

## Original Article

# The feasibility and safety of TCM ironing in patients with long-bone diaphyseal fractures of the extremities during the perioperative period

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**Abstract:** Objective: To investigate the feasibility and safety of traditional Chinese medicine (TCM) ironing in patients with long-bone diaphyseal fractures of the extremities during the perioperative period. Methods: A total of 190 patients with long-bone diaphyseal fractures of the extremities admitted to our hospital were recruited as the study cohort and randomly divided into the study group (n = 95) and the control group (n = 95). The control group underwent conventional fracture intervention during the perioperative period, and the study group underwent TCM ironing in addition to the conventional fracture intervention. The inflammatory factors and hemorheological changes during the perioperative period were compared between the two groups. The patients were followed up for an average of 12 months. The postoperative pain, quality of life, and complications were compared between the two groups. Results: The overall response rates (ORR) were 98.05% in the study group and 92.63% in the control group, and there was no significant difference between the two groups ( $P > 0.05$ ). The comparison of the two groups after the surgeries showed that the inflammatory factors, plasma viscosity, high shear viscosity, and low shear viscosity levels in the study group were lower than they were in the control group ( $P < 0.05$ ). The follow-up showed that the study group had less pain, fewer complications and a higher quality of life than the control group on day 15 and at 1 month after the surgeries ( $P < 0.05$ ). Conclusion: TCM ironing can markedly improve the postoperative inflammatory state, the incidence of postoperative complications, the pain, and the short-term quality of life of patients with long-bone diaphyseal fractures of the extremities during the perioperative period, showing a remarkable efficacy. Therefore, TCM ironing is worthy of clinical promotion and application.

**Keywords:** Long-bone diaphyseal fractures of the extremities, perioperative period, TCM ironing, feasibility, safety

## Introduction

A fracture is a partial or complete break in a bone. Because long-bone diaphysis of the extremities has a wide range of stress surfaces, it is more prone to fracture resulting from a violent shock. Fractures include multiple fractures, comminuted fractures, and multi-segmental fractures [1, 2]. In 1960s, the clinical treatment principle of anatomical reduction, strong internal fixation, and early painless active movement of the muscles and joints was proposed for the treatment of the long-bone diaphysis of the extremities. Under the guidance of this principle, the treatment technique for the long-bone diaphysis of the extremities has been continuously improved, and about 90%-95% of fractures can be cured [3, 4].

However, clinical workers found in clinical practice that some fracture patients, subject to long-term restricted activity, muscle and soft tissue damage and other factors, showed adhesion of their tissues, tendons, or muscles after surgery, and even joint stiffness and a decline in the joint flexion function. This is markedly unfavorable to the prognosis [5, 6]. A retrospective analysis of 1,829 patients with long-bone diaphysis of the extremities showed that about 5.90% of the patients had adhesion of tissues after surgery, and complained that their quality of life was significantly reduced [7]. One study found that the bodies of patients with fractures during the perioperative period are in a high stress state. Restricted activities can remarkably increase the blood viscosity and cause a high incidence of deep

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venous thrombosis (DVT) in the lower extremities, thereby endangering the patients' lives [8]. This provides a background reference for this study.

TCM Ironing, also known as ironing therapy, refers to the intervention measure, namely, stir-fry TCM, which is applied to the affected area, to get access to the blood vessels by means of the physical effects (e.g., medicinal properties or temperature), thus achieving the therapeutic purpose [9]. TCM ironing has been widely used clinically. Some scholars have carried out investigations and research on gonarthrosis and osteoarthropathy, and the results showed that TCM ironing effectively improved the patients' knee joint functions and elevated their Lysholm scores from  $(20.29 \pm 1.29)$  points before the intervention to  $(31.29 \pm 2.30)$  points after the intervention, and the effects were significant [10]. One study found that TCM ironing combined with acupoint adjuvant therapy improved the postoperative muscle spasms and the quality of life of stroke patients [11]. This study aimed to investigate the feasibility and safety of TCM ironing in patients with long-bone diaphyseal fractures of the extremities during the perioperative period, to provide a clinical reference for improving the prognoses of patients with long-bone diaphyseal fractures of the extremities.

### Materials and methods

#### General data

A total of 190 patients with long-bone diaphyseal fractures of the extremities admitted to our hospital from January 2017 to January 2019 were recruited as the study cohort and randomly divided into the study group ( $n = 95$ ) and the control group ( $n = 95$ ). This study was submitted to and approved by the Ethics Committee of Hubei Provincial Hospital of Traditional Chinese Medicine. All the patients signed the informed consent.

Inclusion criteria: (1) patients diagnosed with long-bone diaphyseal fractures of the extremities by imaging, (2) patients with a clear consciousness and the ability to cooperate with the investigation, (3) patients with complete medical records, (4) patients  $\geq 18$  years old, and (5) patients with a clear understanding of the investigation process, methods, and principles.

Exclusion criteria: (1) patients with mental or conscious disorder complications, (2) patients also suffering from coagulation-related diseases, (3) patients also suffering from organic diseases (e.g., coronary heart disease and renal failure), (4) patients allergic to the study drugs, (5) patients who had recently undergone surgery, (6) patients with severe hepatic and renal dysfunction complications, (7) patients also suffering from malignant tumors, (8) patients who are pregnant or lactating, (9) patients with congenital deformities of the extremities, (10) patients suffering from systemic, chronic infections, and (11) patients with pathological fractures.

Rejection criteria: (1) patients who voluntarily withdrew during the investigation, (2) patients who died during the investigation, and (3) patients who were lost to follow up during the investigation.

#### Intervention methods

Both groups underwent the same conventional nursing intervention, treatment and surgery carried out by the same team. The control group did not receive any special intervention, but the study group additionally underwent TCM ironing in addition to the treatment control group underwent. The specific measures were as follows: 25 g of Chinese angelica, 25 g of *Ligusticum chuanxiong* Hort, 20 g of mulberry twig, 20 g of common clubmoss herb, 15 g of *Notopterygium*, 15 g of Rhizoma Corydalis, 15 g of Radix Aconiti Kusnezoffii Preparata, 15 g of Radix Clematidis, 15 g of garden balsam stem, 10 g of Radix Aconiti Preparata, 20 g of Radix Paeoniae Rubra, 20 g of Fructus Evodiae, 20 g of Cortex Cinnamomi, 25 g of Rhizoma Zingiberis, 25 g of Herba Asari, and 25 g of Radix Scrophulariae were selected, mixed, and ground to powder using a comminuter. First, the powder was soaked in mature vinegar for 20 min, and then put in a microwave oven for heating for 5 min, followed by placing the package of medicine on the patient's fracture site to conduct the ironing treatment using TCM manipulation. The TCM manipulation included malaxation, flapping and pressure massage (with a moderate amount of pressure). The treatment lasted for 20 min, once a day. Continuous treatment for 10 d constituted a course of treatment, and there were 2 or 3 courses of treatment.

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### *Observational indices and assessment criteria*

*Comparison of the fracture healing conditions between the two groups:* At 3 months after the surgery, the two groups were followed up. The patients' fracture healing conditions were recorded and compared between the two groups. The clinical efficacies were classified into marked response, moderate response, and no response. Marked response indicated that the clinical symptoms basically disappeared after the treatment, the joint activity was normal, and an X-ray examination showed that the fracture line had basically disappeared. Moderate response indicated that the patients still had pain and restricted joint activity after the treatment, and an X-ray examination showed that the fracture line was visible. No response indicated that the patients had significant pain and restricted joint activity after the treatment, and an X-ray examination showed that the fracture line was clear or flocculent.  $ORR = (\text{Marked response} + \text{Moderate response}) / \text{Total cases} \times 100\%$ .

*Changes in the serum inflammatory factor levels in the two groups during the perioperative period:* Fasting venous serum was collected from the two groups before each surgery and on days 1, 3, and 7 after the surgery, and centrifuged at a low speed. The serum was stored for later use. Enzyme-linked immunosorbent assays (ELISA) were used to determine the serum high-sensitivity C-reactive protein (hs-CRP) and matrix metalloproteinase-9 (MMP-9) levels in the two groups, and the differences were compared between and within the groups.

*Hemorheological changes in the two groups during the perioperative period:* Blood samples were collected before each surgery and on days 1, 3, and 7 after the surgery. The blood samples were analyzed using a SA-9000 hemorheological analyzer (Philips, Netherlands). The indices (e.g., plasma viscosity, high shear viscosity, and low shear viscosity) were recorded, and the differences were compared between and within the groups.

*Comparison of the differences in postoperative pain in the two groups:* On day 15 after each surgery and at 1, 6, and 12 months after the surgery, the differences in the degrees of pain were compared using the visual analogue scale (VAS) in the two groups. VAS is a commonly

used tool for assessing the degree of pain clinically. Specifically, a straight line of 0-10 is drawn on a sheet of paper. 0 represents painless and 10 represents severe pain. The subjects select the degree of pain based on their own feelings. The scale is simple and flexible and has a wide range of applications [12].

*Comparison of differences in the postoperative quality of life scores between the two groups:* On day 15 after the surgery and at 1, 6, and 12 months after the surgery, the quality of life in the two groups was assessed using the SF-36 scale. The scale includes 8 items, namely physiological function, vitality, and emotional function. The scale can assess the patients' quality of life. The scale's total possible score is 100 points, and a higher score indicates higher quality of life [13].

*Comparison of the postoperative complication incidence rates in the two groups:* The postoperative complication incidence rates (e.g., DVT, pulmonary infections, incision infections, osteofascial compartment syndrome) were investigated, and the differences were compared between the two groups.

### *Statistical analysis*

The collected data were input into an EXCEL table, and SPSS 22.0 was used for the statistical analysis. The collected data were analyzed using a normal distribution. The data conforming to normal a distribution were expressed using [n (%)]. The differences between groups were analyzed using chi-square tests. The measurement data were expressed as the mean  $\pm$  standard deviation (mean  $\pm$  SD). The differences between groups were analyzed using t tests, and the comparisons of the differences in the continuous variables were analyzed using Student's t tests.  $P < 0.05$  indicated a statistical difference.

## Results

### *Comparison of the differences in the two groups' general clinical data*

There was no marked difference in the general clinical data (e.g., gender, age, weight, BMI, education level, fractured site, or basic diseases) between the two groups ( $P > 0.05$ ), which were comparable (**Table 1**).

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**Table 1.** Comparison of general clinical indices between the two groups ( $\bar{x} \pm s$ )/[n (%)]

General clinical data		Study group (n = 95)	Control group (n = 95)	t/ $\chi^2$	P
Gender	M	55	53	0.086	0.77
	F	40	42		
Mean age (years)		36.49 $\pm$ 2.32	35.98 $\pm$ 2.44	1.476	0.142
Mean weight (kg)		63.44 $\pm$ 4.21	64.01 $\pm$ 3.98	0.959	0.339
Mean BMI (kg/m <sup>2</sup> )		22.30 $\pm$ 1.20	22.41 $\pm$ 1.41	0.579	0.563
Types of fractures	Fracture of the upper extremity	56	55	0.022	0.883
	Fracture of the lower extremity	39	40		
Education level	University and above	40	37	0.434	0.554
	High school	34	38		
	Junior high school and below	21	20		
Monthly income	<RMB 1000	21	16	0.541	0.521
	RMB 1000-5000	44	40		
	RMB 5000 and above	30	39		
Hypertension	Y	22	20	0.689	0.428
	N	73	75		
Diabetes	Y	20	16	0.891	0.112
	N	75	79		

**Table 2.** Comparison of the fracture healing conditions between the two groups [n (%)]

Group	Number of cases	Marked response	Moderate response	No response	ORR
Study group	95	90 (94.74)	4 (4.21)	1 (1.05)	94 (98.95)
Control group	95	84 (88.42)	8 (8.42)	3 (3.16)	92 (96.84)
$\chi^2$	-	-	-	-	1.022
P	-	-	-	-	0.312

### Comparison of the fracture healing conditions between the two groups

The study group had 90 cases with marked responses and 4 cases with moderate responses, for an ORR of 98.95%, and the control group had 84 cases with marked responses and 8 cases with moderate responses, for an ORR of 96.84%. There was no significant difference in the comparison between the two groups ( $P > 0.05$ ) (Table 2).

### Changes in the serum inflammatory factors in the two groups during the perioperative period

There was no significant difference in the serum inflammatory factor levels between the two groups before the surgery and on day 1 after the surgery ( $P > 0.05$ ). However, the hs-CRP and MMP-9 levels in the study group were sig-

nificantly lower than the levels in the control group on days 3 and 7 after the surgery ( $P < 0.05$ ) (Figure 1).

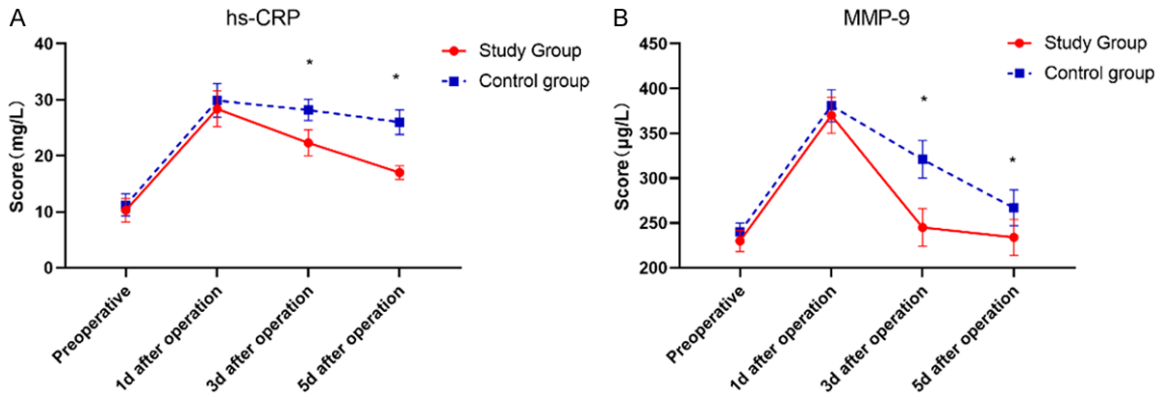
### Hemorheological changes in the two groups during the perioperative period

There was no significant difference in the plasma viscosity, high shear viscosity, or low shear viscosity between the two groups before the surgery and on day 1 after the surgery ( $P > 0.05$ ). The plasma viscosity, high shear viscosity and low shear viscosity in the study group on days 3 and 5 after the surgery were lower than they were in the control group ( $P < 0.05$ ) (Figure 2).

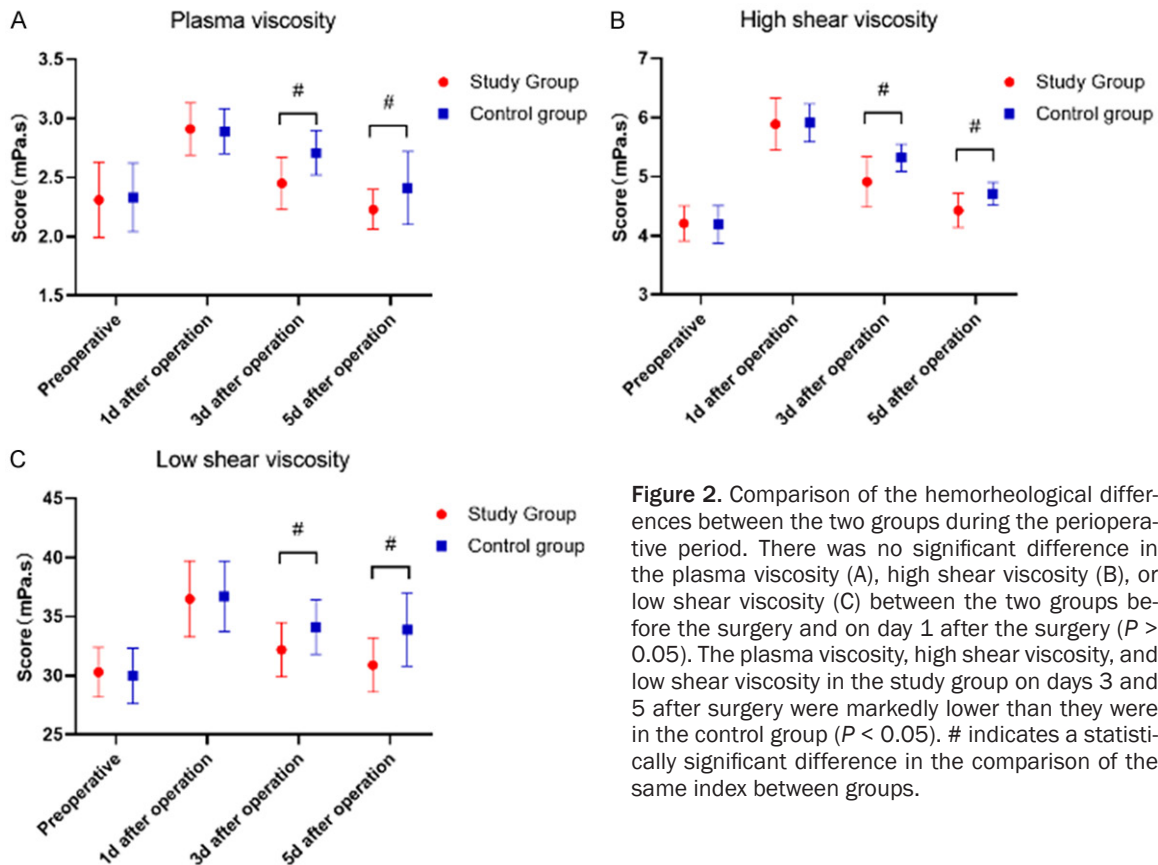
### Comparison of the differences in postoperative pain in the two groups

The two groups were followed up, and the pain was assessed using the VAS scale. The VAS scores in the study group were remarkably lower than the VAS scores in the control group on day 15 after the surgery and at 1 month after the surgery ( $P < 0.05$ ). However, there were no significant differences in the VAS scores in the two groups at 6 and 12 months after the surgery ( $P > 0.05$ ) (Figure 3).

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**Figure 1.** Changes in the serum inflammatory factor levels in the two groups during the perioperative period. There was no significant difference in the hs-CRP (A) or MMP-9 (B) levels in the two groups before the surgery and on day 1 after surgery ( $P > 0.05$ ). The hs-CRP and MMP-9 levels in the study group on days 3 and 5 after the surgery were remarkably lower than they were in the control group ( $P < 0.05$ ). \* indicates a statistically significant difference in the comparison of the same index between groups.



**Figure 2.** Comparison of the hemorheological differences between the two groups during the perioperative period. There was no significant difference in the plasma viscosity (A), high shear viscosity (B), or low shear viscosity (C) between the two groups before the surgery and on day 1 after the surgery ( $P > 0.05$ ). The plasma viscosity, high shear viscosity, and low shear viscosity in the study group on days 3 and 5 after surgery were markedly lower than they were in the control group ( $P < 0.05$ ). # indicates a statistically significant difference in the comparison of the same index between groups.

### Comparison of differences in the postoperative quality of life scores between the two groups

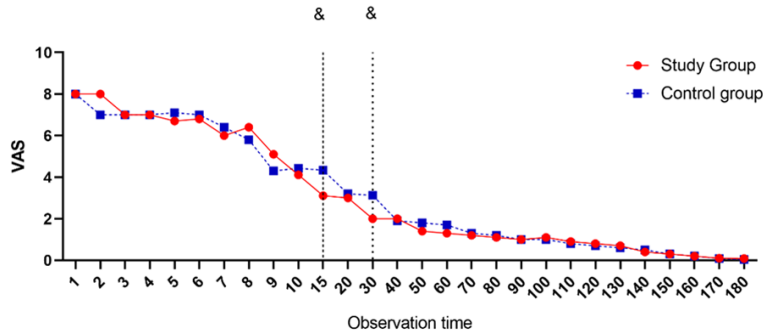
There were noticeable differences in the SF-36 scale scores between the two groups on day 15 after the surgery and at 1 month after surgery ( $P < 0.05$ ). There were no significant differences in the SF-36 scale scores between the two

groups at 6 and 12 months after the surgery ( $P > 0.05$ ) (Figure 4).

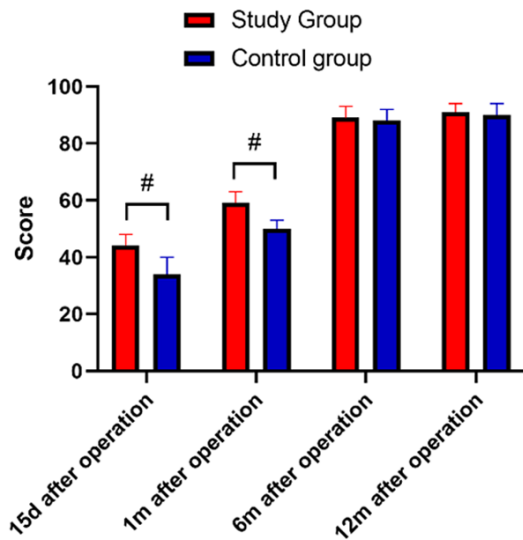
### Comparison of the postoperative complication incidence rates in the two groups

The study had 1 patient with an incision infection after the surgery, for a total complication

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**Figure 3.** Comparison of the postoperative pain between the two groups. The VAS scores in the study group were significantly lower than the VAS scores in the control group on day 15 after the surgery and at 1 month after the surgery ( $P < 0.05$ ). There was no marked difference in the VAS scores between the two groups at 6 and 12 months after the surgery ( $P > 0.05$ ). & indicates a statistically significant difference in the comparison of the same index between the two groups at the same time.



**Figure 4.** Comparison of the differences in the post-operative quality of life scores between the two groups. There were noticeable differences in SF-36 scale scores between the two groups on day 15 after the surgery and at 1 month after the surgery ( $P < 0.05$ ). There was no significant difference in the SF-36 scale scores between the two groups at 6 and 12 months after the surgery ( $P > 0.05$ ). # indicates a statistically significant difference in the comparison of the same index between the groups at the same time.

incidence rate of 1.05%, and the control group had 2 patients with DVT, 1 patient with a pulmonary infection, 3 patients with incision infections, and 1 patient with osteofascial compartment syndrome, for a total complication incidence rate of 7.37%. The differences between the two groups were statistically significant ( $P < 0.05$ ) (Table 3).

## Discussion

Long-bone diaphyseal fractures of the extremities have been extensively observed recently. As the incidence rates of traffic accidents, multiple mechanical and falling injuries are on the rise, there is an increase in the complexity of long-bone diaphyseal fractures of the extremities. The treatment strategy for such fractures focuses on the fastest healing of the fractures and the restoration of extremity function to the maximum extent [14, 15]. In recent years, remarkable progress

has been made in the new theories, techniques, and methods regarding long-bone diaphyseal fractures of the extremities, and the success rate of external and internal fixation has been continuously elevated, and satisfactory effects have been achieved in clinical treatment [16, 17].

Clinical results show that perioperative intervention has a significant effect on the prognoses of patients with long-bone diaphyseal fractures of the extremities. For example, patients with comminuted fractures of the lower extremities must restrict their activities after surgery. However, some elderly patients have a poor tolerance to surgery, and the long-term restriction of activities significantly increases the rate of thrombosis. A retrospective analysis of 981 elderly patients with fractures of the lower extremities revealed that 8.26% of the patients had DVT or DVT symptoms after their surgery under the condition of no special intervention. The scholars believe that the causes were mainly related to postoperative restricted activities and intraoperative vascular damage, and suggested that perioperative intervention should be strengthened to expedite the postoperative prognosis [18]. An investigation suggested that patients with long-bone diaphyseal fractures of the extremities had fewer activities using the affected extremity, the blood viscosity was significantly increased, and the blood flow was slowed down, facilitating thrombosis. The monitoring of the affected extremity after the surgery should be strengthened to prevent thrombosis and improve the prognosis [19, 20]. The aforementioned studies suggest that peri-

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**Table 3.** Comparison of the postoperative complication incidence rates between the two groups [n (%)]

Group	Number of cases	DVT	Pulmonary infection	Incision infection	Osteofascial compartment syndrome	ORR
Study group	95	0 (0.00)	0 (0.00)	1 (1.05)	0 (0.00)	1 (1.05)
Control group	95	2 (2.11)	1 (1.05)	3 (3.16)	1 (1.05)	7 (7.37)
$\chi^2$	-	-	-	-	-	4.698
<i>P</i>	-	-	-	-	-	0.03

operative intervention has a remarkable impact on the prognosis. Therefore, active perioperative intervention is recommended, to alleviate the incidence of adverse events and expedite the restoration of extremity function after surgery.

In this study, the two groups were established to analyze the feasibility and safety of TCM ironing in patients with long-bone diaphyseal fractures of the extremities during the perioperative period. The results indicate that the ORR in the study group (98.95%) was higher than it was in the control group (96.84%), and the complication incidence rate in the study group (1.05%) was lower than it was in the control group (7.37%). A retrospective study of the patients with distal radius fractures found that TCM ironing can facilitate the reduction of fractures and articular surfaces and expedite fracture healing, and the efficacy was satisfactory [21]. The authors believe that the main causes for the poor prognosis of fracture patients include the high incidence of complications and the poor restoration of extremity function. On the one hand, TCM ironing can raise the local skin temperature through thermal stimulation, dilate capillaries, and can increase permeability and expedite the blood circulation. On the other hand, the effective ingredients of TCM can dispel wind and dissipate cold, disperse swelling and relieve pain, soothe the sinews and quicken the network vessels, and exert the effects of the TCM patch, so as to improve the clinical therapeutic effects and mitigate the incidence of complications [22]. Additionally, the changes in the inflammatory factor levels in the two groups after the intervention were analyzed. The results demonstrated that the hs-CRP and MMP-9 levels in the study group were markedly lower than the levels in the control group on days 3 and 7 after the surgery, showing that the inflammatory state in the study group improved more remarkably after surgery.

Some scholars have indicated that fracture and surgical stimulation put the body in a high stress state. An abnormal increase in the inflammatory factor levels notably prolongs the prognosis cycle. The clinical pharmacology has proved that the ingredients (e.g., Cortex Cinnamomi, Herba Lycopodii, and Radix Angelicae Sinensis) can significantly improve the inflammatory state. Meanwhile, the ingredients (e.g., Rhizoma et Radix Notopterygii, Herba Asari, and Radix Scrophulariae) can regulate the metabolism of the body and the vegetative nervous function, soothe the nerves, and rapidly improve the postoperative stress state of the patients [23, 24].

In addition, the postoperative hemorheological changes and the degrees of pain in the two groups were analyzed. The results revealed that the postoperative plasma viscosity, high shear viscosity, and low shear viscosity in the study group were significantly lower than they were in the control group regarding hemorheology. This showed that the postoperative blood flow retardation of the patients was markedly improved. A study has shown that low blood flow rate and vascular injuries are the main causes of postoperative DVT in fracture patients. The study drugs, such as Rhizoma Corydalis and Radix Aconiti Kusnezoffii Preparata, can warm the channels and dissipate cold, and activate the blood circulation and remove stasis. TCM ironing can expedite the blood flow rate through thermal stimulation and stimulate vasodilatation through drug action, thereby optimizing the hemorheological indices of the patients after surgery [25]. Regarding the comparison of the degrees of pain, a study revealed that TCM ironing can introduce thermal stimulation into the nervous system of individuals, and then interfere with the local pain impulses, thus alleviating pain. Additionally, TCM ironing can stimulate sensory nerve endings and further expand blood

vessels through axon reflex, thus effectively alleviating pain symptoms [26].

In summary, TCM ironing can markedly improve the postoperative inflammatory state, the incidence of postoperative complications, and the degree of pain, and the short-term quality of life of patients with long-bone diaphyseal fractures of the extremities during the perioperative period, showing a remarkable efficacy. Therefore, TCM ironing is worthy of clinical promotion and application. The innovation of this study lies in investigating the feasibility of TCM ironing in the treatment of patients with long-bone diaphyseal fractures of the extremities through an analysis of the indices (e.g., postoperative pain, quality of life and hemorheological indices) of patients with long-bone diaphyseal fractures of the extremities, especially the analysis of the hemorheological indices, providing a statistical basis for the treatment mechanism. Therefore, it is worthy of clinical reference. The deficiency of this study includes the incomplete assessment of the patients' postoperative states. We plan to conduct a more detailed observation of the patients' perioperative states in future studies, thus laying an excellent foundation for the clinical promotion and implementation of TCM ironing.

### Disclosure of conflict of interest

None.

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