthesia, the patient was placed in the prone position. The pedicle on both sides of the fractured vertebral body and the L3-L5 spinous process were located by C-arm fluoroscopy and were marked on the skin. The attachment points of the interspinous ligament are just above and below the spinous process. PKP was performed via a bilateral transpedicular approach. When the bone cement (Mendec, Italy) reached the late stage of wire drawing, it was pushed into the vertebral body through bilateral working cannulas under the guide of C-arm fluoroscopy.

2.2 PKP+LAI group: A suspension of lidocaine (5 mL: 100 mg) + triamcinolone acetonide (5 mL: 50 mg) was prepared before the operation. When the instrument nurses prepared the bone cement, the operator injected prepared lidocaine + triamcinolone acetonide suspensions in the places where the cannula was inserted (1 mL per injection point). Subsequently, the attachment points of the superior and inferior interspinous ligaments of the fractured vertebral body, lumbar 4, and lumbar 5 were injected with 1 mL suspensions per injection point (Fig. 1).

Postoperative Management and Follow-Up

The patients were able to get out of bed one day after the surgery. The diffusion of bone cement was evaluated by x-ray. All patients received anti-osteoporosis therapy after the surgery. Pain at the fracture site, dysfunction, and lower back pain were evaluated 1 day, 3 days, 1 week, 1 month, and 3 months after the surgery. The pain at the fracture site was evaluated by VAS, the degree of dysfunction was evaluated by ODI, and the lower back pain was evaluated by VAS ≥ 3. All the measurements were performed independently by 3 spine surgeons with 5 years of experience; the surgeons did not know which group the measured patients were in.

Data Analysis

All statistical tests were conducted using SPSS version 20.0 (IBM Corporation, Armonk, NY). Continuous variables were presented as mean ± standard deviation. A 2-sample t test was used to assess the VAS, ODI differences between PKP and PKP + LAI. Chi-square test was used to compare the ratios of patients with lower back pain (VAS ≥ 3) between PKP and PKP + LAI. $P < 0.05$ was considered significant.

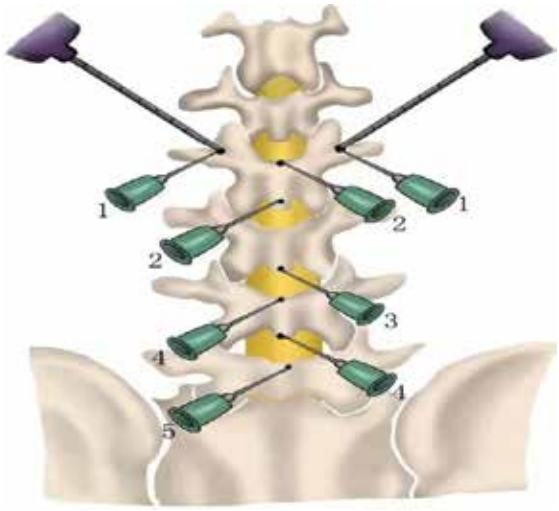

Fig. 1. *A total of 8 points were injected with lidocaine + triamcinolone acetonide suspensions (1 mL per injection point) 1. The surface of bone cortex at the puncture site for vertebroplasty; 2. Attachment points of the superior and inferior spinous ligaments on the vertebral spinous process; 3. Attachment point of the interspinous ligament along the lower edge of the third lumbar spinous process; 4. Attachment points of the superior and inferior interspinous ligament on the fourth lumbar spinous process; 5. Attachment point of the interspinous ligament above the fifth lumbar spinous process.*

Results

Of the 150 eligible patients for this study, 139 patients completed the postoperative follow-up schedule. There were 70 cases (mean age: 73.80 ± 6.35 years; female: 58 and male: 12) in the control group and 69 cases (mean age: 72.62 ± 10.39 years; female: 56 and male: 13) in the PKP + LAI group. The demographic characteristics and surgical information of patients within both groups are summarized in Table 1. No significant differences were observed in the genders, ages, BMI, or surgical levels between the 2 groups ($P > 0.05$, Table 1). Surgery was successful in all patients, and none of the patients experienced lower-limb deep venous thrombosis, pulmonary embolism, or spinal nerve injury. All the patients perform out-of-bed activities one day after operation. All the patients had significant relief of back pain after the operation. The level of DLP was also within the tolerable range of patients. So the treatment after operation was similar in both groups. The postoperative VAS and ODI scores in each of the 2 groups were lower than those before surgery ($P < 0.05$, Table 2, Fig. 2), and the rate of patients with DLP after the surgery was also significantly reduced in each group ($P < 0.05$, Table 3). The VAS scores of fracture site pain in the PKP + LAI group were significantly lower than those in the control group 1 day (1.45 ± 0.65 vs 2.10 ± 0.93, $P < 0.05$, Table 2, Fig. 2), 3 days (1.45 ± 0.65 vs 1.97 ± 0.90, $P < 0.05$, Table 2, Fig. 2), 1 week (1.19 ± 0.65 vs 1.81 ± 0.80, $P < 0.05$, Table 2, Fig. 2) and 1 month (0.86 ± 0.65 vs 1.19 ± 0.77, $P < 0.05$, Table 2, Fig. 2) after surgery. The ODI scores of fracture site pain in the PKP + LAI group were significantly lower than those in the control group 1 day (24.52 ± 3.23 vs 35.93 ± 2.10, $P < 0.05$, Table 2, Fig. 2), 3 days (23.25 ± 3.05 vs 38.09 ± 2.56, $P < 0.05$, Table 2, Fig. 2), 1 week (16.54 ± 2.39 vs 34.50 ± 3.05, $P < 0.05$, Table 2, Fig. 2) and 1 month (14.12 ± 2.15 vs 15.80 ± 2.03, $P < 0.05$, Table 2, Fig. 2) after surgery. There was no significant difference in VAS score and ODI score of fracture site pain between the 2 groups 3 months after the surgery ($P > 0.05$, Table 2, Fig. 2).

A total of 48.20% of patients had DLP before the surgery; there was no significant difference in the location of DLP between the 2 groups ($P < 0.05$, Table 3). The rate of patients with DLP in the PKP + LAI group was significantly lower than that in the control group 1 day (4.35% vs 18.57%, $P < 0.05$, Table 3), 3 days (4.35% vs 18.57%, $P < 0.05$, Table 3), and 1 week (4.35% vs 18.57%, $P < 0.05$, Table 3) after the surgery. The rate of patients with L3-L5 attachment points of the interspinous ligaments pain in the PKP + LAI group was significantly lower than that in the control group 1 day (0 vs 14.29%, $P < 0.05$, Table 3), 3 days (0 vs 14.29%, $P < 0.05$, Table 3), 1 week (0 vs 14.29%, $P < 0.05$, Table 3), and 1 month (0 vs 5.71%, $P < 0.05$, Table 3) after the surgery. There was no significant difference in the rate of patients with DLP between the 2 groups 1 month and 3 months after the surgery ($P > 0.05$, Table 3).

Table 1. *Summary of demographic characteristics and surgical related information of both groups.*

	PKP (n = 70)	PKP + LAI (n = 69)	*P*
Mean age (yrs) (x ± s)	73.80 ± 6.35	72.62 ± 10.39	0.804
Female gender (%)	58 (82.9)	56 (81.2)	0.794
BMI	23.29 ± 2.64	23.14 ± 3.03	0.771
Surgical levels (%)			0.935
T1-T9	5 (7.1)	5 (7.2)	
T10-L2	61 (87.2)	59 (85.6)	
L3-L4	4 (5.7)	5 (7.2)	

*$P < 0.05$ **$P < 0.01$, BMI; body mass index, PKP; control group, PKP + LAI; observation group

Table 2. *Changes in VAS and ODI of back pain pre- and postoperative.*

	Preoperative	1 Day Postoperative	3 Days Postoperative	1 Week Postoperative	1 Month Postoperative	3 Months Postoperative
VAS (x ± s)						
PKP (n =70)	7.59 ± 1.15	2.10 ± 0.93	1.97 ± 0.90	1.81 ± 0.80	1.19 ± 0.77	0.66 ± 0.63
PKP + LAI (n = 69)	7.8 0± 1.01	1.45 ± 0.65	1.45 ± 0.65	1.19 ± 0.65	0.86 ± 0.65	0.49 ± 0.53
P	0.251	0.000**	0.000**	0.000**	0.007**	0.1
ODI (%, x ± s)						
PKP (n = 70)	73.99 ± 3.72	35.93 ± 2.10	38.09 ± 2.56	34.50 ± 3.05	15.80 ± 2.03	13.69 ± 1.79
PKP +LAI (n = 69)	74.94 ± 3.28	24.52 ± 3.23	23.25 ± 3.05	16.54 ± 2.39	14.12 ± 2.15	13.59 ± 1.85
P	0.11	0.000**	0.000**	0.000**	0.000**	0.767

*$P < 0.05$ **$P < 0.01$, VAS; visual analog scale, ODI; Oswestry disability index, PKP; control group, PKP + LAI; observation group

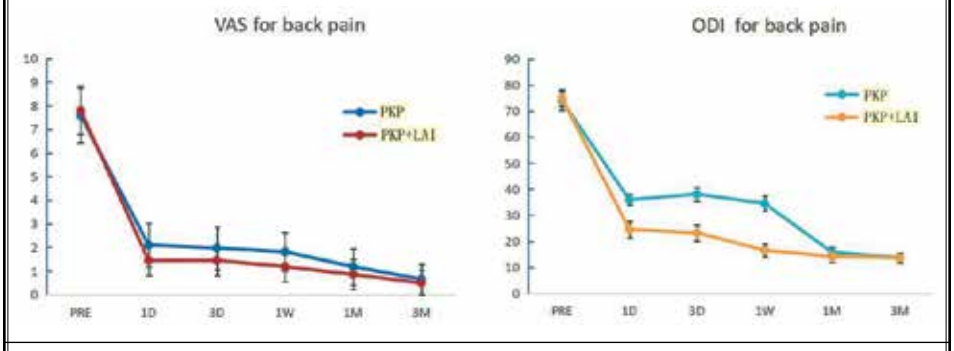

Fig. 2. *Changes in VAS and ODI scores for back pain pre- and postoperative. The VAS and ODI scores of pain at the fracture site in the observation group (PKP + LAI) were lower than those in the control group (PKP) 1 day, 3 days, 1 week, and 1 month after the surgery. There was no significant difference in VAS score and ODI score of fracture site pain between the 2 groups 3 months after operation.*

Discussion

In our study, we identified that DLP reduces ODI and is improved by steroid/LA injections. ODI is improved by 10 points which is clinically significant. Patients can rehabilitate sooner as well as avoid medications that may lead to complicating side effects.

PKP or PVP is a safe and effective treatment and is significantly better than conservative treatment in reducing long-term mortality (19,20). However, PKP or PVP also has shortcomings such as intraoperative bone cement leakage (21), postoperative adjacent vertebral fracture (22,23), and postoperative lumbar pain (24-27). Common causes of postoperative lumbar pain are sagittal imbalance, recurrent fracture, facet-mediated pain, and postural fatigue syndrome (28). It has been observed that in some cases, the pain caused by OVCF is not limited to the level of vertebral fracture but refers to areas away from the injured vertebrae, such as the back, the peri iliac crest, or the hip. This pain is called DLP (7-9). Due to differences in the criteria used to identify DLP, the incidence of DLP reported in the literature ranges from 17.2% to 46.2% (23). In our study, 48.20% of all patients had DLP before the surgery, and 64.2% of these patients had DLP mainly at L3-L5 attachment points of the interspinous ligaments (Table 3). Niu et al considered that thoracolumbar vertebral fractures with accompanying surrounding soft tissues and facet joint injury may stimulate the sympathetic ganglion or dorsal ramus of T11-L2, which in fact leads to the referred DLP. The orientation of the facet joints changed after PKP, which alleviated the irritation to the dorsal ramus, which was the main reason for the distal pain relief (8). We speculate that when patients suffer from low-energy injuries, the first protective response is through soft tissues, such as body muscles and ligaments, which when stressed, resist external forces and protect the bones. Fractures typically occur when the critical point of soft tissue protection is exceeded. Hence, OVCF caused by low-energy impact is usually accompanied by muscle and soft tissue injuries. The lower lumbar spine has a large range of motion, and the injury of muscles, ligaments, and other soft tissues is severe. Therefore, when the lumbar spine is injured, the muscles and soft tissues of the lower lumbar spine are the first to be damaged, which in our opinion, is the cause of DLP in patients with OVCF.

Some studies have confirmed that local anesthesia can significantly relieve lower back pain (14,15). There-

Table 3. *Total patients with distal lumbosacral pain and location of distal lumbosacral pain pre- and postoperative.*

	Preoperative	1 Day Postoperative	3 Days Postoperative	1 Week Postoperative	1 Month Postoperative	3 Months Postoperative
Patients with DLP						
PKP (n = 70)	34(48.57%)	13(18.57%)	13(18.57%)	13(18.57%)	4(5.71%)	1(1.43%)
PKP+LAI (n = 69)	33(47.83%)	3(4.35%)	3(4.35%)	3(4.35%)	1(1.45%)	1(1.45%)
P	0.93	0.009**	0.009**	0.009**	0.177	0.992
Location of DLP: L3-L5 attachment points of the interspinous ligaments						
PKP (n = 70)	22(31.43%)	10(14.29%)	10(14.29%)	10(14.29%)	4(5.71%)	1(1.43%)
PKP + LAI (n = 69)	21(30.43%)	0	0	0	0	0
P	0.899	0.001	0.001	0.001	0.044	0.319
Location of DLP: iliac crest						
PKP (n = 70)	5(7.14%)	1(1.43%)	1(1.43%)	1(1.43%)	0	0
PKP + LAI (n = 69)	4(5.80%)	1(1.45%)	1(1.45%)	1(1.45%)	0	0
P	0.747	0.992	0.992	0.992	-	-
Location of DLP: hip						
PKP (n = 70)	7(10%)	2(2.86%)	2(2.86%)	2(2.86%)	0	0
PKP + LAI (n = 69)	8(11.60%)	2(2.90%)	2(2.90%)	2(2.90%)	1(1.45%)	1(1.45%)
P	0.762	0.988	0.988	0.988	1.022	1.022

*$P < 0.05$ **$P < 0.01$, DLP; distal lumboscacral pain, PKP; control group, PKP + LAI; observation group

fore, it is recommended to apply analgesics to the site of fracture at the time of PKP or PVP (16-18). A study by Bao et al revealed that implanting 5 mL of 1% lidocaine hydrochloride into the vertebral body can effectively alleviate the pain during and after the surgery (16). Ueshima et al considered that bilateral thoracolumbar interfascial plane (TLIP) block combined with general anesthesia provides more effective perioperative pain relief than that provided by general anesthesia alone in patients who undergo lumbar spinal surgery (29). Mao et al found that traditional local anesthesia combined with vertebral anesthesia can effectively alleviate the perioperative pain following PKP (17). Li et al (18) suggested that PKP or PVP should be used with facet joint block at the same time. These studies mainly focus on the treatment of the local fractured area. Local injection of drugs can relieve the pain in the distal region of partial innervation. However, there are abundant sources of innervation in the lower back. The application of local anesthetics for a peripheral area of fracture cannot completely alleviate the lower back pain. Meanwhile, there is a large amount of activity in the lower back, especially at L3-L5 attachment points of the interspinous ligaments. There is a high probability of local interspinous ligament damage. Therefore, this study used local anesthetic and steroid injection at the puncture site and the attachment point of lower lumbar interspinous ligaments in order to achieve satisfactory results.

In our study, 18.57% of the patients in the control group had DLP after surgery, and 76.92% of these patients experienced DLP mainly at L3-L5 attachment points of the interspinous ligaments (Table 3). We believe that after the injury, the pain is most severe at the site of the fracture, which may shadow the pain in the lower lumbar muscles and soft tissues. The pain at the site of the fracture is significantly relieved after the surgery, which results in patients becoming more aware of DLP, and thus affects their quality of life. We believe that the interspinous ligaments are a source of acute and chronic low back pain in the lower lumbar levels. In the PKP + LAI group of this study, lidocaine + triamcinolone acetonide suspensions were injected into the attachment points of the interspinous ligaments above and below the fourth lumbar spinous process, above the fifth lumbar spinous process, and below the third lumbar spinous process, which resulted in a significantly lower incidence in the symptoms of postoperative lower back pain. The effects of local anesthetic injections combined with PKP treatment in our study was similar to that of simple PKP treatment 3 months after the operation. The visible early relief of lower back pain and even a small reduction of the VAS score can significantly enhance the patient's satisfaction with the treatment outcome. This improves their ability to perform out-of-bed activities with ease and enhances their quality of life.

There are also some limitations in this study: The number of cases was small, the follow-up time was short, and the study did not include a placebo group. More cases should be included in future studies, and the follow-up time should be longer. Meanwhile, triamcinolone acetonide extended release was widely used to manage pain associated with knee osteoarthritis, and was designed to limit the rapid efflux from the joint and increase the duration of pain relief (30). If triamcinolone acetonide extended-release was used in this study, whether it increases the duration of pain relief needs to be further studied.

Conclusion

Compared with simple PKP, the addition of a local anesthetic and steroid injection can reduce the intensity of early postoperative DLP in patients with OVCF, and thus enhance their confidence in performing out-of-bed activities and functional exercises soon after surgery. Therefore, this approach could prove to be highly effective in clinical practice and needs to be further investigated and actively applied.

Contributors

All authors contributed significantly to the planning, conduct, and reporting of the work described in the paper. Fanguo Lin and Yuye Zhang contributed equally to this paper. Fanguo Lin and Yuye Zhang are joint first authors.

Ethics Approval

Ethics Committee of Second Affiliated Hospital of Soochow University.

Data Availability Statement

Our data have not been deposited in a repository but are available upon reasonable request to the corresponding author.

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