Randomized Controlled Trial

The Effect of Medial Branch Block on Postoperative Residual Pain Relieve After Percutaneous Kyphoplasty: A Randomized Controlled Trial With 12-Month Follow-up

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Background: Percutaneous kyphoplasty (PKP) is a minimally invasive technique, and effective treatment, for an osteoporotic vertebral compression fracture (OVCF). Residual back pain is the most common complication of PKP. Medial branch block (MBB) is a treatment option for painful OVCF, it can break the vicious cycle to release short- or long-term pain.

Objectives: We aimed to determine the effects of MBB on postoperative residual back pain in OVCF patients after PKP surgery.

Study Design: A randomized, controlled, single-center trial.

Setting: Medical university center and local hospitals.

Methods: A total of 198 patients were recruited and randomly assigned to either the MBB or Non-MBB group. In the MBB group, patients received MBB during PKP surgery, the injection contained a mixture of lidocaine and budesonide. The Non-MBB group was injected with normal saline in the target nerve area during PKP surgery. The primary outcome was back pain assessed by the Visual Analog Scale (VAS), and residual back pain was defined as a VAS score greater than or equal to 4. The secondary outcomes included physical function assessed by Patient-Reported Outcome Measurement Information System Physical Function (PROMIS PF) and satisfaction with surgery was assessed using the S6 satisfaction scale. All parameters were measured at baseline, 1 day, 1 week, 1 month, 3, 6, and 12 months after the intervention.

Results: A total of 179 patients, including 91 patients in the MBB group and 88 patients in the Non-MBB group, were included for a comprehensive assessment. The VAS score in the MBB group was significantly lower than in the Non-MBB group within a one-month follow-up. PROMIS PF score in the MBB group was significantly higher than in the Non-MBB group within a one-month follow-up. The incidence of residual back pain in the MBB group was lower than the Non-MBB group within a one-month follow-up. The MBB group had a significantly higher satisfaction rate compared with the Non-MBB group at final follow-up.

Limitations: Firstly, patients are from a single institution and the sample size is small. Secondly, some of the potential factors which may lead to back pain, such as infection, new symptomatic compression fracture, and serious cement leakage, did not occur. Thirdly, the conservative treatment group is not included. Finally, we were unable to determine individual differences in pain tolerance.

Conclusions: MBB can effectively relieve back pain and reduce the incidence of residual back pain in OVCF patients after PKP surgery. Besides, it can also significantly improve postoperative physical function and patients' satisfaction with treatment.

Key words: Osteoporotic vertebral compression fracture, percutaneous kyphoplasty, residual back pain, medial branch block

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An osteoporotic vertebral compression fracture (OVCF) (1) is the most common and most serious complication in elderly patients with osteoporosis, which can lead to severe low back pain, movement limitation, and low back deformity, thereby reducing the quality of life of the patients. Percutaneous kyphoplasty (PKP) (2) is a minimally invasive technique that includes the injection of polymethyl methacrylate into the compressed vertebral (3) to stabilize the fracture, effectively restore bone height, relieve pain, and improve patients' mobility.

Although PKP has shown good efficiency in the treatment for OVCF, there are still many associated complications (4,5), with the most common one being low back pain. A previous study (6) noted that 10-51% of OVCF patients may continue to suffer from mild to moderate low back pain after successful vertebral augmentation surgery. In another study, the incidence of postoperative residual back pain was reported in 7.3% of OVCF patients (7), 7 days after surgery. Our previous study found that the incidence of residual back pain after kyphoplasty was 7.8%, and the presence of intravertebral vacuum cleft, posterior fascia edema, and facet joint violations were independent risk factors for residual back pain (8). Persistent residual back pain after surgery has become the most complicated problem for postoperative management of OVCF patients since it can cause back dysfunction and reduce patients' satisfaction with surgery.

The medial branch block (MBB) is considered a feasible strategy for back pain relief (9-11). Bogduk et al (9) found that patients who underwent diagnostic MBB for pain and chronic vertebral compression fractures experienced significant pain relief and return to function. Park et al (11) note that medial branch nerve block provided significant pain relief and functional benefit to patients with chronic osteoporotic compression fractures or patients with significant pain after vertebroplasty.

In the present study, we aimed to determine the effect of MBB during PKP on postoperative residual back pain in OVCF patients. We hypothesized that MBB can reduce residual back pain of OVCF patients.

Methods

Study Design

This was a single-center, parallel-group, double-blind randomized clinical trial (RCT) in OVCF patients. Patients were randomly assigned to each treatment group in a ratio of 1:1 and the primary outcome was assessed at baseline (pre-operation), 1 day, 1 week, 1, 3, 6, and 12 months after the intervention. The trial flowchart is shown in Fig. 1. Ethical approval was obtained from The Medical Human Subjects Protection Review Board of Wenzhou Second Affiliated Hospital, reference number LCKY-2019-295. This study was supported by the Clinical Research Foundation of the Second Affiliated Hospital of Wenzhou Medical University and was registered at ClinicalTrials.gov under the identifier: SAHoWMU-CR2018-08-109.

Recruitment

Between August 2019 and November 2019, patients attending the outpatient clinics were screened by participating spinal surgeons, whose responsibility was to determine eligible patients for the trial. Surgeons informed eligible patients about the study's significance and provided them with the patient information forms. Informed consent was obtained from the patients, they completed the baseline assessments, and were randomly assigned to their treatment allocation.

Selection Criteria

The inclusion criteria were as follows: 1) Age $\geq$ 55 years. 2) Acute vertebral compression fracture (within one week). 3) Single segmental fracture (T11-L4). 4) Decreased bone mineral density (T scores < -1.5). We excluded patients with: 1) A combination of other trauma or fractures. 2) Previous spinal surgery or spinal deformity. 3) Metabolic bone diseases, metastasis, or spinal infection. 4) A combination of other systemic diseases that cannot tolerate surgery, such as severe cardiopulmonary or cerebrovascular diseases. 5) Severe psychiatric comorbidity, including factitious disorder, self-harm, anxiety, and depression, which would interfere with the patient's ability to participate in surgery and long-term follow-up. 6) Language barrier or learning disability making it difficult to complete the questionnaires. 7) Unwilling to participate.

Sample Size Determination

This study was designed to assess the treatment effect of the nerve block group compared with the control group. In each treatment group, the study is designed to detect (α = 0.05, β = 0.1). The reported Visual Analog Scale (VAS) scores decreased by 50.0% in the nerve block group and 27.8% in the control group after treatment, in OVCF patients with low back pain (12). To detect a 22.2% difference in the VAS scores at

the 5% level of significance with 90% power, we required 166 patients, 83/group. Presuming a 20% dropout rate (32 patients) implied inclusion of at least 99 patients in each treatment group and at least 198 patients in total.

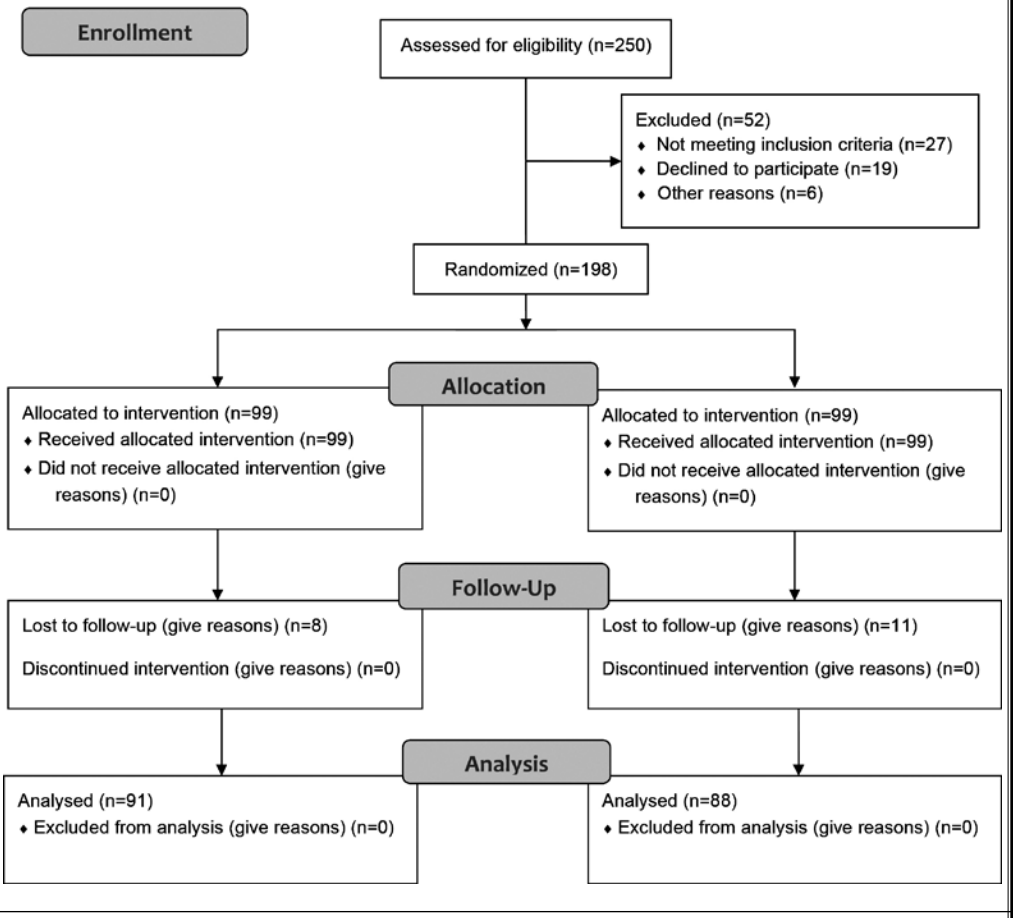

Fig. 1. *The trial flowchart.*

Randomization and Blinding

Eligible patients who consented to participate in this study were randomized to the MBB and non-MBB groups in a ratio of 1:1 using an online computer-based randomization service. To ensure that the patients and study team were masked to the treatment assignments and data collection, an unmasked third party, including 3 spinal surgeons, were involved. The investigator provided the unmasked surgeons with the necessary information to support treatment assignment and data collection.

PKP Surgical Procedure

Patients lying prone on the operating table were supported with a pillow on their chest and administered with general anesthesia. The operations were performed by 2 senior orthopedic surgeons. Guided by a C-arm, bone puncture trocars were placed through the lateral margin of the pedicles at 10 o'clock on the left side and 2 o'clock on the right side, respectively, as entry points at the fractured segment were progressively passed through pedicles into the anterior third of the vertebral body. Then, an inflatable bone balloon was used and polymethyl methacrylate was carefully injected into the vertebral body (approximately 3-5 mL per segment). If the cement reached the cortical edge of the vertebral body or if it leaked into the extraosseous structures or veins, the injection was stopped.

MBB Group

Based on the anatomical characteristics of the medial dorsal branch, the injured vertebral and the superior vertebral body were selected as the target of the nerve block. For the MBB, where the outline of the Millard's "Scotty dog" is visible, a puncture point was selected by placing the needle tip directly on the skin along the x-ray beam, and the target point behind the "eye" (13). Once the tip of the needle hits a bone, the insertion was terminated, which was on the neck of the superior articular process, and superior-dorsal to the silhouette of the transverse process. Correct placement was confirmed by obtaining a posterior-anterior

view, in which the needle tip was at least opposite the lateral edge of the superior articular process. Once the needle was in the correct position, the bevel was directed caudally to avoid the spread of the injectate to the intervertebral foramen (13). The surgeons ensured that there was no venous uptake, and a 1.0 mL nerve block drug was injected onto the target nerve of the bilateral sides. The injection was a mixture of 5 mL of 2% lidocaine and 20 mg budesonide.

Non-MBB Group

Studies have shown that injection of normal saline is an effective control method (14), which can effectively reduce the false positive rate of a nerve block (15). The procedure was similar to that for the MBB group, and 1.0 mL of normal saline was injected to target the nerve of the bilateral sides.

Co-Interventions

All patients received antero-posterior and lateral plain radiographs and computed tomography (CT) 3 days after surgery to determine the distribution of bone cement. Moreover, the patients used a soft lumbar support belt for one month after surgery, resumed routine functional exercise one week after the operation, and regularly checked in at the outpatient clinic. Three days after surgery, frontal and lateral x-rays and CT were performed on the patients to determine the distribution of bone cement. All patients used a soft lumbar support belt within one month after surgery. All patients resumed routine functional exercises one week after surgery and went to the outpatient clinic regularly.

Outcome Measures

The primary outcome was back pain assessed using the VAS before the operation, 1-day, 1-week, 1-, 3-, 6-, and 12-months post PKP. Residual back pain was defined as a VAS score greater than or equal to 4 (16). The secondary outcome (i.e., physical function) was measured using the Patient-Reported Outcome Measurement Information System Physical Function (PROMIS PF) (17,18) at each timepoint. PROMIS PF is increasingly used in orthopedic and spine conditions to capture patient-centered health indicators for clinical care and research (18), a higher PROMIS PF score means better physical function. At the final follow-up, satisfaction with treatment was assessed using the S6 satisfaction scale (19).

Demographic variables, including age, gender, body mass index (BMI), decreased bone mineral density T score (BMD T score), diabetes status, and insurance status were assessed at baseline. Serious complications, such as cement leakage, infection, new compression fractures, etc., were determined postoperatively.

Statistical Analysis

The mean values and standard deviations were calculated for all the parameters. Continuous variables were analyzed by Student's t test, while ordinal and nominal variables were analyzed by the chi-squared test. P value ≤ 0.05 was considered to be statistically significant. All statistical analyses were performed using Statistical Package for Social Sciences (SPSS) version 18.0.

Results

Patients

The trial flowchart is presented in Fig. 1. A total of 250 patients with OVCF were recruited, and 198 patients met the inclusion criteria and were randomly assigned to the MBB and Non-MBB groups. During the 12-month follow-up, 8 patients in the MBB group and 11 patients in the Non-MBB group were lost to follow-up. Finally, a total of 179 patients including 91 patients in the MBB group and 88 patients in the Non-MBB group were available for the complete assessment. The demographic characteristics are summarized in Table 1. All demographic variables were identified to have no significant differences between the 2 treatment groups ($P > 0.05$). Serious complications, such as cement leakage, infection, and new compression fractures were not reported in any of the patients within the 12-month follow-up.

Primary Outcome

There was no significant difference in preoperative VAS scores between the 2 groups ($P > 0.05$). The postoperative VAS scores were significantly lower than the preoperative scores in both groups (Table 2, Fig. 2). The VAS score in the MBB group was significantly lower than in the Non-MBB group at 1-day (2.6 ± 1.2 vs. 4.0 ± 1.4, $P = 0.000$), 1-week (2.4 ± 1.0 vs. 3.2 ± 1.1, $P = 0.000$), and 1-month (2.2 ± 0.8 vs. 2.8 ± 1.0, $P = 0.016$) follow-up. No significant difference in VAS score was found between the 2 groups at 3-, 6-, and 12-months follow-up ($P > 0.05$). The incidence of residual back pain in the MBB and Non-MBB groups at postoperative 1-day was 5.50% (5/91) and 17.05% (15/88), respectively (P

Table 1. *Patients demographics at baseline.*

	MBB (n = 88)	Non-MBB (n = 91)	*P* value
Age (Mean ± SD)	73.8 eB (I	74.2 eB (I	0.208
BMD T score (Mean ± SD)	-3.4 eB (I	-3.2 eB (I	0.629
BMI	23.8 eB (I	24.2 eB (I	0.456
Gender (n)			0.683
Women	78	73	
Men	13	15	
Diabetes Status (n)			0.678
Non-Diabetic	76	74	
Diabetic	15	14	
Insurance Status (n)			0.538
Social Insurance	54	57	
Non-Social Insurance	37	31	

Abbreviations: MBB, medial branch block; n, number; BMD, bone mineral density; SD, standard deviation.
Data are presented as number or Mean ± SD.

= 0.040) (Table 3). The incidence of postoperative residual back pain after 1-week in the MBB and Non-MBB group was 2.20% (2/91) and 10.23% (9/88), respectively (*P* = 0.031). There was no significant difference in the incidence of residual back pain between the 2 groups at 1-, 3-, 6-, and 12-months follow-up (*P* > 0.05).

Secondary Outcomes

No significant difference in PROMIS PF scores was found between the 2 groups preoperatively (*P* > 0.05). The PROMIS PF scores significantly increased in both groups postoperatively (Table 4, Fig. 3). The PROMIS PF score in the MBB group was significantly higher than in the Non-MBB group at 1-day (40.4 ± 5.5 vs. 35.1 ± 4.8, *P* = 0.000), 1-week (47.1 ± 6.4 vs. 40.3 ± 5.2, *P* = 0.014), and 1-month (51.8 ± 7.5 vs. 45.5 ± 7.3, *P* = 0.021) follow-up. No significant difference in PROMIS PF scores was found between the 2 groups at 3, 6, and 12-months follow-up (*P* > 0.05).

At the end of the 12-month follow-up, the satisfaction survey indicated that the MBB group had a higher satisfaction rate compared with the Non-MBB group, and the satisfaction rates were 82.95% (73/88) and 69.23% (63/91), respectively (*P* = 0.036) (Table 5).

Discussion

PKP is an available and effective treatment for OVCF. Postoperative adverse events (20-22), including pulmonary embolism, infection, and insufficient postoperative pain relief, have negative impacts on the clinical outcomes. Of these complications (22), residual back pain imposes a considerable impact on the ability of OVCF patients to perform daily activities (23,24), reduces the patients' surgical satisfaction and quality of life. Several studies report the presence of residual back pain after successful PKP surgery. Li et al (8) report a 7.8% incidence of postoperative residual back pain in OVCF patients after PKP surgery. In another study (7), 7.3% of OVCF patients were identified as having

Table 2. *Back pain (VAS score).*

	MBB	Non-MBB	*P* value
Preoperative	8.5 ± 2.4	8.3 ± 1.9	0.528
1 Day	2.6 ± 1.2	4.0 ± 1.4	0.000**
1 Week	2.4 ± 1.0	3.2 ± 1.1	0.000**
1 Month	2.2 ± 0.8	2.8 ± 1.0	0.016*
3 Month	2.1 ± 0.8	2.3 ± 0.5	0.069
6 Month	2.1 ± 0.4	2.2 ± 0.7	0.315
12 Month	1.8 ± 0.5	1.7 ± 0.5	0.287

Abbreviations: VAS, visual analog scale; MBB, medial branch block.
Data are presented as number or Mean ± SD.
*$P \leq 0.05$; **$P \leq 0.001$.

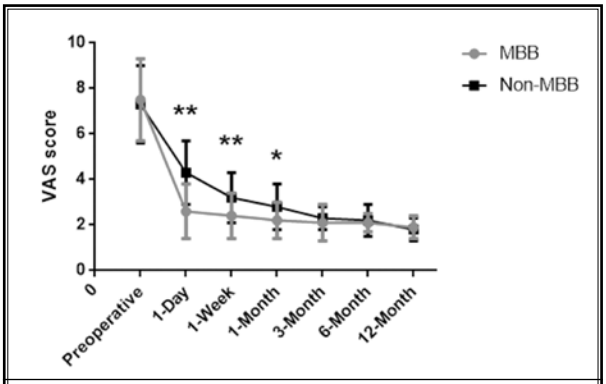

Fig. 2. *Back pain of patients described as VAS score. MBB: medial branch block; Non-MBB: without medial branch block. *P ≤ 0.05, ** P ≤ 0.001.*

Table 3. *Residual back pain (VAS score ≥ 4).*

	MBB	Non-MBB	*P* value
1 Day	5.50% (5/91)	17.05% (15/88)	0.040*
1 Week	2.20% (2/91)	10.23% (9/88)	0.031*
1 Month	2.20% (2/91)	7.95% (7/88)	0.096
3 Month	3.30% (3/91)	4.55% (4/88)	0.069
6 Month	2.20% (2/91)	2.27% (2/88)	0.315
12 Month	1.10% (1/91)	2.27% (2/88)	0.287

Abbreviations: VAS, visual analog scale; MBB, medial branch block.
Data are presented as number or Mean ± SD.
*$P \leq 0.05$

Table 4. *Physical function (PROMIS PF score).*

	MBB	Non-MBB	*P* value
Preoperative	32.2 ± 4.4	31.6 ± 5.7	0.250
1 Day	40.4 ± 5.5	35.1 ± 4.8	0.000**
1 Week	47.1 ± 6.4	40.3 ± 5.2	0.014*
1 Month	51.8 ± 7.5	45.5 ± 7.3	0.021*
3 Month	51.2 ± 8.1	50.5 ± 7.0	0.144
6 Month	52.8 ± 10.2	51.6 ± 9.8	0.351
12 Month	54.0 ± 8.6	52.3 ± 9.2	0.298

Abbreviations: PROMIS PF, patient-reported outcome measurement information system physical function; MBB, medial branch block. Data are presented as number or Mean ± SD.
*$P \leq 0.05$; **$P \leq 0.001$

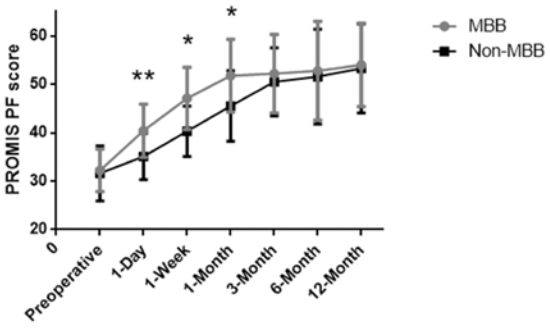

Fig. 3. *Physical function of patients described as PROMIS PF score. MBB: medial branch block; Non-MBB: without medial branch block. * $P \leq 0.05$, ** $P \leq 0.001$.*

Table 5. *Satisfaction with surgery (S6) at final follow-up.*

	MBB	Non-MBB
Extremely Satisfied	10	6
Very Satisfied	49	35
Somewhat Satisfied	17	20
Neither Satisfied nor Dissatisfied	7	15
Somewhat Dissatisfied	3	8
Very Dissatisfied	5	4
Satisfaction Rate	83.52%	69.32%

Abbreviations: MBB, medial branch block. *$P = 0.034$, compared with Non-MBB

residual back pain on postoperative day 7. Back pain in OVCF patients may arise directly from the vertebral fracture or indirectly from spinal deformity, or degenerative changes. In patients undergoing PKP surgery, residual back pain may result from infection, cement leakage, a nonhealing bone-cement interface, and idiopathic pain (5,25). Moreover, the presence of intravertebral vacuum cleft, posterior fascia edema, and facet joint violations are identified as independent risk factors for residual back pain (8).

Lumbar facet joints have been considered as potential sources of chronic low back pain (26,27). A previous study report that about 9.6% of facet joints in OVCF patients were invaded by puncture needles after kyphoplasty (28). Yan et al (29) found that OVCF patients experienced significant pain in the puncture sites after surgery, and speculated that the pain was related to facet joint violations and the use of local block treatment for pain relief. Li et al (24) report that facet joint violations have adverse effects on clinical outcomes, including high VAS scores and low surgical satisfaction. The facet joint is the only synovial joint in the interosseous connection of the lumbar vertebrae, which comprises the articular surface of the superior and inferior articular process of adjacent vertebrae. Like other synovial joints, such as knee joint and hip joint, internal degeneration can occur, followed by synovial hyperplasia, articular cartilage degeneration, inflammatory changes, and so on. The surface of the facet joint capsule is rich in nerves, including low threshold mechanical receptors, mechanically sensitive pain receptors, and resting pain receptors; therefore, they are sensitive to high tension and torsional stress under spinal load (29,30). Nerve fibers containing the pain-mediator substance P and calcitonin gene-related peptide have been isolated in the joint capsules and facet joint subchondral bone, and an overload of this richly innervated capsule potentially causes pain transmitted by nociceptive nerves (31). Pain signals are triggered during postural changes, such as lumbar torsion and extension, and they are transmitted upward through the sensory branches of the dorsal medial branch of the spinal nerve around the joint capsule (32). Since the medial branch of the spinal nerve is the only pathway causing facet joint pain and its anatomical position is relatively stable, the MBB is a simple and feasible strategy to relieve facet joint-related pain. Manchikanti et al (33) report that 85% of patients with lumbar facet joint pain who received the MBB showed 50% or more reduction in pain and 40% or more functional improvement at one-year follow-up. Park et al (11) note that medial branch nerve blocks provided significant pain relief and functional benefit in patients with OVCF or those without significant pain relief at least 3 months after vertebroplasty.

To our knowledge, the MBB is widely used as an adjunct in pain management when OVCF patients develop residual back pain after surgery. This study reports for the first time the use of MBB with PKP surgery to prevent the incidence of postoperative residual back pain in OVCF patients. In the present study, OVCF patients who underwent MBB and PKP surgery had a significantly lower incidence of residual back pain one-week postoperatively ($P \leq 0.05$). The incidence of residual back pain was lower in the MBB group compared with the Non-MBB group one-month postoperatively, but no statistical difference was found, which may have resulted from the insufficient sample size. The nerve block drug used in this study was a mixture of lidocaine and budesonide. The use of local anesthetic agents (34,35) has long-term blocking effects achieved through the suppression of nociceptive discharge, blockade of the sympathetic reflex arc, blockade of axonal transport, blockade of sensitization, and anti-inflammatory effect. The effect of steroids as MBB on facet joint pain may be expressed as anti-inflammation, immunosuppression, antiedema, and inhibition of neurotransmission in the C nerve fiber (36,37). Studies have shown that long-term use of steroids can accelerate bone loss and increase the risk of osteoporosis and fractures (38,39). Considering that only single, low-dose, and local use of steroids was reported in this study, there was no associated risk as mentioned above.

Understanding the distribution of the medial branch nerve may help to accurately select the nerve block target. The posterior ramus of the spinal nerve is divided into 3 branches, including the medial, lateral,and intermediate (13). The medial branch originates from the stem of the posterior ramus of the spinal nerve on the superior side of the transverse process of the lower vertebral. The medial branch then takes a posteromedial direction and passes through the area posterior to the origin of the transverse process, and from there the branch passes through the bony floor under the mammillo-accessory ligament. Then, it delivers branches to the upper and lower facet joints before providing branches to the multifidus muscle. The medial branch supplies motor fibers to the multifidus muscle, which runs along the spinous process and interspinous ligament in the multifidus muscle. Finally, an extension of the main stem of the medial branch produces fine branches in the subcutaneous region, which supplies the cutaneous region near the midline. The target of the MBB selected is the area posterior to the origin of the transverse process, where the medial branch originates from the posterior branch of the spinal nerve. Based on the anatomical characteristics of the medial dorsal branch, the research group selected the injured vertebra and the superior vertebral body as the nerve block target. The medial branches of L1-L4 dorsal rami course across the top of their respective transverse process one level below the named spinal nerve (for example, L4 crosses the transverse process of L5, traversing the dorsal leaf of the intertransverse ligament at the base of the transverse process). Each facet joint receives dual innervation from medial branches arising from the posterior primary rami at the same level and one level above the facet joint (13,14). For example, the inferior pole of the L4-L5 facet joint receives innervation from the L4 medial branch, and its superior pole is innervated by the L3 medial branch, which is typically blocked on the transverse processes of L5 and L4, respectively.

This study has a few limitations. Firstly, it is a single-center RCT, where patients were from a single institution and the sample size was not large enough. Secondly, some of the potential factors which may lead to back pain, such as infection, new symptomatic compression fracture, and serious cement leakage, did not occur. Thirdly, a conservative treatment group was not included. Finally, individual differences in pain tolerance were not estimated.

Conclusions

This single-center, parallel-group, double-blind, RCT in OVCF patients found that MBB during PKP surgery can effectively relieve back pain and reduce the incidence of postoperative residual back pain. It can also significantly improve postoperative physical function and patients' satisfaction with treatment. This provides a new treatment strategy for OVCF patients in the future.

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Author Contributions

All authors equally contributed to the design, conduct, analyses, writing of the manuscript, and approval of the final version of the article.

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