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Early Curative Effect Observation of Shenqi Hexue Decoction in the Treatment of Qi Blood Deficiency Syndrome after PKP for Thoracolumbar Metastases with Pathological Vertebral Fractures

Xihua Zhang[1,2], Pingqin Luo[1,2], Zhongyu Peng [1,2], Huzhen Liu [1,2], Chengzheng Zhou[1,2], Hongchi Yi[1,2]*, Chen Tao[1,2]*

[1]Yunnan Provincial Hospital of Traditional Chinese Medicine/Yunnan University of Traditional Chinese Medicine First Affiliated Hospital Bone Injury Center Third Ward, Kunming 650021, Yunnan, China

[2]Yunnan University of Traditional Chinese Medicine, Kunming 650500, Yunnan, China

**Authors to whom correspondence should be addressed.*

Abstract: *Objective*: After percutaneous kyphoplasty (PKP), patients with pathological vertebral fractures of thoracolumbar metastases often have Qi and blood deficiency syndrome and hidden blood loss, resulting in postoperative debilitation syndrome. This study aimed to evaluate the clinical efficacy and mechanism of Shenqi Hexue Decoction on early postoperative recovery of such patients. *Methods*: 36 Patients were randomly divided into an experimental group (Shenqi Hexue Decoction + conventional treatment) and a control group (conventional treatment). The changes of hemoglobin (HB), Karnofsky functional status (KPS) score, and TCM syndrome score on the 1st, 4th, and 7th day after operation were observed. *Results*: The HB value of the experimental group was significantly higher than that of the control group on the 4th and 7th days after operation ($p<0.01$), and the maximum decline value of HB decreased by 42.1% ($p < 0.001$); The improvement rate of KPS score in the experimental group was 94.4% on the 7th day after operation, which was significantly better than 66.7% in the control group ($p < 0.05$). The total effective rate of TCM syndrome efficacy was 94.4% in the experimental group and 72.2% in the control group ($p < 0.05$); No drug-related serious adverse reactions were found. *Conclusion*: Shenqi Hexue decoction can effectively improve the anemia state and activity ability of patients with Qi blood deficiency syndrome in the early stage after PKP, and its possible mechanism involves multi-target regulation such as hematopoietic regulation, microcirculation improvement and inflammation inhibition, with good safety.

Keywords: Thoracolumbar metastases; Qi and blood deficiency syndrome; Shenqi Hexue Decoction; Curative effect

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1. Introduction

Bone is the third most common site of metastasis for malignant tumors, with thoracolumbar metastases accounting for 60%-80% of bone metastases [1]. Pathological vertebral fractures can cause severe pain, neurological dysfunction, and limited mobility, which can lead to paraplegia [2]. Percutaneous kyphoplasty (PKP), as a minimally invasive surgery, can effectively stabilize the vertebral body and relieve pain [3]. However, clinical observations have found that patients often experience "postoperative frailty syndrome" manifestations such as progressive anemia and decreased mobility after PKP, but without significant external bleeding, which is referred to as "occult blood loss". Studies have shown that the amount of occult blood loss after orthopedic surgery can reach 2-3 times that of overt blood loss, which is more prominent in cancer patients [4].

From the perspective of traditional Chinese medicine theory, patients with malignant tumors inherently have a deficiency of healthy Qi [5]. Surgical trauma further depletes Qi and blood, leading to a syndrome of Qi and blood deficiency, as "Qi cannot generate blood, and blood cannot carry Qi" [6]. According to "Medical Formula Examination," this formula is prescribed for those with a deficiency of both Qi and blood. Qi is the father of all bones and muscles, while blood is the mother. They must not be deprived of nourishment." The specific manifestations include a lusterless complexion, lack of energy and desire to speak, fatigue, palpitations and insomnia, pale tongue with a weak pulse, and other symptoms, which are highly consistent with the postoperative frailty syndrome described in modern medicine.

Shenqi Hexue Decoction is derived from the modification of Bazhen Decoction from "Ruizhu Tang's Experienced Formulas," incorporating the principles of Danggui Buxue Decoction and Xuefu Zhuyu Decoction [7]. The complete formula consists of 30 g of Huangqi (Astragalus), 15 g of Renshen (Ginseng), 15 g of Danggui (Angelica), 30 g of Baizhu (Atractylodes), 30 g of Fuling (Poria), 30 g of Baishao (Paeoniae), 15 g of Shengdihuang (Rehmanniae), 15 g of Chuanxiong (Ligustici), 10 g of Taoren (Persicae), 15 g of Xuduan (Dipsaci), 10 g of ZhiQiao (Citri), 10 g of Jiegeng (Platycodi), 10 g of Sharen (Amomi), and 10 g of Zhigancao (Glycyrrhizae). It has the effect of "tonifying Qi and harmonizing blood, removing blood stasis and dredging meridians." Modern pharmacological studies have shown that polysaccharides from Huangqi and ginsenosides from Renshen can promote the proliferation of hematopoietic stem cells [8], polysaccharides from Danggui can increase peripheral blood cell counts [9], total glucosides of paeony can regulate immune function [10], and tetramethylpyrazine from Chuanxiong can improve microcirculation [11].

The multi-disciplinary treatment (MDT) model has become the standard management strategy for bone metastases. The MDT team for bone metastases integrates expert resources from orthopedics, oncology, radiotherapy, and integrated Chinese and Western medicine departments [12]. In this context, this study aims to scientifically evaluate the clinical efficacy of Shenqi Hexue Decoction for Qi and blood deficiency syndrome after PKP surgery, providing a basis for optimizing perioperative management.

2. Materials and methods

2.1. Study design

A retrospective randomized controlled analysis was conducted, adhering to the relevant guidelines of the hospital ethics committee. Patient and medical record data were objective, authentic, and the dataset was essentially complete.

2.2. Study subjects

A retrospective analysis was performed on 36 patients with thoracolumbar metastatic tumors accompanied by pathological vertebral fractures who were treated between January 2020 and December 2023. All patients underwent single-segment PKP surgery. After accessing medical records, the included patients were divided into an experimental group and a control group, with 18 cases in each group based on the study methodology.

Inclusion criteria: (1) The primary lesion was confirmed by tissue biopsy, and single thoracolumbar metastasis (T5-L5 segment) was diagnosed by imaging (MRI/CT/PET-CT); (2) Vertebral compression fracture (compression rate 30–70%); (3) Meeting the diagnostic criteria for Qi and blood deficiency syndrome (referencing the 2022 edition of "Guiding Principles for Clinical Research of New Chinese Medicines"): Main symptoms: fatigue and sallow complexion; Secondary symptoms: dizziness, palpitations and shortness of breath, poor appetite, pale tongue with white coating, and weak pulse; (4) Age between 65 and 75 years.

Exclusion criteria: (1) Coagulation dysfunction (INR > 1.5, PLT < 80×10^9/L); (2) Severe liver and kidney dysfunction (Child-Pugh Class C, eGFR < 30 mL/min); (3) Spinal infection or active systemic infection; (4) Psychiatric disorders or cognitive impairments; (5) Expected survival < 3 months (assessed by Tokuhashi score ≤ 8).

2.3. Treatment methods

Control group: Routine treatment after PKP surgery.

(1) Anti-bone resorption: Intravenous infusion of zoledronic acid 4 mg (once monthly).

(2) Empirical prophylactic infection control.

(3) Empirical nutritional support.

(4) Rehabilitation training: Bed rest for 24 hours after surgery, overall turning every 2 hours, wearing protective gear and ambulating with functional training after 24 hours.

Experimental group: Routine treatment + oral administration of ShenQi Hexue Decoction starting 6 hours after surgery.

(1) Medication composition: Astragalus 30 g, Ginseng 15 g, Angelica 15 g, Atractylodes 30 g, Poria 30 g, Paeoniae 30 g, Rehmanniae 15 g, Chuanxiong 15 g, Persicae 10 g, Dipsaci 15 g, Aurantii 10 g, Platycodi 10 g, Amomi 10 g, Glycyrrhizae 10 g.

(2) Preparation method: Chinese herbal pieces were uniformly decocted by the hospital's designated decoction pharmacy and concentrated into 200 mL × 3 bags per dose.

(3) Usage and dosage: 200 mL/1 bag per time, 3 times a day, taken warm after meals, continuously for 7 days.

(4) Symptomatic modifications: For poor appetite, add Eupatorii 10 g and Atractylodis 15 g; for constipation, add Cannabisi 15 g; for insomnia, add Polygoni Multiflori 15 g.

2.4. Observation indicators

(1) Hemoglobin (Hb): Venous blood samples were collected before surgery and on the 1st, 4th, and 7th days after surgery for testing (using the Sysmex XN-1000 fully automated blood analyzer).

(2) Activity status score: The Karnofsky Performance Status (KPS) was used to evaluate activity capacity on the 1st, 4th, and 7th days after surgery.

(3) Traditional Chinese Medicine (TCM) syndrome score: A scale was developed based on the 2022 edition of the "Guiding Principles for Clinical Research of New Drugs of Traditional Chinese Medicine." It includes 5 primary symptoms (fatigue, sallow complexion, dizziness and vertigo, palpitations and shortness of breath, poor appetite, 0–6 points per item) and 3 secondary symptoms (spontaneous sweating, numbness

of hands and feet, insomnia, 0–3 points per item), with a total score ranging from 0–39 points.

(4) Clinical recovery: Syndrome score reduction ≥ 95%.

(5) Significant effect: Score reduction ≥ 70%.

(6) Effective: Score reduction ≥ 30%.

(7) Ineffective: Score reduction < 30%.

(8) Safety evaluation: Adverse reactions such as nausea, vomiting, and diarrhea were recorded, and liver and kidney function (ALT, Cr) were monitored.

2.5. Statistical methods

Data were analyzed using SPSS 25.0 software. Measurement data were expressed as mean ± standard deviation (SD) and comparisons between groups were performed using the *t*-test. Repeated measures ANOVA was used for repeated measurement data. Count data were expressed as rates (%), and comparisons were made using the χ^2 test or Fisher's exact test. A *P*-value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of baseline data

There were no statistically significant differences in age, gender, primary tumor type, fracture segment, preoperative Hb, and KPS scores between the two groups ($P > 0.05$), indicating comparability (**Table 1**).

Table 1. Comparison of baseline data between the two groups

Item	Experimental group ($n = 18$)	Control group ($n = 18$)	Statistical value	*P*-value
Age (years)	67.8 ± 3.2	68.3 ± 2.9	$t = 0.521$	0.605
Gender (Male/Female)	10/8	9/9	$\chi^2 = 0.118$	0.731
Primary tumor Type				
- Lung cancer	7	6		
- Breast cancer	5	6		
- Prostate cancer	4	4		
- Renal cancer	2	2	$\chi^2 = 0.273$	0.965
Fracture level				
- Thoracic (T5-T10)	11	10		
- Lumbar (L1-L5)	7	8	$\chi^2 = 0.128$	0.721
Pre-op Hb (g/L)	112.6 ± 11.2	114.8 ± 10.7	$t = 0.632$	0.532
Pre-op KPS Score	61.7 ± 6.3	60.9 ± 5.8	$t = 0.427$	0.672

3.2. Hemoglobin changes

The Hb levels in both groups showed a trend of decreasing first and then increasing after surgery, but the decrease in the experimental group was significantly lower than that in the control group ($F = 18.37$, $P < 0.001$) (**Table 2**):

(1) On the 1st day after surgery: There was no significant difference in Hb between the two groups ($P > 0.05$);

(2) On the 4th day after surgery: The Hb level in the experimental group (102.5 ± 8.7 g/L) was significantly

higher than that in the control group (94.3 ± 9.2 g/L)(t = 2.873, P = 0.007);

(3) On the 7th day after surgery: The Hb level in the experimental group rose to (110.6 ± 9.4 g/L), significantly higher than that in the control group (100.8 ± 8.9 g/L)(t = 3.274, P = 0.002);

(4) Maximum Hb decrease: The experimental group (15.3±4.2 g/L) showed a 42.1% decrease compared to the control group (26.5 ± 5.1 g/L)(t = 7.112, P < 0.001).

Table 2. Comparison of postoperative hemoglobin changes between the two groups of patients (g/L, mean ± SD)

Group	Pre-op	Post-op day 1	Post-op day 4	Post-op day 7	Maximum Hb decline
Test group	112.6 ± 11.2	105.8 ± 9.3	102.5 ± 8.7*▲	110.6 ± 9.4**▲▲	15.3 ± 4.2**
Control group	114.8 ± 10.7	104.7 ± 10.1	94.3 ± 9.2	100.8 ± 8.9	26.5 ± 5.1

Note: Compared with the control group, *P < 0.05, **P < 0.01; compared with 1 day after surgery, ▲P < 0.05, ▲▲P < 0.01

3.3. Karnofsky Performance Status (KPS) score

The recovery of post-surgical activity in the experimental group was significantly better than that in the control group (F = 12.84, P < 0.001)(**Table 3**):

(1) On the 1st day after surgery: The KPS scores of both groups were relatively low (experimental group 53.6 ± 5.2, control group 52.8 ± 4.9, P > 0.05);

(2) On the 4th day after surgery: The KPS score of the experimental group (68.4 ± 6.3) was significantly higher than that of the control group (62.7 ± 5.8)(t = 2.954, P = 0.006);

(3) On the 7th day after surgery: The KPS score of the experimental group (78.9±7.1) was significantly higher than that of the control group (70.3 ± 6.5)(t = 3.864, P < 0.001);

(4) Improvement rate (increase of ≥ 10 points): The experimental group was 94.4% (17/18), and the control group was 66.7% (12/18), with a significant difference (χ^2 = 4.433, P = 0.035).

Table 3. Comparison of post-surgical KPS scores between the two groups (score, mean ± SD)

Group	Post-op day 1	Post-op day 4	Post-op day 7	Improvement rate (%)
Test group	53.6 ± 5.2	68.4 ± 6.3**▲▲	78.9 ± 7.1**▲▲	94.4*
Control group	52.8 ± 4.9	62.7 ± 5.8	70.3 ± 6.5▲▲	66.7

Note: Compared with the control group, *P < 0.05, **P < 0.01; compared with 1 day after surgery, ▲▲P < 0.01

3.4. Therapeutic effect of TCM syndromes

The improvement of TCM syndromes in the experimental group was significantly better than that in the control group (**Table 4**):

(1) TCM syndrome score: The score on the 7th day after surgery in the experimental group (8.5 ± 2.7) was significantly lower than that in the control group (14.6 ± 3.8) (t = 5.682, P < 0.001)

(2) Total effective rate: The experimental group was 94.4% (17/18: 2 cases of clinical recovery, 8 cases of marked effectiveness, 7 cases of effectiveness), while the control group was 72.2% (13/18: 5 cases of marked effectiveness, 8 cases of effectiveness, 5 cases of ineffectiveness), with significant differences (χ^2 = 4.433, P = 0.035)

Table 4. Comparison of therapeutic effect of TCM syndromes between the two groups on the 7th day after surgery

Group	n	Clinical cure	Markedly effective	Effective	Ineffective	Total effective rate (%)
Test group	18	2	8	7	1	94.4*
Control group	18	0	5	8	5	72.2

Note: Compared with the control group, *$P < 0.05$*

3.5. Safety Evaluation

No serious adverse reactions occurred in both groups: (1) 2 cases in the experimental group experienced mild nausea (which resolved spontaneously without intervention); (2) 1 case in the control group had constipation (relieved with glycerin enema); (3) Liver and kidney function indicators were all within the normal range.

4. Discussion

4.1. Mechanism of Shenqi Hexue Decoction in reducing hidden blood loss

This study found that the decrease in Hb in the experimental group was 42.1% lower than that in the control group ($P < 0.001$), which is consistent with Zou Wenzhen's research conclusions on Bazhen Decoction [13]. The mechanism of action of ShenQi Hexue Decoction may involve the following three aspects (**Figure 1**).

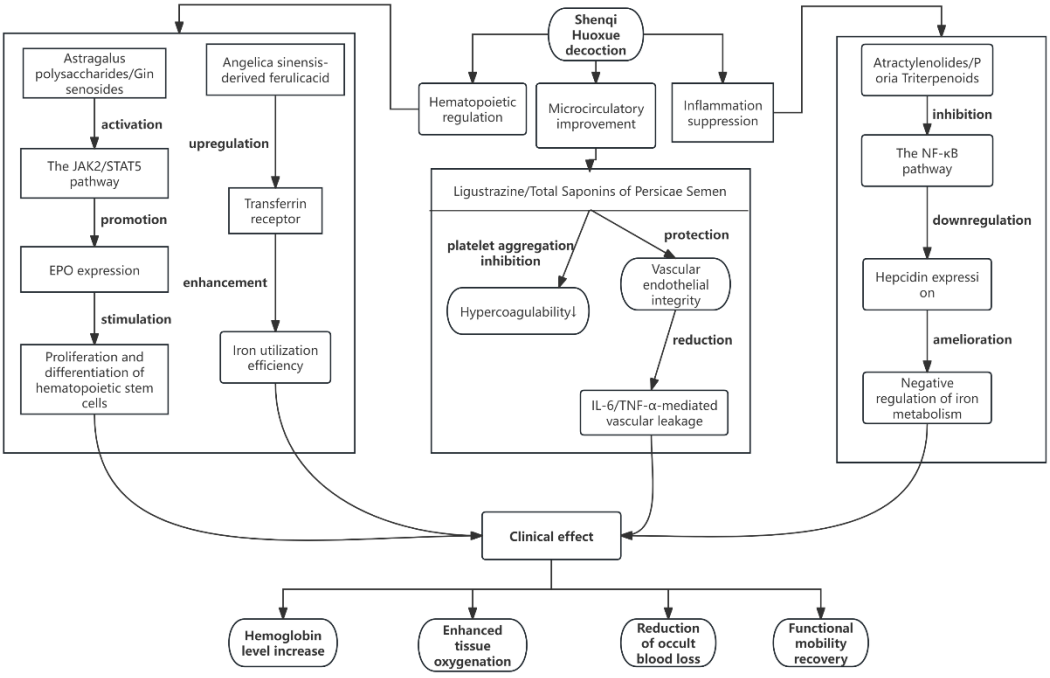

Figure 1. Schematic diagram of the potential mechanism of SHENQI Hexue Decoction.

(1) Promoting hematopoietic regulation: Astragalus polysaccharides and ginsenoside Rg1 in the prescription can activate the JAK2/STAT5 signaling pathway, promote the expression of erythropoietin (EPO), and stimulate the proliferation and differentiation of bone marrow hematopoietic stem cells [14]. Ferulic acid in

Angelica sinensis can enhance the utilization efficiency of iron ions and improve the iron deficiency state of tumor anemia by up-regulating the expression of transferrin receptor [15].

(2) Improving microcirculation disturbance: Tetramethylpyrazine and total saponins of peach kernel have anti-platelet aggregation effects, reduce blood hypercoagulability, and protect the integrity of vascular endothelium, reducing inflammation factors (IL-6, TNF-α) mediated vascular leakage [16]. This is consistent with the effect of "removing blood stasis and dredging meridians" in Shenqi Hexue Decoction, which can reduce blood stagnation in tissue spaces [17,18].

(3) Reducing inflammatory consumption: Atractylenolide and pachyman triterpenes can inhibit the NF-κB inflammatory pathway, down-regulate the expression of hepcidin, relieve its negative regulation of iron metabolism, and reduce iron utilization disorders in inflammatory anemia [19,20].

4.2. Effects of Qi and blood double nourishing method on postoperative functional recovery

This study showed that the KPS score of the experimental group was significantly higher than that of the control group on the 7th day after surgery ($P < 0.01$), and the total effective rate of TCM syndromes was 94.4% ($P < 0.05$), reflecting the clinical effect of "tangible blood comes from invisible Qi":

(1) Improving tissue oxygen supply and energy metabolism: The increase in Hb level directly enhances oxygen transport capacity and improves skeletal muscle hypoxia. Catalpol in Rehmannia glutinosa can activate the HIF-1α pathway, promote glycolysis and angiogenesis, and increase tissue oxygen utilization [21]. Asperosaponin VI can promote the synthesis of Bone Morphogenetic Protein (BMP) and accelerate fracture healing [22], laying a foundation for early functional exercise.

(2) Regulating neuro-muscular function: Paeoniflorin can reduce the incidence of muscle spasms by regulating GABAergic neurotransmission [23]. Ginsenoside Rg3 can cross the blood-brain barrier, act on the hypothalamus-pituitary-adrenal axis, regulate the balance of 5-HT/DA neurotransmitters, and improve symptoms such as "lack of energy, lazy speech, and mental fatigue" [24,25].

(3) Reducing cancer-related fatigue: Shenqi Hexue Decoction improves immune function by increasing the CD4+/CD8+ ratio and NK cell activity. Both Zou Wenzhen's clinical research and Liu Hui's Meta-analysis have confirmed that Bazhen Decoction and similar prescriptions can significantly improve the immune function and activity scores of cancer patients [13,26].

4.3. Positioning and value of traditional Chinese medicine in the MDT model

The MDT model for bone metastases has been operating maturely in many medical institutions at home and abroad, integrating expert resources from orthopedics, oncology, radiotherapy, and integrated Chinese and Western medicine departments. Under this framework, the application value of ShenQi Hexue Decoction is reflected in the following aspects:

(1) Precise symptom management: Targeting the specific syndrome of "Qi and blood deficiency" after surgery, modular processing of symptoms is achieved through syndrome differentiation and treatment. For example, in this study, the addition of Peilan and Cangzhu for appetite loss stimulates the spleen and improves appetite; the addition of Huoma Ren for constipation moistens the intestines and promotes bowel movement, reflecting the strategy of "corresponding formulas and syndromes". Studies by Fang Hua and others have confirmed that modified Bazhen Decoction can reduce the incidence of digestive

tract reactions in chemotherapy patients and improve their quality of life [27,28].

(2) Synergistic efficacy enhancement and risk control: Shenqi Hexue Decoction can reduce the myelosuppression of targeted drugs and improve peripheral blood counts. Studies by Zhao Han and others have found that ginsenoside Rg3 can increase anti-tumor effects by activating the MAPK/ERK pathway to promote the killing effect of CD8+ T lymphocytes [29], reducing the risk of tumor metastasis. At the same time, blood-activating components such as Taoren and Chuanxiong can improve blood hypercoagulability and prevent deep vein thrombosis (DVT) [30,31].

(3) Facilitating the implementation of Rapid Rehabilitation Surgery (ERAS): By reducing hidden blood loss, improving anemia and physical condition, patients can get out of bed and move around on the first day after surgery, just like patients with osteoporotic vertebral pathological fractures. This significantly shortens the length of hospital stay and reduces medical costs.

4.4. Research limitations

This study has the following limitations: (1) Small sample size: Only 36 patients were included from a single center, which may affect the generalizability of the results; (2) Short observation period: The study only observed patients up to 7 days after surgery, lacking medium- and long-term follow-up data; (3) Insufficient exploration of mechanisms: Changes in hematopoietic regulatory factors such as EPO and hepcidin were not detected; (4) No evaluation of tumor prognosis: The effect of the drug on tumor progression was not observed. Future research directions should focus on large-sample multicenter studies, extending follow-up time, and deeply exploring the regulatory mechanism of "Yiqi Shengxue" through molecular biology techniques such as single-cell sequencing. At the same time, it is necessary to evaluate the impact of traditional Chinese medicine compounds on the tumor microenvironment and clarify their precise positioning in MDT.

5. Conclusion

This study confirms that SHENQI Hexue Decoction can effectively improve the hidden blood loss caused by early Qi and blood deficiency syndrome after PKP surgery for patients with thoracolumbar metastatic tumors, enhance postoperative functional activity, and alleviate pathological syndromes of traditional Chinese medicine with good safety. Its mechanism of action involves multi-target regulation such as hematopoietic control, microcirculation improvement, and inflammation inhibition. Under the MDT model for bone metastases, this formula can be used as an important component of integrated Chinese and Western medicine treatment, providing new ideas for optimizing perioperative management of cancer patients.

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Disclosure statement

The authors declare no conflict of interest.

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