Bone and Arthrosurgery Science, 2023, Volume 1, Issue 3
http://ojs.bbwpublisher.com/index.php/BAS

Evaluation of the Clinical Effect of Modified *Dipsacus* Decoction in the Treatment of Osteoporotic Fractures

Chunyang Bi*

Department of Orthopedics III, Changping District Hospital of Integrated Traditional Chinese and Western Medicine, Beijing 102208, China

***Corresponding author:** Chunyang Bi, yuhang050625@163.com

Abstract: *Objective:* To observe the clinical effect of modified and subtracted *Dipsacus* Decoction in the treatment of osteoporotic fractures (OPF). *Methods:* 60 OPF cases were divided into two groups based on the double-blind method. Both groups underwent fracture reduction under X-ray guidance and took calcitriol soft capsules simultaneously, while *Dipsacus* Decoction was added to the observation group. The clinical treatment effectiveness, fracture healing time, bone density, laboratory indicators, and incidence of adverse reactions of the two groups were compared. *Results:* The total effective rate of clinical treatment in the observation group was higher than that in the control group, the fracture healing time was shorter than that of the control group, and the bone density and laboratory indicators after treatment were better than those of the control group ($P < 0.05$). There were no severe adverse reactions in either group. *Conclusion:* The addition and subtraction of *Dipsacus* Decoction based on conventional Western medicine treatment for OPF can further improve the effectiveness of clinical treatment and speed up fracture healing, which is worthy of promotion.

Keywords: *Dipsacus* Decoction; Osteoporotic fracture; Effective rate

Online publication: December 26, 2023

1. Introduction

Osteoporotic fracture (OPF) is one of the common clinical orthopedic trauma events. Its occurrence is primarily based on decreased individual bone density and bone quality and increased bone fragility caused by menopause, advanced age, or related diseases [1]. In recent years, integrated traditional Chinese and Western medicine treatment has gradually become a mainstream clinical trend. Compared with the symptomatic treatment of Western medicine, traditional Chinese medicine (TCM) puts more emphasis on "syndrome differentiation and treatment" and considers the relationship between the disease and the body's meridians and the movement of qi and blood, thus allowing a more targeted and comprehensive treatment, addressing both the symptoms and the root causes [2]. *Dipsacus* Decoction is a traditional Chinese medicine prescription that mainly treats orthopedic diseases. It has profound effects of strengthening muscles and bones, consolidating the body and supporting

yang, activating blood circulation, and removing blood stasis. Relevant practice has proven that it has relatively ideal application advantages in promoting fracture healing [3]. This study aims to explore the clinical benefits of the modified *Dipsacus* Decoction on OPF patients.

2. Materials and methods

1.1. Materials

A total of 60 OPF cases admitted from March 2019 to March 2022 were selected as the study samples. Using the double-blind method, the cases were grouped into two groups. The control group had 30 cases with 12 male patients and 18 female patients; age ranged from 52 to 86 years old, with a mean of 69.35 ± 4.87 years old; based on their educational background, 4 completed primary school and below, 12 completed junior high school, 9 with a junior college education, and 5 with a bachelor's degree and above. The observation group had 30 cases with 15 male patients and 15 female patients; age ranged from 53 to 88 years old, with an average of 69.41 ± 4.92 years; according to their educational background, 5 completed primary school and below, 10 completed junior high school, 11 with a junior college education, and 4 with a bachelor's degree and above. After a normalized comparison of the data shown between the groups, there was no significant difference ($P > 0.05$).

Inclusion criteria included patients who are consistent with the relevant diagnostic criteria of the "Chinese Guidelines for the Diagnosis and Treatment of Osteoporotic Fractures - Principles of Diagnosis and Treatment of Osteoporotic Fractures" [4]; the disease has been confirmed by imaging, bone density, and other examinations; patients who have no missing information in their medical records; patients who have no history of mental, cognitive, or psychological diseases; patients who are conscious and can communicate normally; patients who are informed with documented information about the patient; patients who have demonstrated their independent will. Exclusion criteria were patients with malignant tumors; patients with severe dysfunction of vital organs; patients with coagulation disorders and immune system diseases; patients who have received systemic treatment for osteoporosis 2 months before enrollment; patients with severe fractures and life-threatening conditions; patients with extremely poor medical compliance; patients who leave before the completion of the study.

2.2. Methods

After both groups were admitted to the hospital, fracture reduction was performed under X-ray guidance, and external fixation and braking intervention were performed at the same time. Subsequently, the patient was provided with calcitriol soft capsules (National Drug Approval Number: H20213963, Manufacturer: Henan Taifeng Biotechnology Co., Ltd.) for treatment, and was instructed to continuously take 0.25 **μg** each time with warm water, 3 times a day. There were 5 courses of medication, and one course of treatment lasted for 10 days. For the 30 cases enrolled in the observation group, based on the above treatment, modified and subtracted *Dipsacus* Decoction was used. The basic prescription is 15g each of *Dipsacus* spp., psoralen, and *Drynariae*, 10g each of *Astragalus membranaceus*, *Salvia miltiorrhiza*, and natural copper. 1 dose was taken every day, and 400ml of water was added and boiled until there was approximately 200ml juice left, in which 100ml was taken warmly in the morning and evening. It was taken continuously for 5 courses, with 10 days as a course of treatment.

2.3. Observation indicators

(1) Clinical treatment effectiveness

Based on "Guiding Principles for Clinical Research of New Traditional Chinese Medicines" [5], the

symptoms of dizziness, tinnitus, soreness, and weakness of waist and knees, and lumbar spine pain in the two groups were treated with points. The reduction rate of TCM syndrome points (Reduction rate = [points before treatment - points after treatment] / points before treatment × 100%), along with the results of physical examination, X-ray, and other examination were used to evaluate the clinical treatment effectiveness. Basically recovered: TCM syndrome point reduction rate ≥ 95%, no vertical axis percussion pain or abnormal movement, no tenderness, X-ray film shows blurred fracture line, and continuous callus formation; Markedly effective: TCM syndrome point reduction rate is between 70% and 94%, painless percussion, slight local tenderness, X-ray shows sound reduction with relatively blurred fracture line; Effective: TCM syndrome point reduction rate is between 30% and 69%, slight percussion pain and tenderness, X-ray shows basic reduction, with less than 1mm displacement and less than 2mm crack; Ineffective: the relevant content does not meet the above standards.

(2) Fracture healing time

(3) Bone density and laboratory parameters

Bone density of the two groups before and after treatment was accurately measured through X-ray examination. At the same time, 5ml of fasting venous blood was drawn from two groups of patients to determine the specific concentrations of serum vascular endothelial growth factor (VEGF) and osteocalcin (BGP), which were compared between the groups.

(4) Adverse reactions

2.4. Statistical analysis

Using SPSS25.0 software for Windows as the statistical basis, all the obtained data were divided by nature. Measurement data were displayed as mean ± standard deviation (SD), and a parallel *t* test was performed. Count data were displayed as %. At the same time, the chi-square test was performed. $P < 0.05$ indicated that there was a statistically significant difference.

3. Results

3.1. Comparison of clinical treatment effectiveness between the two groups

As shown in **Table 1**, the total effective rate of clinical treatment in the observation group was significantly higher than that in the control group, $P < 0.05$.

Table 1. Comparison of clinical treatment effectiveness [n (%)]

Group	Number of cases	Basically recovered	Markedly effective	Effective	Ineffective	Total effective rate
Control group	30	4 (13.33)	6 (20.00)	12 (40.00)	8 (26.67)	22 (73.33)
Observation group	30	6 (20.00)	9 (30.00)	14 (46.67)	1 (3.33)	29 (96.67)
χ^2	-	-	-	-	-	6.405
P	-	-	-	-	-	0.011

3.2. Comparison of fracture healing time between the two groups

Observation showed that the fracture healing time of the control and observation groups were 13.72 ± 5.14 weeks and 11.11 ± 3.95 weeks, respectively, $t = 2.205$, $P = 0.031$, and the difference between the groups was statistically significant.

3.3. Comparison of bone density and laboratory indicators between the two groups

In **Table 2**, there was no statistically significant difference between the groups in bone density, VEGF, and BGP before treatment, $P > 0.05$. After treatment, the levels of various indicators in the observation group were higher than those in the control group, $P < 0.05$.

Table 2. Comparison of bone density and laboratory indicators (mean ± SD)

Group	Time	Bone density (g/cm^2)	VEGF (μg/L)	BGP (ng/mL)
Control group (n = 30)	Before treatment	0.52 ± 0.19	12.41 ± 5.62	2.37 ± 1.05
	After treatment	0.61 ± 0.24	16.58 ± 6.74	4.88 ± 2.12
Observation group (n = 30)	Before treatment	0.54 ± 0.20	12.39 ± 5.58	2.39 ± 1.06
	After treatment	0.78 ± 0.31	23.72 ± 9.87	8.35 ± 3.69
t	Before treatment	0.397	0.014	0.073
	After treatment	2.375	3.272	4.466
P	Before treatment	0.693	0.989	0.942
	After treatment	0.021	0.002	0.001

3.4. Comparison of adverse reactions between the two groups

After observation, no severe adverse reactions such as liver and kidney damage, occurred in both groups. Only one case of nausea and skin itching occurred in the control group, but these symptoms subsided spontaneously after discontinuing the drug.

4. Discussion

It is widely known that healing after a fracture is a relatively lengthy process. During this period, fracture healing may be affected by factors such as biomechanics, histology, biochemical factors, hormones, etc., leading to slow or even stagnant healing process. In severe cases, healing deformities may even occur and significantly hinder the patient's motor function [6]. Since OPF is not just a simple fracture event, the clinical treatment of this disease goes beyond mere fracture management. In addition to prompt fracture reduction and active use of medication to promote bone healing, it also necessitates targeted treatment of the primary disease, osteoporosis. This comprehensively enhances bone strength and stimulates bone formation [7]. In the past, clinical treatments for OPF were mainly based on Western medicine treatment concepts. Although they did exert a certain degree of therapeutic benefit, they were prone to failure due to long medication cycles and individuals' different tolerance levels to Western medicines. Western medicine treatment causes more adverse reactions, and the overall treatment cost is relatively high, which reduces the patient's treatment compliance and directly affects the overall treatment effect [8,9].

In recent years, due to the long-term accumulation of toxic and side effects of Western medicine and the continuous development of traditional Chinese medicine, most patients have gradually favored conventional Chinese medicine for its advantages of greenness, safety, and significant efficacy. From the perspective of traditional Chinese medicine, osteoporosis can be classified as "bone dryness," "bone paralysis," and "bone fistula." It is mainly affected by individual kidney yang deficiency, spleen weakness, blood deficiency, and blood stasis blocking the meridians. When fractures occur, they will further aggravate the disorder of qi and blood circulation, resulting in bone malnutrition and difficulty in effectively producing marrow. In other words, the basic pathology of OPF is multiple deficiency and blood stasis, so the treatment should be include

nourishing the kidney and strengthening the yang, removing blood stasis and stagnation, with emphasis on promoting blood circulation, dredging collaterals, strengthening bones, and regenerating marrow [10,11]. In the *Dipsacus* Decoction used in this article, Radix Dipsaci exhibit the effects of strengthening muscles and bones and replenishing the liver and kidneys. When used in medium and high doses, it can accelerate the proliferation of bone cells and further increase the expression of osteocalcin and other substances. Psoralen has the effects of strengthening essence, supporting yang, warming the spleen, and absorbing qi, and its extract has high application value in promoting bone formation. *Drynariae* can activate blood circulation, remove blood stasis, strengthen bones, and nourish the kidneys, and its extract also exhibit high application value in promoting bone formation. The total flavonoids in the extraction can speed up the absorption of calcium and phosphorus at the fracture site and further enhance bone density; *Astragalus* has the effect of strengthening the spleen and raising yang, assisting qi and deficiencies, and *Salvia miltiorrhiza* can remove blood stasis, relieve pain, activate and nourish the blood. All of them increase the levels of blood calcium, blood phosphorus, osteocalcin, etc.; natural copper can replenish trace elements such as copper, iron, zinc, manganese, etc., which can further increase collagen content and promote the formation of callus [12-15]. Based on the results of this article, the total clinical treatment effectiveness of the observation group was 96.67%, the fracture healing time was significantly shorter than that of the control group, and bone density and laboratory indicators were significantly improved, suggesting that combined Chinese and Western medicine treatment has higher application advantages, exerting a synergistic effect to further improve the efficiency of clinical treatment and speed up fracture healing.

5. Conclusion

In summary, the addition and subtraction of *Dipsacus* Decoction based on conventional Western medicine treatment for OPF patients can further improve the clinical treatment efficiency without causing severe adverse reactions, and it has high application and promotion values.

Disclosure statement

The author declares no conflict of interest.

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