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Clinical Efficacy of Gujian Powder Combined with Shockwave in the Treatment of Early Osteonecrosis of the Femoral Head

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Abstract: *Objective:* To observe the clinical efficacy of Gujian powder combined with extracorporeal shockwave therapy for early osteonecrosis of the femoral head (ONFH). *Methods:* Sixty patients with early ONFH were selected and randomly divided into three groups, with 20 cases in each group. The experimental group was treated with oral gujian powder combined with extracorporeal shockwave therapy. Control group A was treated with gujian powder orally, while control group B was treated with Xianling Gubao capsules orally. *Result:* Compared with before treatment, the VAS score, Harris score, and bone density of the experimental group and control groups A and B were significantly improved at 30, 90, and 180 days after treatment, with statistically significant differences. Compared with the control groups A and B, the experimental group showed more significant improvements in VAS score, Harris score, and bone density at 30, 90, and 180 days after treatment, with statistically significant differences. *Conclusion:* The combination of gujian powder and extracorporeal shockwave therapy significantly improves VAS score, Harris score, and bone density in patients with early osteonecrosis of the femoral head, effectively reduces pain, and improves patient quality of life. Thus, it is worth promoting in the clinics.

Keywords: Traditional Chinese medicine; gujian powder; Extracorporeal shockwave; Femoral head necrosis

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1. Introduction

Osteonecrosis of the femoral head (ONFH) is a difficult-to-treat disease caused by the interruption of blood supply to the proximal femur, which leads to the death of bone cells, affects the body's self-repair, and ultimately leads to structural changes of the femoral head. According to the epidemiological survey, the number of patients with ONFH in China has exceeded 8.15 million [1], and its prevalence has been increasing year by year, primarily affecting young and middle-aged patients. This disease is treated with artificial prosthesis in the late stage, which has the disadvantage of long-term usage, so preventing and controlling it effectively in the early stage is the key direction in this field. Study [2] found that traditional Chinese medicine and shockwave can effectively improve symptoms in the early treatment of ONFH. Based on this, this study combines the two to observe the efficacy of gujian powder combined with extracorporeal shockwave on early ONFH, which was created by Prof. Wei Guikang, a master of national medicine.

2. Information and methods

2.1. General information

A total of 60 patients with ONFH in Ruikang Hospital of Guangxi University of Traditional Chinese Medicine were included in this study and randomly divided into three groups according to the random number method: gujian powder combined with extracorporeal shockwave in the experimental group; gujian powder alone in control group A, and Xianling Gubao capsules in control group B, 20 cases in each group.

2.2. Inclusion criteria

(1) Western medical diagnosis in accordance with the "Chinese Adults with Osteonecrosis of the Femoral Head Clinical Diagnosis and Treatment Guidelines" standard [3] ; Chinese medicine diagnosis in accordance with the "Chinese Medicine Diagnosis and Treatment Criteria" [4] in the "bone erosion" standard; (2) Ficat stage I, II; (3) Hip joint activity limitation, hip pain; (4) No mental, speech, hearing-related diseases; (5) Understand and be informed of the study and be able to provide complete information.

2.3. Exclusion criteria

(1) Hip dysplasia; (2) Cardiac, hepatic, and renal pathologies, coagulation disorders; (3) History of alcoholism, drug dependence; (4) Pregnancy or lactation.

2.4. Methodology

2.4.1. Experimental group

gujian powder combined with extracorporeal shockwave therapy. gujian powder: Deer antler 100 g, *Cistanche* 200 g, American ginseng 100 g, *Panax ginseng* 100 g, jackfruit 200 g, *Cornus officinalis* 100 g, *Pericarpium Citri Reticulatae* 100 g, *Litsea cubeba* 200 g. These ingredients were crushed and made into pills using honey as a binder. Each pill weighs 1.5 g, and the dosage is 3–5 pills taken 2–3 times daily. One course of treatment lasts for 30 days, and a total of six courses were administered.

Extracorporeal shockwave therapy (ESWT): The ESWT device used was the LGT-2510B model from Guangdong Longzhijie Medical Devices Co., Ltd. Under fluoroscopic guidance, the necrotic area was identified and marked on the body surface, carefully avoiding arterial and venous vessels as well as peripheral nerves. Two to four treatment points were selected. Therapy was initiated with low-energy settings and gradually progressed to higher energy levels, depending on the patient's pain tolerance. Each session involved 2,400 shocks, administered every two days at a frequency of twice per week. Each course of treatment lasted 30 days, with a total of six courses completed.

2.4.2. Control group A

gujian powder was taken internally, the same as the experimental group.

2.4.3. Control group B

Patients were given oral Xianling Gubao capsules (National Drug License Z20025337 produced by National Pharmaceutical Group Tongjitang [Guizhou] Pharmaceutical Co., Ltd.), 3 capsules each time, 2 times a day. One course of treatment lasts for 30 days, and a total of six courses were administered.

2.5. Observation indexes

VAS score: VAS score was used as the index of pain degree, and the pain was 0–10 points from mild to severe,0 points for no pain, 1–3 points for mild pain, 4–6 points for moderate pain, and 7–10 points for severe pain.

Harris score: Harris score was used as the patient's hip joint function index, scoring from pain, function, limb deformity, and joint mobility, with a total score of 0–100.

Bone mineral density: Bone densitometer (Qisheng Medical Devices Co., Ltd.) was used to measure the femoral neck, femoral trochanter, and Ward's triangle of the affected side of the hip before, 30d, 90d, and 180d after treatment.

Efficacy criteria: Efficacy was evaluated according to the Expert Consensus on Diagnostic and Treatment Criteria for Adult Femoral Head Necrosis, a combination of imaging and clinical scoring of hip function was adopted, with a ratio of 4:6. Significantly effective: total score ≥ 90 points; effective: total score 70–89 points; ineffective: total score < 70 points.

2.6. Data management and statistical analysis

SPSS 20.0 statistical software was used to analyze the data, the count data were tested by chi-square; the measurement data were expressed as mean ± standard deviation (SD), and the *t*-test was used; the comparison of multi-group data conformed to the normal distribution with ANOVA; the non-normal distribution was tested by rank sum. When $P < 0.05$, the difference was statistically significant.

3. Results

3.1. Comparison of general information

During the process, one patient in group B was withdrawn. Gender and staging were tested by chi-square tests, and age was analyzed by one-way ANOVA. Comprehensive baseline information (see **Table 1**) of the three groups showed that the difference was not statistically significant ($P > 0.05$), and the three groups of patients were comparable.

Table 1. Baseline information

Indicators	Experimental group (n = 20)	Control group A (n = 20)	Control group B (n = 19)	Statistical value	P value
Gender (cases, male/female)	11/9	8/12	13/6	$\chi^2 = 3.178$	0.204
Age (years, ± SD)	40.45 ± 7.48	40.35 ± 6.69	41.05 ± 8.14	$F = 0.04$	0.959
Staging (phase, I/II)	12/8	13/7	9/10	$\chi^2 = 1.310$	0.519

3.2. Comparison of VAS scores

Analyzed by repeated measures ANOVA, Mauchly's sphericity test $P = 0.047 < 0.05$ did not satisfy the sphericity test, and based on the results obtained by the multivariate ANOVA test (**Table 2**), the difference was statistically significant ($P < 0.05$).

Table 2. VAS scores (points, mean ± SD)

Group	*n*	Before treatment	Treatment 30d	Treatment 90d	Treatment 180d
Experimental group	20	5.00 ± 1.02	3.10 ± 0.91	1.85 ± 0.67	1.50 ± 0.68
Control group A	20	4.85 ± 1.26	4.20 ± 1.28	2.95 ± 0.88	2.35 ± 0.67
Control group B	19	4.89 ± 0.93	3.89 ± 1.44	3.16 ± 0.68	2.63 ± 0.49
F value	-	0.10	4.251	17.048	17.403
P value	-	0.905	0.019	0.000	0.000

F_{time} = 100.38, P = 0.000; F_{group} = 14.524, P = 0.000; $F_{alternately}$ = 108.000, P = 0.018

3.3. Harris scores

Data were analyzed by repeated measures ANOVA. Mauchly's test of sphericity $P = 0.158 > 0.05$ satisfies the test of sphericity, and the difference was statistically significant ($P < 0.05$) by the within-subjects effect test (**Table 3**).

Table 3. Harris scores (points, mean ± SD)

Group	*n*	Before treatment	Treatment 30d	Treatment 90d	Treatment 180d
Experimental group	20	62.25 ± 4.87	72.60 ± 4.60	79.75 ± 5.78	84.90 ± 5.95
Control group A	20	64.30 ± 4.93	69.85 ± 4.70	74.60 ±7 .30	78.80 ± 8.95
Control group B	19	63.21 ± 4.31	70.16 ± 5.76	73.05 ± 8.30	76.58 ± 8.95
F value	-	0.943	1.778	4.688	5.613
P value	-	0.395	0.178	0.013	0.006

F_{time} = 69.558, P = 0.00; F_{group} = 11.323, P = 0.000; $F_{alternately}$ = 2.382, P = 0.036

3.4. Bone density

Data were analyzed by repeated measures ANOVA. Mauchly's sphericity test *P* femoral neck = 0.169 > 0.05, *P* Ward's triangle = 0.272 > 0.05 satisfy the test of sphericity, and the within-subjects effect test was used (**Tables 4** to **6**); and the *P* femoral trochanter = 0.001 < 0.05 was used for multivariate testing. The difference was statistically significant ($P < 0.05$).

Table 4. Bone density of femoral neck (g/cm2, mean ± SD)

Group	*n*	Before treatment	Treatment 30d	Treatment 90d	Treatment 180d
Experimental group	20	0.609 ± 0.025	0.630 ± 0.018	0.645 ± 0.027	0.669 ± 0.013
Control group A	20	0.612 ± 0.020	0.619 ± 0.016	0.641 ± 0.029	0.644 ± 0.028
Control group B	19	0.615 ± 0.030	0.621 ± 0.014	0.629 ± 0.027	0.641 ± 0.022
F value	-	0.215	2.526	1.6838	9.472
P value	-	0.807	0.089	0.195	0.000

F_{time} = 31.741, P = 0.000; F_{group} = 5.607, P = 0.000; $F_{alternately}$ = 2.263, P = 0.045

Table 5. Bone density of femoral trochanter (g/cm2, mean ± SD)

Group	*n*	Before treatment	Treatment 30d	Treatment 90d	Treatment 180d
Experimental group	20	0.510 ± 0.011	0.526 ± 0.018	0.537 ± 0.024	0.560 ± 0.042
Control group A	20	0.516 ± 0.016	0.519 ± 0.025	0.529 ± 0.023	0.530 ± 0.031
Control group B	19	0.514 ± 0.020	0.522 ± 0.017	0.524 ± 0.018	0.527 ± 0.026
F value	-	0.714	0.624	1.648	5.534
P value	-	0.294	0.540	0.202	0.006

F_{time} = 54.000, P = 0.000; F_{group} = 5.854, P = 0.005; $F_{alternately}$ = 108.00, P = 0.029

Table 6. Bone density in Ward's triangle (g/cm2, mean ± SD)

Group	*n*	Before treatment	Treatment 30d	Treatment 90d	Treatment 180d
Experimental group	20	0.401 ± 0.149	0.419 ± 0.017	0.433 ± 0.019	0.455 ± 0.029
Control group A	20	0.403 ± 0.020	0.407 ± 0.016	0.418 ± 0.023	0.428 ± 0.021
Control group B	19	0.402 ± 0.014	0.413 ± 0.018	0.416 ± 0.023	0.422 ± 0.020
F value	-	0.215	2.526	1.6838	9.472
P value	-	0.807	0.089	0.195	0.000

F_{time} = 30.184, P = 0.000; F_{group} = 9.227, P = 0.000; $F_{alternately}$ = 3.026, P = 0.01

3.5. Efficacy criteria

Table 7 shows the efficacy of treatment in each group.

Table 7. Efficacy of treatment in each group

Group	*n*	Significantly effective	Effective	Ineffective	Overall effective rate
Experimental group	20	14	5	1	95%
Control group A	20	8	9	3	85%
Control group B	19	6	10	4	80%

4. Discussion

ONFH can be categorized as "bone erosion" in Chinese medicine. In this study, we used the formula gujian powder, which was created by Prof. Wei after decades of medical practice, and it is effective in the treatment of early ONFH. According to Prof. Wei, ONFH is caused by qi stagnation and blood stasis due to insufficiency of the liver and kidney, and the combination of the two leads to the development of ONFH. Insufficient kidney yang leads to a lack of nourishment for the medulla oblongata, causing it to become depleted and the bones to wither. Meanwhile, the liver, which stores blood and governs the tendons as their main source of nourishment, also plays a key role in the regulation of qi and blood. Liver deficiency results in the disruption of this regulation, leading to blood deficiency, qi and blood weakness, inadequate moistening of the organs, and impaired function of the tendons and bones. Consequently, the body becomes susceptible to external pathogens such as wind, cold, and dampness, ultimately resulting in the erosion of the bones. Therefore, Prof. Wei suggested that we should nourish the innate to treat this deficiency, promote menstruation and blood circulation, and resolve blood stasis and open the veins in order to treat the symptoms. There are eight herbs in gujian powder, deer antler and *Cistanche* are the kingpin herbs, which can nourish the kidney, strengthen the bones, and benefit the essence. According to modern pharmacology, antler velvet contains nearly one hundred chemical components, among which antler velvet polysaccharide and antler velvet polypeptide can improve bone density, promote the activity of osteogenic factors in the body, and prevent osteonecrosis [5] . *Cistanche* components can effectively resist bone loss and regulate bone metabolism [6] . American ginseng, *Panax ginseng*, jackfruit, and cornelian cherry are used together as ministerial herbs to enhance the efficacy of the two monarchical herbs. American ginseng nourishes yin and tonifies qi, generates fluids and quenches thirst, and its components can enhance immunity, regulate metabolism, and exert anti-inflammatory and antioxidant properties [7] . *Panax ginseng* activates blood circulation and removes blood stasis, reduces swelling and relieves pain, and its constituents can strengthen the osteogenic function of the body [8] . Jackfruit dispels wind and induces dampness, eliminates blood stasis and detoxifies toxins, and its constituents are analgesic and anti-inflammatory and regulate immunity [9] . *Cornus officinalis* tonifies the liver and kidney, and its constituents achieve anti-osteoporosis effects by regulating calcium and activated oxygen, and osteoclast differentiation [10] . Chenpi and *Litsea cubeba* are the three medicines. Chenpi regulates qi and strengthens the spleen, helps qi to pass; *Litsea cubeba* disperses cold and removes dampness, warms the middle and relieves pain. The whole formula combines the efficacy of strengthening the tendons and bones, regulating qi and dredging, activating blood circulation and relieving pain.

ESWT is a kind of high-pressure, strong sound wave with a short period and low frequency, which produces different forces at the contact surface of the object in its conduction due to the different medium [11] . In the field of ONFH, it has been included in the guidelines as a therapeutic measure because of its simplicity, noninvasiveness, low side effects, and obvious efficacy. Studies on its mechanism of action have shown that ESWT mainly produces effects from mechanomechanics, piezoelectric effect, cavitation effect, sensory closure, etc[12] . ESWT, due to its own acoustic wave qualities, comes into contact with bone in conduction and produces stresses that can induce bone formation; and the charge of the receiving site will change accordingly when it is in conduction to promote osteogenesis. In addition, the small bubbles in human tissues expand rapidly due to the change of pressure, and the high heat generated can improve blood circulation; finally, the stimulation of sensory nerves by ESWT will change the local medium, inhibit nociceptive conduction, and relieve pain.

5. Conclusion

In summary, this treatment has good clinical efficacy for early ONFH, and the effect improves with the passage of time, which has a certain delaying effect on the early disease progression. For the young and middle-aged patients, it greatly delays the time node when the disease progresses to the advanced stage and requires surgical treatment, and it provides a therapeutic idea for the prevention and treatment of ONFH in the early stage.

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Disclosure statement

The authors declare no conflict of interest

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