

## Original Article

# Clinical effect of modified drug and small splint fixation on osteoporotic proximal humeral fractures

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**Abstract:** Objective: To explore the clinical effect of a modified drug and small splint fixation in the treatment of osteoporotic proximal humeral fractures. Methods: Eighty-six patients with osteoporotic proximal humeral fractures were included in this study and randomly divided into an observation group (43 cases) and a control group (43 cases). Patients in the observation group were treated with Xiaoding ointment combined with modified small splint fixation, while those in the control group were treated with locking plate fixation. The shoulder joint function (Constant-Murley and Neer scores) of patients in the two groups were compared one year after treatment. The time of callus appearance, fracture healing, swelling resolution and hospitalization were analyzed, as well as shoulder joint function recovery and complications. The changes of Visual Analogue Scale (VAS) and EuroQol five dimensions questionnaire (EQ-5D) scores before and 3, 6, and 12 months after treatment were compared between the two groups. Results: No significant differences were observed in Constant-Murley and Neer scores and excellent and good rate of shoulder joint function between the two groups ( $P > 0.05$ ). Compared with the control group, the time of callus appearance, fracture healing, swelling resolution and hospitalization time were all shorter in the observation group ( $P < 0.001$ ). After treatment, there were 2 cases of infection, 1 case of ischemic necrosis of the femoral head and 3 cases of screw penetration in the control group, with a complication rate of 13.95%. Whereas, no complication was observed in the observation group, and the difference between the two groups was statistically significant ( $P = 0.026$ ). The VAS and EQ-5D scores did not differ statistically between the two groups before and 12 months after treatment ( $P > 0.05$ ). At 3 and 6 months after treatment, the VAS score decreased while the EQ-5D score increased in both groups; compared with the control group, the VAS score was significantly lower and the EQ-5D score was significantly higher in the observation group (all  $P < 0.05$ ). Conclusion: Modified drug and small splint fixation for the treatment of osteoporotic proximal humeral fractures can significantly improve shoulder joint function, relieve pain and accelerate fracture healing, with a low incidence of complications.

**Keywords:** Modified drug small splint fixation, osteoporosis, humerus, fractures

## Introduction

Osteoporosis is an age-related disease characterized by a decrease in bone mass per unit volume, degeneration in the microstructure of bone tissue, and a decrease in bone strength, leading to an increased risk of fracture. With the development of society and the extension of people's life expectancy, the incidence of osteoporosis keeps increasing each year. Epidemiological data show that in China, the prevalence of osteoporosis among people over 50 years old is 18.6% [1, 2]. Accounting for 5% of the total body fractures, proximal humeral

fracture is common in osteoporosis, most of which is found in the elderly [3-5]. Unfortunately, at present, there is no unified opinion concerning the treatment of proximal humerus fracture in clinic, and the specific treatment scheme is depended on the patients' conditions. In addition, due to the decline of various functions of the elderly, the surgical tolerance of these people is also reduced, resulting in a difficulty to achieve the expected rehabilitation effect; moreover, a decrease in bone strength can also increase surgery difficulty and postoperative complications, such as infection and the risk of screw penetration [6-9]. Therefore, for the treat-

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**Table 1.** General information

Group	Observation group (n = 43)	Control group (n = 43)	t/ $\chi^2$	P
Gender			0.189	0.664
Male	25	23		
Female	18	20		
Age	71.2±4.4	71.5±4.2	0.323	0.747
Time of injury to hospital	1.9±0.6	1.8±0.4	0.909	0.366
Diabetes			0.307	0.579
Yes	9	7		
No	34	36		
Hypertension			0.091	0.763
Yes	6	7		
No	37	36		
Cardiovascular			0.551	0.458
Yes	5	3		
No	38	40		
Neer classification			0.187	0.665
3 partial fractures	24	22		
4 partial fractures	19	21		
Injury mode			0.270	0.874
Tumble	23	22		
Falling injury	11	10		
Traffic injury	9	11		
T	-2.81±0.23	-2.78±0.25	0.579	0.564

ment of osteoporotic proximal humeral fractures, functional recovery should be considered and the safety of the treatment plan should also be ensured.

Small splint fixation, which was first documented in the Central Treasury Canon, is characterized by a simple operation and accurate clinical effects, and it has been widely used in various types of fracture treatment [10]. However, with advances in medical technology, small splint fixation has also exhibited some shortcomings, such as when the swelling subsides, the fixed part is difficult to adjust, resulting in ineffective fixation, and the plank fixation is easily lost [10]. In view of this, the present study improved the traditional small splint fixation, changed the key structure of “diamond knot” to a “triangle roof”, and adopted a new polymer external fixation device for small splint fracture, so as to improve the fixation effect. At the same time, a traditional ointment, capable of promoting blood circulation, removing blood stasis, diminishing inflammation and relieving pain, and promoting bone healing “Xiaoding ointment” made by the Affiliated Hospital of Gansu University of

Chinese Medicine, which has been proven to possess a certain clinical effect in the treatment of fractures, was applied in this study [11]. Based on this, the present study aims to provide a new basis for the clinical treatment of osteoporotic proximal humeral fractures by using a modified small splint fixation combined with the prescription “Xiaoding Ointment”.

### Materials and methods

#### General information

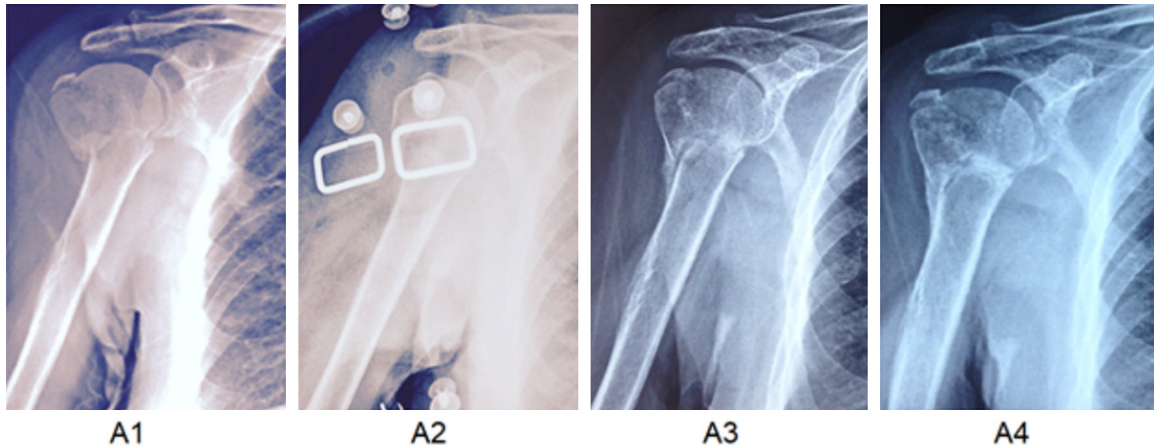
A total of 86 patients with osteoporotic proximal humeral fractures treated in the Affiliated Hospital of Gansu University of Chinese Medicine from January 2017 to January 2019 were selected as the research participants, and were randomly divided into the observation group (43 cases) and the control group (43 cases). There were no statistically significant differences between

the two groups in general data such as gender composition, age, Neer classification, injury mode and bone mineral density T value ( $P > 0.05$ ), showing a balanced group comparability (**Table 1**). All enrolled patients and their families were informed and provided written informed consent to participate. This study was approved by Ethics Committee of the Affiliated Hospital of Gansu University of Chinese Medicine.

#### Inclusion and exclusion criteria

Inclusion criteria: (1) Patients with a definite history of trauma with corresponding symptoms and were diagnosed with proximal humeral fractures by X-ray and computerized tomography (CT) examination; (2) patients with bone mineral density test T value  $\leq -2.5$  SD, who can be clearly defined as having osteoporosis [12]; (3) patients aged  $\geq 60$  years; (4) patients with new closed fractures but no vascular or neurological abnormalities; (5) patients with normal shoulder function before injury; (6) patients with no previous history of fracture; (7) patients with non-comminuted intra-articular fracture,

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**Figure 1.** X-ray picture of the observation group. A1: The orthographic film of the proximal right humerus fracture; A2: The orthographic fixation film with a combined shoulder splint; A3: The orthographic film after 3 weeks of fixation; A4: The orthographic film after 8 weeks.

meeting the indications for diagnosis and treatment.

Exclusion criteria: (1) Patients with multiple or open fractures; (2) patients with old or pathological proximal humeral fractures; (3) patients who were intolerant to the treatment scheme adopted in this study; (4) patients with poor compliance; (5) patients with other underlying diseases.

### Methods

Patients in the control group were treated with internal plate fixation. Kirschner wire was used for fixation. Under good reduction, the humeral locking plate was placed at the appropriate position below the trailing edge of the intertubercular groove and under the top of the major tubercle, and the plate was fixed with cortical bone screws. After good fixation, the surgical incision was cleaned, the drainage tube was placed, the wound was sutured, and the affected limb was suspended with a triangular bandage.

Patients in the observation group received modified drug and small splint fixation treatment. Local infiltration anesthesia was applied to the affected area, and the rectification was started after the anesthesia took effect. For patients with displaced proximal humeral fractures, the three-person reduction method was used for the abduction type, and the abduction over-vertex method was applied for the adduc-

tive type. After reduction, Xiaoding ointment (provided by the Pharmacy Department of the Affiliated Hospital of Gansu University of Chinese Medicine, China), which mainly composed of Pyrolusite, Catechu, rhubarb root parched in wine and Kadsura Root-bark, were pasted to the fracture end. Cotton slivers were applied to the surface of the drug, and then fixed with a new type of polymer splint fracture external fixation device. The triangle roof was fixed above the affected shoulder, and the three wings were connected with the front, middle and rear splints respectively. The length of the anterior splint was determined by the patient's ability to bend 90 degrees. The upper end of the medial splint was level with the armpit, and the lower end was level with the medial epicondyle of the humerus. For adduction fractures, the compression pad was placed on the medial epicondyle of the humerus; while for abduction fractures, the compression pad was placed under the armpit. The band was tied to the middle and lower part of the small splint. After fixation, the affected limb was suspended with a triangle bandage of the forearm. When the splint became loose, the doctor was informed to make adjustments in time. The fracture healing was observed by X-ray on the day of fixation and 3, 8 and 12 weeks after fixation, as shown in **Figure 1**.

Typical cases: A1 is the orthographic film of the proximal right humeral fracture; A2 is the orthographic fixation film with a combined shoulder splint; A3 is the orthographic film after 3 weeks

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**Table 2.** Comparison of Constant-Murley scores

Group	Pain	Shoulder's range of motion	Activities of daily living	Muscle strength	Total score
Observation group (n = 43)	10.28±2.84	15.59±1.72	30.27±2.88	20.45±1.17	77.58±5.59
Control group (n = 43)	11.34±3.35	15.42±1.13	29.74±2.91	20.71±2.14	77.21±5.97
t/ $\chi^2$	1.583	0.554	0.849	0.699	0.297
P	0.117	0.590	0.398	0.487	0.767

of fixation; A4 is the orthographic film after 8 weeks.

Postoperative prophylactic antibiotics were administered to all patients for 3 days. In addition, all patients received anti-osteoporosis treatment: Calcium carbonate 2 times/d, 2 tablets/time (each tablet contains 600 mg of calcium); Calcitriol capsules once/d, 0.5  $\mu$ g/time; Intramuscular injection of salmon calcitonin injection 200 IU/time, once/2 d. The drugs were taken continuously for 1 year.

### Outcome measures

**Primary outcome measures:** Patients were evaluated for shoulder function recovery by Constant-Murley and Neer Scores one year after treatment [13, 14]. Covering pain, shoulder's range of motion, activities of daily living and muscle strength, Constant-Murley shoulder joint score has a score ranges from 0 to 100 points, and a higher score indicates a better recovery of shoulder joint function. The Neer total score ranges from 0 to 100 points, and the score is in direct proportion to the shoulder joint function.

The shoulder function was evaluated according to the Neer score: > 90 as excellent; 80-90 as good; 71-79 as medium;  $\leq$  70 as poor. Excellent and good rate = the number of (excellent + good) cases/the total number of cases in the group \* 100%.

**Secondary outcome measures:** X-ray was performed once a week on patients to observe the appearance of callus and fracture healing, and the swelling resolution time, hospitalization time and complications were recorded.

VAS scale was used to assess the pain of patients in the two groups before and 3, 6 and 12 months after treatment: the score ranges from 0 to 10 points, with 0 being painless and 10 being severe pain [15].

EQ-5D was utilized to evaluate the quality of life of patients in the two groups before and 3, 6

and 12 months after treatment [16]. The higher the score is, the better the quality of life of patients.

### Statistical analysis

SPSS 22.0 was used for statistical analysis. The counting data were described as number of cases and percentage. While expressed as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ), all the measurement data were tested to be in accordance with a normal distribution, and were compared by independent sample t test. Repeated measurements such as VAS and EQ-5D were analyzed by repeated measures analysis of variance combined with post Bonferroni test. The counting data were compared by  $\chi^2$  test. A statistical difference was assumed at  $P < 0.05$ .

## Results

### Comparison of Constant-Murley scores

The results showed that there was no significant difference in the Constant-Murley score one year after treatment ( $P > 0.05$ ). See **Table 2**.

### Comparison of Neer scores

No significant differences were observed in the Neer score and excellent and good rate of shoulder joint function one year after treatment ( $P > 0.05$ ). See **Table 3**.

### Comparison of callus appearance time, fracture healing time, swelling resolution time and hospitalization time

The results showed that compared with the control group, the time of callus appearance, fracture healing, swelling resolution and hospitalization were shorter in the observation group ( $P < 0.001$ ). See **Table 4**.

### Comparison of VAS and EQ-5D scores

The VAS and EQ-5D scores differed insignificantly between the two groups before and 12

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**Table 3.** Comparison of Neer scores

Group	Observation group (n = 43)	Control group (n = 43)	t/ $\chi^2$	P
Neer score	83.79±2.16	82.85±2.24	1.981	0.051
Excellent	10	7	2.205	0.531
Good	23	20		
Medium	8	12		
Poor	2	4		
Excellent and good rate (%)	76.74	62.79	1.985	0.159

**Table 4.** Comparison of the Callus appearance time, fracture healing time, swelling resolution time and hospitalization

Group	Observation group (n = 43)	Control group (n = 43)	t/ $\chi^2$	P
Callus appearance time (d)	37.9±3.4	41.2±3.8	4.365	< 0.001
Fracture healing time (d)	129.5±10.2	148.4±9.8	8.727	< 0.001
Swelling resolution time (d)	13.4±2.3	15.9±2.4	5.08	< 0.001
Hospitalization (d)	15.4±2.8	18.4±3.0	4.753	< 0.001

**Table 5.** Comparison of VAS and EQ-5D health index scores

Group	Observation group (n = 43)	Control group (n = 43)	t/ $\chi^2$	P
VAS				
Before treatment	7.48±2.21	7.52±2.34	0.081	0.935
3 months after treatment	2.01±1.13 <sup>a</sup>	4.09±1.24 <sup>a</sup>	8.130	< 0.001
6 months after treatment	1.62±0.33 <sup>a,b</sup>	2.04±0.58 <sup>a,b</sup>	4.127	< 0.001
12 months after treatment	1.03±0.04 <sup>a,b,c</sup>	1.05±0.07 <sup>a,b,c</sup>	1.627	0.108
F	275.431	189.523		
P	< 0.001	< 0.001		
EQ-5D scores				
Before treatment	0.41±0.12	0.43±0.11	0.806	0.423
3 months after treatment	0.74±0.22 <sup>a</sup>	0.55±0.19 <sup>a</sup>	4.286	< 0.001
6 months after treatment	0.89±0.19 <sup>a,b</sup>	0.78±0.14 <sup>a,b</sup>	3.056	0.003
12 months after treatment	0.97±0.06 <sup>a,b,c</sup>	0.95±0.07 <sup>a,b,c</sup>	1.423	0.159
F	102.739	127.975		
P	< 0.001	< 0.001		

Note: Compared with before treatment at the same group, <sup>a</sup>P < 0.05; compared with 3 months after treatment at the same group, <sup>b</sup>P < 0.05; compared with 6 months after treatment at the same group, <sup>c</sup>P < 0.05. VAS: visual analogue scale; EQ-5D: EuroQol five dimensions' questionnaire.

months after treatment. While the VAS score decreased and the EQ-5D score increased in both groups 3 and 6 months after treatment, and the VAS score was significantly lower while the EQ-5D score was significantly higher in the observation group compared with the control group (all P < 0.05). See **Table 5**.

### Comparison of complications

In the control group, there were 2 cases of infection, 1 case of ischemic necrosis of the humerus head, and 3 cases of screw penetra-

tion, with a complication rate of 13.95%. While no complication occurred in the observation group, and the difference between the two groups was statistically significant (P = 0.026).

### Discussion

Osteoporotic proximal humeral fractures are characterized by difficulty in treatment and slow functional recovery. Thanks to the advances in medical technology and the continuous improvement of fracture internal fixation technology, the clinical treatment of osteoporotic

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proximal humeral fractures has yielded remarkable results. However at present, there is no uniform standard for the treatment of the disease. Locking plate fixation has been shown to produce a good therapeutic effect on patients with osteoporotic proximal humeral fractures [17-19], but it can also lead to complications such as loosening of internal fixation, screw penetration, and acromion impingement. Besides, mostly aged, the patients with osteoporotic proximal humeral fractures are generally afraid of surgery and anesthesia, and worry about the high cost of surgery, so they are more likely to receive conservative treatment [20-22]. Therefore, it is of great clinical significance to explore low-cost, safe and effective conservative treatment methods.

In this study, a modified drug and small splint fixation scheme was adopted. In traditional small splint fixation, the four boards are mainly connected by "diamond knot". However, in the early activities of shoulder joint, the "diamond knot" is easily loosened due to traction and deformation, which requires the physician to make multiple adjustments [10]. In addition, when the swelling of the affected area subsides, the traditional fixation method is difficult to self-adjust and match, leading to poor fixation effect, and even cause the fracture to relocate again. In view of the above problems, the small splint was improved and the structure of "triangle roof" was added, thus avoiding the instability of traditional fixation and the complexity of operation. Studies have shown that compared with traditional small splints, the improvement can significantly improve the comfort and compliance of patients, and obtain better clinical effects [23]. As a biological repair process, bone healing involves various aspects including the regulation of blood circulation, cytokines, biochemistry and physics [24]. Traditional medicine holds that bone healing means "removing blood stasis, regeneration, bone union", so promoting blood circulation and removing blood stasis is the main theoretical basis for treating fracture. In this study, "Xiaoding Ointment", which mainly consists of Pyrolusite, Catechu, rhubarb root parched in wine and Kadsura Root-bark, was utilized to treat the disease in perfect combination with modified small splints. Pyrolusite, the sovereign drug of this recipe with the main component of manganese dioxide, is capable of elimi-

nating carbuncle, dispelling swelling, removing blood stasis and relieving pain, promoting bone regeneration and granulation, and accelerating fracture healing while exerting a certain degree of anti-inflammatory and analgesic effect [11]. Catechu, the minister drug, plays the role of promoting blood circulation and removing blood stasis, which is mainly used for traumatic hemorrhage, traumatic injury and falling pain. The assistant drugs are rhubarb root parched in wine and Kadsura Root-bark. Rhubarb can increase the osmotic pressure of plasma, thereby reducing the viscosity of blood and improving the microcirculation of blood. Kadsura Root-bark can reduce swelling, activate blood circulation, with detoxification capacity, and it has significant anti-inflammatory, antioxidant and analgesic effects. Therefore, this prescription has the effects of promoting blood circulation, removing blood stasis, diminishing inflammation and relieving pain, and promoting fracture healing. In addition, in this study, this recipe was made into ointment, which can be applied to the affected area by mixing the drug with a hydrophilic matrix, thus promoting the better release of drug properties, with less irritation to the skin and less likelihood of allergic reaction. The results showed that compared with locking plate fixation, modified drug and small splint fixation had better clinical results in clinical indicators such as fracture healing time, hospitalization time and callus appearance time, the pain of patients was significantly reduced, and the health index score was higher at 3 months and 6 months after treatment, which also suggested that the modified drug and small splint fixation could reduce the hospitalization cost, alleviate the pain of patients and improve their quality of life. At 12 months, there were no significant differences in pain, health index and shoulder joint function between the two groups, indicating that the long-term effect of the two methods was consistent. Observation of complications showed that infection, ischemic necrosis of the humerus head, screw penetration were present in the locking plate fixation group; while complications were absent in the modified drug small splint group, suggesting that conservative treatment with modified drug and small splint fixation can achieve better clinical effect and avoid complications such as rejection and inflammation caused by surgical treatment.

However, this study also has the following deficiencies: (1) The selected participants are all from our hospital and are single center samples; (2) The sample size is small, with only 86 cases included. Therefore, results still need to be confirmed by the follow-up of a multi-center and large sample study.

To sum up, modified drug and small splint fixation for osteoporotic proximal humeral fractures can significantly improve shoulder joint function, ease pain, and accelerate fracture healing, with low incidence of complications.

### Disclosure of conflict of interest

None.

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