

Study on the effect of gukangling liquid on fracture patients

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ABSTRACT. Objective: To observe the clinical efficacy and healing time of small splint fixation and gukangling liquid in the treatment of patients with closed traumatic fracture treated with conventional western medicine plaster fixation. **Methods:** The patients were divided into two groups: gukangling liquid treatment group and western medicine conventional plaster control group. **Results:** The total effective rate of the experimental treatment group was higher than that of the conventional western medicine control group. **Conclusions:** Gukangling liquid has a good curative effect on the treatment of closed fractures. The clinical healing time of gukangling liquid is one third earlier than that of conventional western medicine.

Keywords: gukangling-liquid; Treatment; Fracture patients; curative effect; research

1. Introduction

Fracture healing has a slow and complex biological process . Delayed fracture healing or fracture nonunion caused by various reasons severely affects the quality of life of patients. Gukangling-fluid[(Z)20092434A] , as an externally applied liquid medicine developed by Kunming Medical University, is composed of ten traditional Chinese Medicinal Herbs, including dipsacus, peach kernel, safflower and panax notoginseng, etc. Gukangling fluid used in this study has been synthesized by

cleaning, chopping, drying and extracting with 80%-95% ethanol from the raw herbals above mentioned. The extracted product has such functions as improving blood circulation, reliving analgesia and swelling, promoting callus generation and fracture healing, which is believed to be suitable for the therapy of traumatic injury and closed fracture.

The process of new fracture repair is accomplished by endochondral ossification and cartilage. Traditional Chinese medicine believes that local qi and blood stasis after fracture could lead to poor blood circulation, blockage of blood stasis and occurrence of blood stasis syndrome. Gukangling fluid exerts various functions, it has been found that it could promote blood circulation, remove blood stasis, eliminate swelling and relieve pain. The effects of Gukangling are dependant on the concrete and potential actions produced by each of the components of it. For example, the efficacy of yanhusuo is involved in promoting blood circulation and removing blood stasis, regulating qi and relieving pain; The efficacy of blood exhaustion huoxuedingtong, is associated with removing blood stasis and hemostasis, generating myocardial ulcer; The efficacy of safflower is related to promote blood circulation and relieve pain; And it has been demonstrated that angelica sinensis could moisten bowel to relieve constipation, promote blood circulation so as to remove blood stasis, regulate meridians, thereby relieve pain; And as for peach kernel, another content of Gukangling fluid, is believed to have multiple efficacies, such as promoting blood circulation, removing blood stasis, moistening intestines and relieving cough and asthma; The other contents of gukangling, such as sappan wood, ligusticum chuanxiong, wei ling fairy, banxia and borneol, has similar and congenerous effects on blood circulation amelioration, pain relieving and blood stasis removing. The above 10 ingredients are commonly used together, it has been indicated that they altogether played roles in promoting blood circulation, removing blood stasis, reducing swelling and relieving pain. In this study,

Based on the previous studies and reports, we conducted an experimental clinical study on the treatment of closed fractures with gukangling fluid. with aim to elucidate the function of gukangling fluid and its associated action mechanism. This will shed a new light on a superior therapeutic strategy in traumatic closed fracture by using Gukangling fluid.

2. Clinical data

2.1 General information

A total of 900 patients with different types of closed traumatic fractures were enrolled in Yunnan provincial orthopaedic hospital from October 2015 to October 2018. They were randomized into two groups. The treatment group consisted of 699 patients who were treated with small splint to fix bone+Gukangling fluid, and the control group consisted of 201 patients who were treated with traditional gypsum. At the time of grouping, there was no marked difference for the degree of fracture between the two groups ($p>0.05$).,And the treatment time-course of the patients depends on the individual fracture situation. .

2.1.2 Medicine

Gukangling fluid (100ml/ bottle), provided by Yunnan provincial hospital of orthopedics, Kunming Medical University, in which professional clinician and X-ray radiography machine were equipped.

2.1.3 Therapeutic method

Treatment group: X-ray- diagnosis - reduction - small splint fixation - fixation and external use of gukangling fluid - reexamination – photography again.

Control group: X-ray- diagnosis - reduction - gypsum fixation - review – photography again.

Patients with closed traumatic fracture of the different type should be diagnosed by X-ray photograph before the treatment. In order to determine the type of fracture, patients in the treatment group were wrapped with thin medicine cotton or gauze at the damage local, and then fixed with small splint. After the fixation, Gukangling-fluid was soakedthrough the medicine cotton into the affected area ,The frequency of Gukangling fluid was 4 times a day, so as to ensure the type of fracture was accurately re-localized by surgical manipulation. The patients in the treatment group were wrapped with thin medicine cotton or gauze and fixed with small splint. The cotton wool was often kept moist in the affected area so as to promote the

opening of skin pores and facilitate the drug absorption. The control group was treated with plaster ,a routine treatment in the Western medicine. Two groups were treated every 10-15 days and then returned to the hospital for follow-up or following the doctor's guidance for treatment, and were subjected to X-ray detection to ascertain the therapeutic effect of fracture and the time course for fracture healing. The clinical efficacy and healing time were revealed by X- line.

2.1.4 Criteria of therapeutic effect

(1) Rehabilitation: Swelling subsides in the affected area, local tenderness and longitudinal tapping pain are absent. X-ray photographs shows that callus grew well at both ends of fracture, hematoma is fully absorbed, clinical fracture is healed completely and function returns to normal state.

(2) Prominent effect: Red, swelling, pain and other symptoms disappear and there exists slight sequelae. X-ray photographs show that callus growth at both ends of fracture is basically possible, hematoma is not fully absorbed, and function is nearly restored to normal state.

(3) Effective: Symptoms and signs disappear and X-ray films show callus grows well but hematoma is not fully absorbed.

(4) Invalid: Symptoms and signs do not disappear and X-ray shows that callus grows not well and hematoma organization is not fully absorbed..

2.1.5 Standard of fracture healing

No local tenderness and longitudinal percussion pain, no abnormal activity in the injured region; X-ray film shows continuous callus formation and the fracture line is blurred. After the removal of external fixation, the fracture was followed up for 2 weeks to be confirmed without deformation.

2.2 Statistical analysis

All data were expressed as mean \pm X, and analyzed with SPSS statistical software package, T test for measurement data, and chi-square test for counting data,

and rank sum test for rank data. A level of $P < 0.05$ was considered as statistically significant.

3. Results

3.1 Comparison of therapeutic efficacy between the two groups (case)

3.1.1 Comparison of fracture sites of different genders

All data were used to compare the fracture sites of different genders, and the differences were not statistically significant ($P = 0.444$). There was no significant difference for fracture sites between the two groups. (See Table 1. and Figure 1.)

Table 1 Comparison of fracture sites of different genders [n(%)]

Sex	long bone	short bone	flat bone l	tota
Male	302(65.9)	83(18.1)	73 (15.9)	458
Female	288(65.2)	71(16.1)	83(18.8)	442
totalL	590(65.6)	154(17.1)	156(17.3)	900

$$\chi^2 = 1.642 \quad P = 0.444$$

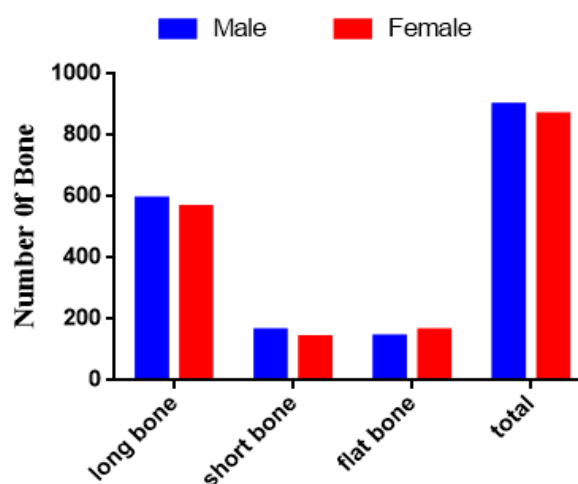


Fig.1

3.1.2 Comparison of therapeutic efficacy between different sexes

All data were used to compare the curative effect of fracture treatment in different genders, and the difference was not statistically significant (P=0.066). There was no marked differenceThe for therapeutic effect between the two groups.(See Table 2. and Figure 2.)

Table 2 Comparison of therapeutic efficacy between different sexes [n(%)]

sexes	Curative	effect	effective	ineffective	Total
Female	324(73.3)	32(7.2)	40(9.0)	46(10.4)	442
Total	630(70.0)	103(11.4)	55(6.1)	112(12.4)	900

The rank sum test z=1.837 P=0.066

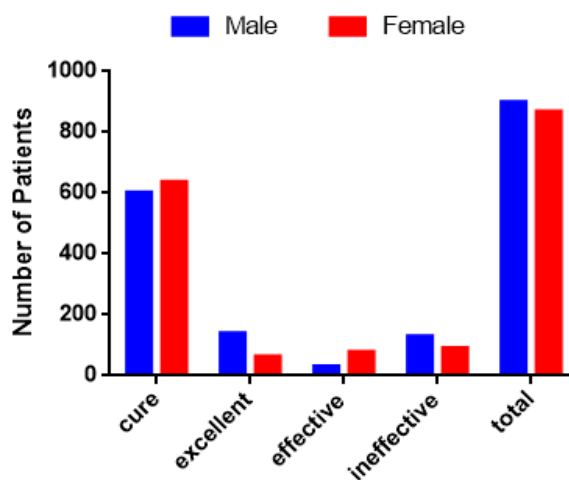


Fig.2

3.1.3 Gender comparison for therapeutic effect between the treatment group and the control group

The difference between the treatment group and the control group was not statistically significant ($P=0.120$), and the two groups had basically the same gender distribution and were comparable. (See Table 3. and Figure3.)

Table 3 Comparison of fracture sites between different genders [n(%)]

groups	men	women	Total
The treatment group	346(49.5)	353(50.5)	699
Control group	112(55.7)	89(44.3)	201
Total	458(50.9)	442(49.1)	900

$\chi^2 = 2.418 \quad P = 0.120$

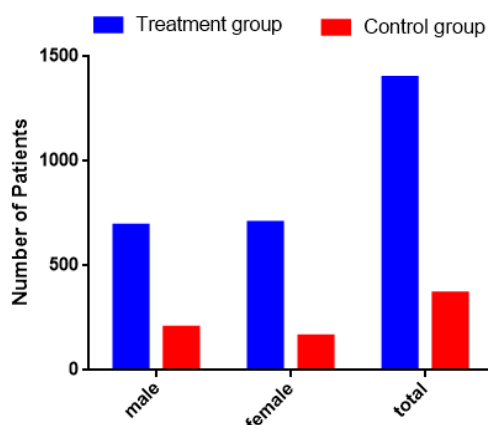


Fig.3

3.1.4 Comparison of fracture sites between the treatment group and the control group

There was no substantial difference for fracture sites between the treatment group and the control group ($P=0.093$). (See Table 4. and Figure4.)

Table 4 Comparison of fracture sites between different genders [n(%)]

Group	long bone	short bone	flat bone	total
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Treatment group	471(67.4)	112(16.0)	116(16.6)	699
Control group	119(59.2)	42(20.5)	40(119.9)	201
Total	590(65.6)	154(17.1)	156(17.3)	900

$$\chi^2 = 4.743 \quad P = 0.093$$

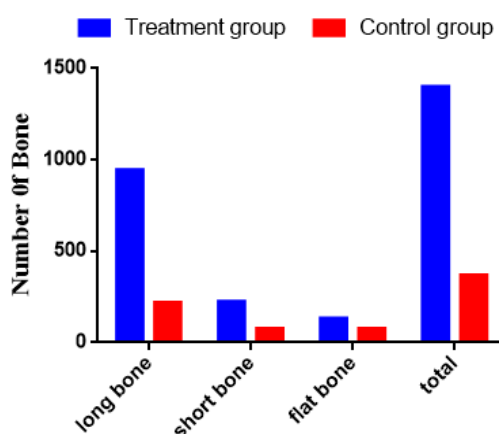


Fig. 4

3.1.5 Comparison of therapeutic efficacy between the treatment group and the control group

In the treatment group, among 699 cases there were 516 cases were cured, accounting for 80.3%, A total of 45 cases were markedly effective, accounting for 6.4%, Among which, 37 cases were effective, accounting for 5.3% and 56 cases were ineffective, accounting for 8%. In the control group, among 201 cases, 69 cases were cured, accounting for 34.3%, 58 cases were markedly effective, accounting for 28.9%, , and another 18 cases were effective, accounting for 9% and 56 cases were ineffective, accounting for 27.9%.

There was significant difference between the two groups as for the therapeutic effects ($P < 0.001$). The cure rate of the treatment group was substantially higher than that of the control group. The total therapeutic effective rate was 92% in the treatment group while 72.1% in the control group. The curative effect of the treatment group was better ($P < 0.001$) than that of the control group. The total

therapeutic effective rate of the treatment group was markedly higher than that of the control group (See Table 5 and Figure5)

Table 5 Comparison of therapeutic efficacy between treatment group and control group [n(%)]

Group	Curative	effect	effective	ineffective	total	Total effective rate (%)
Treatment group	56(80.3)	45(6.4)	37(5.3)	56(8.0)	699	92.0
Control group	69(34.3)	58(28.9)	18(9.0)	55(27.9)	201	72.1
Total	63(70.0)	10(11.5)	55(6.1)	11(12.4)	900	87.6

The rank sum $z=-12.100$ $P<0.001$

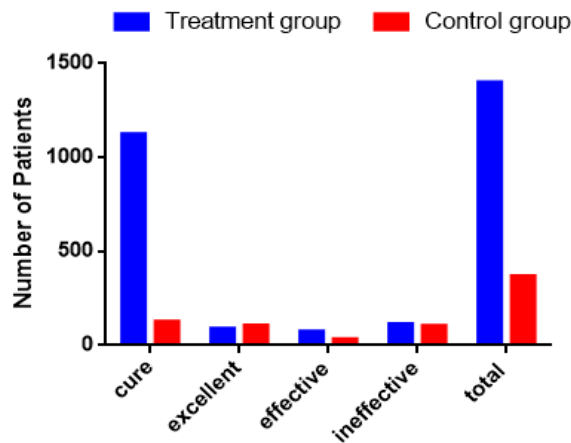


Fig.5

3.1.6 Comparison of healing time between the treatment group and control group

There was significant difference for healing time between the treatment group and the control group ($P < 0.001$). The clinical healing time of the treatment group was obviously shorter than that of the control group (about 17 days ahead of time, $P < 0.001$). (See Table 6. and Figure6.)

Table 6: Comparison of healing time between treatment group and control group

$$(\bar{x} \pm s)$$

Group	<i>n</i>	healing time (day, $\bar{x} \pm s$)	<i>t</i>	<i>P</i>
Treatment group	699	34.19±8.598	-17.169	<0.001
Control group	201	47.35±9.841		

The rank sum test $z=-12.100$ $P<0.001$

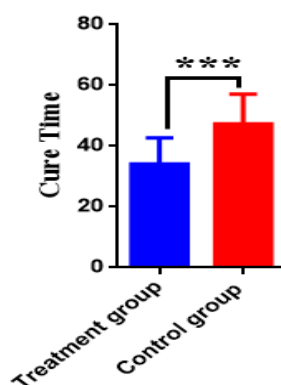


Fig. 6

4. Discussion

The above research results showed that there were 699 cases in the treatment group and 201 cases in the control group. The total effective rate of gu kangling liquid was 92 %, and the total effective rate of conventional western medicine control was 72.1 %. The rank-sum test of grade data comparison between the two groups showed that the efficacy distribution of the two groups was statistically significant ($P<0.05$), and the efficacy of the treatment group was better than that of the control group. The total effective rate of the treatment group was higher than that of the control group (see table 5). Shows that through the use of bone fracture

patients Kang Ling after fluid, X-ray line radiography showed clinical healing time than the average of conventional western medicine treatment of clinical healing(see table 6), about 17 days ahead of time one clinical healing about 17 days ahead of time, 699 people (699 X 17 days / = 11883 days) for 11883 days in advance to improve, if a person save cost 10 yuan a day, 699 people could save 120000 multivariate economic expenses.This drug is simple to use, painless to patients and easy to accept.

5. Summary

In conclusion, gukangling liquid has a good therapeutic effect on patients with closed fractures,The clinical healing time was earlier than that of conventional western medicine.

6. Conflict of interest

The authors confirm that there is no conflict of interest in this manuscript.

Fund project:

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Ethical approval

The patients were informed consent (supplementary 1). The experiment was authorized by the Ethics Committee of Kunming Medical University (supplementary 2).

Informed consent (signature page)

Informed consent statement of subjects:

I have read this informed consent and obtained information about the background, purpose, steps, risks and benefits of this trial. I have enough time and opportunity to ask questions related to this clinical trial and have received satisfactory answers.

I understand that participation in this experiment is voluntary.

I allow my medical information to be used and Shared as described in the informed consent form.

I know that I can withdraw from the study at any time without loss of interest or other adverse consequences.

I am willing to cooperate with researchers for relevant examination or treatment.

I understand that the identity and privacy of individuals participating in this study will be strictly confidential.

I was also told who to contact when I had questions or wanted further information.

I will receive a signed and dated copy of this informed consent.

Signature (print)

Signature date: copy

Legal representative signature (printed, please indicate the direct relationship with the subject)

At Signed by legal representative

Statement of the investigator performing informed consent:

I or my research team have fully explained and explained the background, purpose, steps, risks and benefits of this clinical trial to the subject, given him/her enough time to read the informed consent form, discuss with others, and answer his/her questions about the study; I have informed the contact information of the subject when encountering problems; I have informed the subject (or legal representative) that he/she may withdraw from the study at any time during the study period without any reason.

The investigator's signature (in print)

The investigator's signature (handwriting)