

Exploring the Efficacy of Shaoyang Zhugu Formula in Treating Residual Pain After Vertebroplasty Based on the Shaoyang Governs Bones Theory

Yangwang Zhou, Jincai Liu, Zhijun Chen, Lei Xie, Donghui Cai, Zeyi Li

Chuxiong Yi Autonomous Prefecture Hospital of Traditional Chinese Medicine, Chuxiong 675000, Yunnan, China

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Abstract: *Objective:* To investigate the clinical efficacy of the Shaoyang Zhugu Formula based on the “Shaoyang Governing Bones” theory in treating residual pain after vertebroplasty. *Methods:* A total of 60 outpatients and inpatients from the Second Orthopedics Ward and Preventive Treatment Center of Chuxiong Prefecture Hospital of Traditional Chinese Medicine between January 2024 and December 2024 were selected and randomly divided into a control group (celecoxib capsules, 30 cases) and an observation group (Shaoyang Zhugu Formula + celecoxib capsules, 30 cases) using a lottery method. Postoperative pain levels, TCM symptom scores, Japanese Orthopaedic Association (JOA) scores for the lumbar spine, and adverse reactions were compared between the two groups. *Results:* The observation group showed better pain relief than the control group ($P < 0.05$). The TCM symptom efficacy in the observation group was superior to that of the control group ($P < 0.05$). After two treatment courses, both groups exhibited improved JOA scores, but the observation group demonstrated significantly better postoperative JOA scores ($P < 0.05$). Additionally, the observation group had fewer adverse reactions ($P < 0.05$). *Conclusion:* The Shaoyang Zhugu Formula, based on the “Shaoyang Governing Bones” theory, effectively alleviates residual pain after vertebroplasty, improves TCM symptoms and lumbar function, and demonstrates high safety.

Keywords: Shaoyang Governing Bones theory; Shaoyang Zhugu Formula; Vertebroplasty; Residual pain

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1. Introduction

With the global aging population, the incidence of osteoporosis continues to rise, leading to a significant increase in fracture risk. Osteoporotic vertebral compression fractures (OVCFs) have become a common condition among the elderly, severely impacting patients' health and quality of life. Percutaneous vertebroplasty (PVP) is a widely adopted clinical treatment for OVCFs, recognized as a safe and effective minimally invasive procedure with fewer complications^[1]. However, due to factors such as trauma, soft tissue injury, and bone cement leakage, patients often experience residual postoperative pain, resulting in prolonged bed rest and impaired functional recovery.

Currently, Western medications like celecoxib are commonly used for pain relief, offering rapid efficacy but limited long-term applicability due to adverse effects.

Traditional Chinese Medicine (TCM) attributes postoperative residual pain after PVP to the categories of “bone impediment” and “lumbar pain”, with pathogenesis involving tendon-bone injury, Qi-blood stagnation, and meridian blockage. Recent studies suggest a close relationship between the Shaoyang meridian and the skeletal system. The Yellow Emperor’s Inner Canon proposes the theory that “Shaoyang governs bones”, highlighting the critical role of Shaoyang meridian Qi in bone growth, repair, and pain modulation ^[2]. Based on this theory, the Shaoyang Zhugu Formula, designed to regulate pivot mechanisms, promote Qi-blood circulation, and nourish tendons and bones, has demonstrated unique advantages in treating orthopedic disorders.

Given this background, this study explores the therapeutic effects of the Shaoyang Zhugu Formula on residual pain after PVP, grounded in the “Shaoyang governs bones” theory. The findings are reported as follows.

2. Materials and methods

2.1. General information

A total of 60 patients with osteoporotic vertebral compression fractures (OVCF) who were treated or hospitalized in the Second Orthopedics Ward and Preventive Treatment Center of Chuxiong Prefecture Hospital of Traditional Chinese Medicine from January 2024 to December 2024 were enrolled. They were divided into two groups (30 patients each) using a lottery method, which is as follows: (1) Control group: Seven male and twenty-three female patients, aged 60–90 years (mean: 73.82 ± 2.16), disease duration (7.62 ± 1.37) days. (2) Observation group: Eleven male and nineteen female patients, aged 53–90 years (mean: 70.7 ± 2.18), disease duration (7.59 ± 1.38) days.

There were no statistically significant differences in baseline data between the two groups ($P > 0.05$), allowing for comparative analysis.

2.1.1. Inclusion criteria

- (1) Met the diagnostic criteria for OVCF, confirmed by X-ray, CT, or MRI, and underwent percutaneous vertebroplasty (PVP).
- (2) No recent use of other analgesic medications.
- (3) Voluntarily participated in the study.
- (4) Able to cooperate and complete the treatment cycle.

2.1.2. Exclusion criteria

- (1) Non-osteoporotic fractures.
- (2) Allergy to study drug components.
- (3) Severe cardiac, hepatic, or renal insufficiency.
- (4) Mental disorders or cognitive impairment affecting treatment compliance.

2.2. Methods

2.2.1. Control group

A single-drug treatment regimen was adopted, in which celecoxib capsules (Pfizer Pharmaceuticals Ltd., National Medicine Approval No. J20140072, specification: 0.2 g/capsule) were administered orally. The specific dosing protocol was as follows: 0.2 g once daily, taken in the morning on an empty stomach with warm water to ensure rapid

drug absorption. The treatment course lasted 3 days, and medication was discontinued after 2 consecutive courses.

2.2.2. Observation group

An integrated traditional Chinese and Western medicine treatment strategy was implemented. In addition to the celecoxib capsules (same dosage and administration as the control group), the Shaoyang Zhugu Formula was applied for synergistic intervention. The Shaoyang Zhugu Formula consisted of the following herbs: Chaihu (*Bupleurum*) 10 g, Banxia (*Pinellia ternata*, processed) 10 g, Dangshen (*Codonopsis pilosula*) 10 g, Gancao (*Glycyrrhiza uralensis*) 6 g, Huangqin (*Scutellaria baicalensis*) 6 g, Dazao (*Ziziphus jujuba*) 10 g, Gusuibu (*Drynaria fortunei*) 10 g, Huainiuxi (*Achyranthes bidentata*) 6 g, Shanzhuyu (*Cornus officinalis*) 10 g.

The hospital pharmacy uniformly prepared the decoction using a standardized decoction machine. Each dose was boiled to yield 400 mL of medicinal liquid, divided into 2 bags (200 mL each). The administration method was twice daily (1 bag in the morning and 1 bag in the evening, with a 12-hour interval), taken warm 30 minutes after meals to minimize gastrointestinal irritation. Medication was discontinued after 2 consecutive courses.

2.3. Observation indicators

- (1) Degree of pain: Use the Visual Analog Scale (VAS) to quantitatively evaluate the degree of pain in both groups before treatment and after two courses of treatment. This scale ranges from 0 to 10, where 0 represents no pain and 10 represents unbearable severe pain. The score is positively correlated with the intensity of pain.
- (2) Therapeutic effect of TCM syndromes: Adopt the criteria for grading the efficacy of TCM syndromes as outlined in Article 7 of the “Guiding Principles for Clinical Research on New Drugs of Traditional Chinese Medicine.” If the improvement ratio of symptom scores is higher than 90%, it is considered cured. If symptoms are reduced by 70% or more, it is judged as significantly effective. If the symptom score decreases by more than 30%, it is judged as effective. Below this standard range is considered ineffective^[3]. The total effective rate is calculated as the percentage of the sum of cured, significantly effective, and effective cases out of the total number of cases.
- (3) Improvement of low back pain and function: Before and after treatment, use the Japanese Orthopaedic Association (JOA) scoring system to evaluate improvement. This scoring system includes four dimensions: subjective symptoms covering lower back pain, lower extremity pain, and gait abnormalities; clinical signs including the results of the straight leg raising test, sensory function, and limitations in motor function; limitations in activities of daily living; and assessment of bladder function. The total JOA score is 29 points. A higher score indicates better functional improvement, quantitatively reflecting the improvement in the patient’s condition.
- (4) Adverse reactions: Observe and record adverse reactions such as nausea, dizziness, fever, and soft tissue pain that occur during the study period.

2.4. Statistical methods

Statistical analysis was performed using SPSS 25.0 software. The pain level and JOA scores were presented as mean \pm standard deviation, and differences between data were tested using the t-test. The efficacy of TCM syndrome scores and adverse reactions were presented as frequency (n) and percentage (%), and further analyzed using the chi-square (χ^2) test. A P-value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of pain levels before and after treatment in both groups

There was no statistically significant difference in VAS scores between the two groups before treatment and after the first course of treatment ($P > 0.05$). However, after the second course of treatment, the VAS score in the observation group was lower compared to the control group ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of pain levels (VAS) scores before and after treatment in both groups ($\bar{x} \pm S$, score)

Group	Cases (n)	Before treatment	After 1st course	After 2nd course
Study group	30	4.33 \pm 1.34	2.61 \pm 1.17*	1.97 \pm 0.92*
Control group	30	4.31 \pm 1.36	2.72 \pm 1.25*	2.52 \pm 1.03*
χ^2 value	-	0.057	0.352	2.181
P-value	-	0.954	0.033	0.033

Note: Compared with before treatment, * $P < 0.05$

3.2. Comparison of the efficacy of TCM syndrome scores before and after treatment between the two groups

After two courses of treatment, the effective treatment rate of the observation group was significantly higher than that of the control group (93.33% $>$ 73.33%, $P < 0.05$), as shown in **Table 2**.

Table 2. Comparison of the efficacy of TCM syndrome scores before and after treatment between the two groups (n,%)

Group	n	Cured	Markedly effective	Effective	Ineffective	Total effective (%)
Study group	30	0	2	26	2	28 (93.33)
Control group	30	0	1	21	8	22 (73.33)
t	-					4.32
P	-					0.038

3.3. Comparison of JOA scores before and after treatment between the two groups

There was no statistically significant difference in JOA scores between the two groups before treatment ($P > 0.05$). After two courses of treatment, the JOA scores of the observation group were higher than those of the control group ($P < 0.05$), as shown in **Table 3**.

Table 3. Comparison of JOA scores before and after treatment between the two groups ($\bar{x} \pm S$, score)

Group	Cases (n)	Baseline	After 1st course	After 2nd course
Study group	30	12.67 \pm 3.25	16.42 \pm 2.87	22.23 \pm 2.56
Control group	30	12.84 \pm 3.32	14.37 \pm 2.51	19.97 \pm 2.31
χ^2 value	-	0.200	2.945	3.590
P-value	-	0.842	0.005	0.001

3.4. Comparison of adverse reactions between the two groups of patients

After treatment, the incidence of adverse reactions in the observation group was better than that in the control group ($3.33\% < 20.0\%$, $P < 0.05$), as shown in **Table 4**.

Table 4. Comparison of adverse reactions between the two groups of patients (n,%)

Group	n	Nausea	Dizziness	Fever	Soft tissue pain	Total incidence (%)
Treatment group	30	1	0	0	0	1 (3.33)
Control group	30	3	2	0	1	6 (20.00)
<i>t</i> -value	-					4.043
<i>P</i> -value	-					0.044

4. Discussion

Osteoporotic vertebral compression fractures (OVCF) are a common skeletal disease among the elderly. As the mainstream clinical treatment, percutaneous vertebroplasty (PVP) can quickly stabilize fractures and relieve pain, but the incidence of residual pain after surgery is as high as 20% to 40%. Residual pain not only leads to long-term bed rest, delays the recovery process but also may cause complications such as muscle atrophy and deep vein thrombosis, seriously affecting the quality of life^[4, 5]. Currently, non-steroidal anti-inflammatory drugs (such as celecoxib) are commonly used clinically to relieve pain, but long-term use can have adverse effects, affecting their application effectiveness. The theory of “Shaoyang governing the bones” originates from the “Huangdi Neijing” (Yellow Emperor’s Inner Canon of Medicine), emphasizing that the Shaoyang meridian plays a key role in bone physiological functions and injury repair by regulating Qi and blood circulation and relaxing muscles and bones^[6]. The Shaoyang governing bone prescription uses Chai Hu (*Bupleurum*), Huang Qin (*Scutellaria*) to reconcile the Shaoyang, bai shao (*Paeoniae Radix Alba*), Ge Gen (*Puerariae Radix*) to soften tendons and urgently relax them, Gu Sui Bu (*Drynariae Rhizoma*), and Yan Hu Suo (*Corydalis Rhizoma*) to nourish the kidneys, promote blood circulation, and relieve pain. The entire prescription works together to harmonize Qi and blood, facilitate the pivotal function, nourish muscles and bones, which is consistent with the treatment goals of modern medicine: anti-inflammatory and analgesic effects, and promoting tissue repair.

The results of this study showed that in terms of improving pain levels, the VAS of the observation group was significantly lower than that of the control group after treatment ($P < 0.05$). This may be attributed to the synergistic effect of combined Chinese and Western medicine treatment. Celecoxib reduces prostaglandin synthesis by inhibiting cyclooxygenase-2, quickly exerting anti-inflammatory and analgesic effects. The Chai Hu (*Bupleurum*) and Huang Qin (*Scutellaria*) in the Shaoyang governing bone prescription have the effect of regulating inflammatory factors, while Bai Shao (*Paeoniae Radix Alba*) and Yan Hu Suo (*Corydalis Rhizoma*) can exert analgesic effects by regulating neurotransmitter release. The combination of the two can quickly relieve pain and regulate body functions holistically, enhancing the analgesic effect. Comparison of the efficacy of TCM syndrome scores showed that the effective rate of treatment in the observation group (93.33%) was significantly higher than that in the control group (73.33%, $P < 0.05$). This result confirms the advantage of the Shaoyang governing bone prescription in improving TCM syndromes. This prescription targets the pathogenesis of “Qi and blood stagnation, pivot dysfunction” after OVCF surgery. It restores qi and blood circulation through Chai Hu (*Bupleurum*) and Huang Qin (*Scutellaria*), harmonizing the Shaoyang pivot. Gu Sui Bu (*Drynariae Rhizoma*)

nourishes the kidneys and strengthens the bones, promoting fracture repair, thereby improving the effect of TCM syndromes^[7, 8].

The JOA score results showed no significant difference between the two groups before treatment ($P > 0.05$). However, after treatment, the JOA scores of the observation group were higher than those of the control group at the end of the 1st and 2nd courses of treatment ($P < 0.05$), suggesting that the combined therapy has more advantages in improving waist function. This may be because *Radix Puerariae* and *Radix Paeoniae Alba* in the Shaoyang Zhugu formula can relax muscles and alleviate spasms, reducing the limitation of waist movement caused by pain. Meanwhile, kidney-tonifying herbs such as *Rhizoma Drynariae* can promote bone metabolism and accelerate fracture healing, synergistically working with the analgesic effect of Celecoxib to more effectively restore patients' waist function^[9]. In terms of adverse reactions, the incidence of adverse reactions in the observation group was lower than that in the control group ($3.33\% < 20.0\%$, $P < 0.05$), indicating that the combined therapy of traditional Chinese and Western medicine can reduce the dosage and side effects of Western medicine, thereby reducing the risk of adverse reactions^[10].

5. Conclusion

In summary, the combined therapy of traditional Chinese and Western medicine based on the “Shaoyang Zhugu” theory has shown good application effects in relieving residual pain after vertebroplasty, improving TCM syndromes, promoting functional recovery, and ensuring safety. It can be further applied in clinical practice.

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Disclosure statement

The authors declare no conflict of interest.

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