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Effect of Quyu Shengxin Capsule on Hemorheology and RHS Score of Patients with Early Femoral Head Necrosis

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Abstract: ***Purpose: Based on the clinical work and related experimental research, this subject is to clarify the influence of Quyu Shengxin Capsule on hemorheology and RHS score of patients with early ONFH through randomized controlled trials, so as to analyze and judge the clinical efficacy of Quyu Shengxin Capsule in treating ONFH, and to study Quyu Shengxin Capsule by analyzing the specific mechanism of action through experiments, so as to provide theoretical basis for clinical application. Forty patients with early ONFH were randomly divided into Quyu Shengxin Capsule group (n=20) and Xianling Gubao Capsule group (n=20). Hemorheological indexes were measured before and after 8 weeks of treatment. Results: After treatment, the hemorheology indexes of the two groups were significantly improved compared with those before treatment, and there were significant differences between the two groups before and after treatment After treatment, the repair and reconstruction (RHS) scores of femoral head necrosis in both groups were significantly higher than those before treatment, and the differences between the two groups before and after treatment were statistically significant (P<0.05). Conclusion: Randomized controlled trials proved that Quyu Shengxin Capsule could significantly improve hemorheology and RHS scores of patients with early ONFH, effectively relieve hip pain and discomfort, improve mobility and joint mobility of patients with ONFH, and improve hemorheology indexes, indicating that Quyu Shengxin Capsule could improve symptoms of patients with ONFH and improve hemorheology indexes of patients with ONFH. Comprehensive embodiment of Quyu Shengxin capsule on early ONFH has a good therapeutic effect.***

Keywords: Necrosis of femoral head, Quyu Shengxin capsule, Hemorheology, RHS score**.**

1. Introduction

Femoral head necrosis Osteonecrosis of the FemoralHead (ONFH) is a disease in which multiple traumatic and non-traumatic factors cause damage to the blood supply of the femoral head, repair osteocytes and bone marrow after necrosis, and cause hip pain and dysfunction symptoms [1]. It is predicted that in the next ten years, the total number of people suffering from femoral head necrosis in the world will reach 20 million. It is estimated that there are about 8.12 million non-traumatic femoral head necrosis patients aged over 15 years in China [2]. For patients with femoral head necrosis, early diagnosis and early treatment can effectively delay and curb the progression of the disease; for finding effective drugs for early femoral head necrosis, it is very important to control the development of the disease, delay the process of femoral head necrosis and improve the quality of life of patients [3]. in this context, Quyu Shengxin capsule, a drug for that treatment of femoral head necrosis in Shaanxi Province hospital of traditional Chinese medicine, has been widely use in clinical practice, mainly in the treatment of hip pain and discomfort, movement limitation and other symptoms of femoral head necrosis patient, and scientific research on Quyu Shengxin capsule is also steadily carried out. Quyu Shengxin capsule, which originated from the clinical application experience of many years in Shaanxi Province hospital of traditional Chinese medicine, has been approved by the hospital preparation (Batch number: Z20150050), composed of Astragalus membranaceus, Rhizoma Sparganii, Rhizoma Zedoariae, Ramulus Cassiae, Rhizoma Fritillariae Cirrhosae and Semen Strychni. It has the functions of invigorating qi, activating blood circulation, removing blood stasis and relieving pain [4]. It has obvious effect on improving hip pain, flexion and extension limitation of early femoral head necrosis. It is mainly used in early or late femoral head necrosis patients who do not want surgery. Quyu Shengxin Capsule is widely used in the treatment of femoral head necrosis because of its convenience, low price and definite curative effect. It provides scientific basis for the standard application, popularization and further research and development of Quyu Shengxin capsule in preventing and treating femoral head necrosis.

2. Data and Methods

2.1 Diagnostic Criteria

Those who meet the diagnostic criteria of ONFH in China Clinical Guidelines for the Diagnosis and Treatment of Femoral Head Necrosis in Adults [5]: 1) The symptoms are pain in hip, hip and groin area, occasional knee joint pain, mainly limited internal rotation of hip joint; 2) The patients often have a history of alcoholism and hormone abuse; 3) X-ray, CT, MRI or other examinations suggest osteonecrosis.

2.2 Inclusion Criteria

(1) patients who met the diagnostic criteria and were in ARCO stages 1, 2, and 3A; (2) age>18 years old, regardless of gender; (3) withdrawal of hormones or other immune preparations for more than 3 months, prohibition of alcohol consumption; (4) consent and voluntary truthful information on disease changes, adherence to hip preservation therapy, and refusal of surgical treatment; (5) Patients and their families were informed of the study contents and voluntarily signed the consent form, and the patients accepted and were treated and followed up in full

accordance with the study protocol.

2.3 Exclusion Criteria

(1) traumatic necrosis of femoral head caused by trauma; (2) previous liver and kidney dysfunction, or severe cardiovascular and cerebrovascular diseases; (3) malignant tumor, hematological diseases or severe mental disorders; (4) allergy to study drug; (5) failure to cooperate with treatment and follow-up, still drinking heavily during treatment, continuing oral hormones, etc.; (6) pregnant and lactating women.

2.4 Treatment Methods

This study recruited eligible subjects from the Orthopedics Clinic of Shaanxi Province Hospital of Traditional Chinese Medicine from December 2021 to August 2022. Forty patients numbered 1-40 who met the inclusion criteria were randomly divided into treatment group and control group, with the ratio of 1:1. The treatment group: oral Quyu Shengxin Capsule, 3 capsules/time, 3 times/day, after meals. The control group: Xianling Gubao capsule was orally taken 3 capsules/time, 3 times/day after meals. The treatment group and the control group were treated for 4 weeks for 2 courses.

2.5 The Drug Composition

Treatment group: Quyu Shengxin Capsule (hospital preparation of Shaanxi Province Hospital of Traditional Chinese Medicine, batch number: Z20150050), composed of Astragalus membranaceus, Rhizoma Sparganii, Rhizoma Zedoariae, Ramulus Cassiae, Fritillaria tubulosa, Semen Strychni. The drug composition of control group: Xianlinggubao Capsule (Guizhou Tongjitang Pharmaceutical Co., Ltd., batch number: Z20025337), composed of Dipsacus root, Epimedium, Fructus Psoraleae, Radix Rehmanniae, Radix Salviae Miltiorrhizae, Rhizoma Anemarrhenae.

2.6 Outcome Measures

Before treatment and after 8 weeks of treatment, 4ml of fasting venous blood was taken from the patients, and the whole blood viscosity, plasma viscosity, hematocrit and other hemorheological indexes were measured with SA-9000 automatic hemorheological tester in Beijing Saikesid Hospital and Laboratory Department of Shaanxi Province

2.6.1 Femoral Head Necrosis Repair and Reconstruction (RHS) Score

Repair and reconstruction of femoral head necrosis (RHS) score: Before treatment and after 8 weeks of treatment, RHS score data including pain, mobility, joint range of motion and X-ray examination were collected.

2.7 Statistic Analysis

SPSS27.0 software package was used. $\chi 2$ test was used for counting data. Normal distribution of measurement data was expressed as "mean ± standard deviation (x±s)". Independent sample t test was used for inter-group comparison, and paired t test was used for intra-group comparison. $\alpha=0.05$, $P>0.05$ indicated that the difference was not statistically significant; $P<0.05$ indicated that the difference was statistically significant; $P<0.01$ indicated that the difference was statistically significant.

3. Results

3.1 General Condition

40 patients with femoral head necrosis in early and middle stage were included, 40 patients completed the design scheme, and 40 patients entered the result analysis.

3.2 Comparison of Age, Height, and Weight

Comparison of baseline data between the two groups showed statistical differences ($P>0.05$).

Table 1: Comparison of baseline data between the two groups (x±s, score)

Group	Number of cases	Age	Height/m	Weight/kg
treatment group	20	55.35±14.18	1.62±0.06	60.93±10.39
control group	20	58.95±14.55	1.64±0.06	62.53±10.70
t value		-0.792	-0.737	-0.478
P value		0.433	0.856	0.908

3.3 Comparison of Hemorheology

3.3.1 Whole Blood High Shear Viscosity Results

The study showed that there was no statistically significant difference in whole blood high shear viscosity between the two groups before treatment ($P>0.05$). After treatment, the results of each group were lower than before; among them, the whole blood high shear viscosity of the treatment group decreased more significantly ($P<0.05$), Table 2.

Table 2: Whole blood high shear viscosity/(mPa·s) of the treatment group and the control group.

Group	Number of cases	before treatment	posttreatment	t
treatment group	20	5.36±0.20	4.31±0.14	19.60
control group	20	5.35±0.14	4.64±0.15	15.507
t value		0.156	-7.178	
P value		0.877	<0.01	

3.3.2 Whole Blood Mid-shear Viscosity Results

The results showed that there was significant difference between the two groups before treatment ($P>0.05$). The scores of all groups after treatment were lower than those before treatment; the whole blood low shear viscosity of the treatment group decreased more significantly ($P<0.05$), Table 3.

Table 3: The whole blood middle shear viscosity/(mPa·s) of the treatment group and the control group decreased more significantly ($P<0.05$).

Group	Number of cases	before treatment	posttreatment	t
treatment group	20	10.10±0.36	6.44±0.37	318.533
control group	20	10.11±0.35	6.71±0.3	304.527
t value		-0.176	-24.514	
P value		0.871	<0.01	

3.3.3 Whole Blood Low Shear Viscosity Results

The study showed that there was significant statistical difference between the whole blood low shear viscosity of the two groups before treatment (P>0.05). The scores of each group after treatment were lower than those before treatment; among them, compared with the control group, the whole blood low shear viscosity of the treatment group decreased more significantly (P<0.05), Table 4.

Table 4: Whole blood low shear viscosity/(mPa·s) of the treatment group and the control group

Group	Number of cases	before treatment	posttreatment	t
treatment group	20	15.58±0.06	9.59±0.07	247.172
control group	20	15.55±0.09	10.02±0.07	267.216
t value		-0.025	-19.589	
P value		0.980	<0.01	

3.3.4 Plasma Viscosity Results

The study showed that the plasma viscosity of the two groups showed statistically significant difference before treatment (P>0.05). After treatment, the scores of the two groups were lower than before, and the treatment group was opposite to the control group, and the plasma viscosity decreased more significantly (P<0.05), Table 5.

Table 5: Plasma viscosity/(mPa·s) in the two groups

Group	Number of cases	before treatment	posttreatment	t
treatment group	20	2.23±0.06	1.85±0.04	23.936
control group	20	2.23±0.07	2.04±.081	7.976
t value		0.026	-9.565	
P value		0.980	<0.01	

3.3.5 Hematocrit results

The study showed that the hematocrit of the two groups showed statistically significant difference before treatment (P>0.05). After treatment, the scores of the two groups were lower than before, and the treatment group was significantly lower than the control group (P<0.05), Table 6.

Table 6: Hematocrit of two groups

Group	Number of cases	before treatment	posttreatment	t
treatment group	20	0.55±0.049	0.35±0.06	11.331
control group	20	0.55±0.056	0.45±0.04	6.397
t value		0.026	-5.811	
P value		0.980	<0.01	

3.4 Comparison of Repair and Reconstruction (RHS) Scores for Femoral Head Necrosis

The study showed that the RHS scores of the two groups showed statistically significant difference before treatment (P>0.05). After treatment, the RHS scores of the two groups were lower than before, and the treatment group was opposite to the control group, and the RHS scores of the two groups decreased more significantly (P<0.05), Table 7.

Table 7: Comparison of RHS scores between treatment group and control group (x±s, points)

Group	Number of cases	before treatment	posttreatment	t
treatment group	20	53.73±4.83	78.00±7.145	-20.856
control group	20	53.50±4.894	71.70±5.155	-17.121
t value		0.163	3.299	
P value		0.850	<0.01	

4. Discussion

Quyu Shengxin Capsule, whose predecessor is Quyu Shengxin Formula, has been shown by preliminary basic research that Quyu Shengxin Formula can improve hemorheology indexes, increase blood flow velocity and blood flow, correct blood viscosity, concentration, coagulation and aggregation, reduce blood viscosity, change blood hypercoagulability and hyperviscosity, improve microcirculation, and has good effect of “activating blood circulation and removing blood stasis”[6]. It provides good conditions for bone metabolism absorption and bone formation repair by reducing blood fat, correcting lipid metabolism disorder and protecting blood vessel wall in head. Comprehensive experimental results show that the mechanism of Quyu Shengxin Formula in treating ONFH may be related to improving hemorheology and regulating blood fat [7-9]. Quyu Shengxin Capsule, an improved preparation based on Quyu Shengxin Formula, was found to be scientific and reasonable in extraction and inclusion technology of volatile oil, and its quality standard was comprehensive and scientific [10]. Compared with the model group, Quyu Shengxin Capsule of high, medium and low doses can significantly improve the degree of foot swelling and pain in model mice, further proving that Quyu Shengxin Capsule has significant curative effect in relieving pain and improving local swelling discomfort symptoms [11].

Hemorheology is a discipline that studies the law of blood flow deformation in the flow of blood [12]. Hemorheology detection has close contact with clinical subjects, ONFH is also closely related to it [13]. Hemorheology reflects the consistency, viscosity, plasma viscosity, blood cell aggregation and coagulation type of blood cells. Many reasons cause abnormal hemorheology, which can be manifested in increased whole blood viscosity, red blood cell aggregation state, blood flow slowdown, increased blood flow resistance, etc. Further development of these abnormalities will result in decreased microcirculation perfusion, ischemia and hypoxia of tissues and organs, even capillary occlusion, blood flow stagnation, internal environment disorder.

Hemorheology indicators due to various reasons abnormal, can lead to the body blood flow showed slow speed, fluency abnormal, thus showing systemic or local microcirculation disorders. Studies have found that ONFH patients with hemorheology indicators test, in which whole blood high shear, low shear, plasma viscosity are abnormally high, breaking through the normal range, suggesting that ONFH patients with hemorheology abnormal performance [14]. Hemorheology index, whole blood viscosity is its basic parameter, but also reflects the important index of blood viscosity. Hematocrit reflects the concentration of red blood cells in the blood, abnormal increase of hematocrit reflects the increase of blood viscosity, blood fluidity deterioration. Hemorheology index in the early diagnosis of avascular necrosis of the femoral head, not only in the early diagnosis, but also for early intervention, delay the development of the disease has a certain guiding significance.

The repair and reconstruction of femoral head necrosis (RHS) score evaluates the treatment of ONFH patients in four aspects: pain degree, mobility, joint mobility and X-ray examination [7]. Pain is one of the main symptoms of ONFH, mobility and joint mobility are the main factors affecting the quality of life and work of ONFH patients. RHS score provides detailed evaluation and score, thus intuitively reflecting the patient's intuitive feedback on various treatment methods. It is worthy of application and promotion to ONFH clinical efficacy evaluation because of its intuitive expression of the degree of pain relief, mobility and joint mobility optimization of ONFH pain symptoms [15].

5. Summary

This trial proves that Quyu Shengxin Capsule can effectively relieve the pain and discomfort symptoms of patients with early ONFH, greatly improve the patient's painful and uncomfortable disease experience, and greatly optimize the mobility and joint mobility of patients with early ONFH, so that the drug treatment can finally be implemented to relieve the subjective feelings of patients, improve the patient's mobility, optimize the joint mobility, and thus improve the quality of life of patients. At the same time, the test also verified that Quyu Shengxin Capsule can reduce the hemorheology indexes of early ONFH patients, including whole blood viscosity, plasma viscosity and hematocrit, improve and correct blood fluidity and viscosity, thus improving systemic microcirculation. For venous stasis and microcirculation disorders of early ONFH, it has superior prevention and treatment effects, truly achieving early treatment and early remission of ONFH and effectively controlling the development of ONFH. From the angle of disease prevention, it greatly reduces the possibility of rapid progression and deterioration of ONFH due to failure of timely and effective treatment, thus effectively reducing the destructive power to the life and quality of life of ONFH patients. To sum up, Quyu Shengxin capsule can effectively alleviate the symptoms of early ONFH patients, improve mobility and joint mobility, and has superior hemorheology improvement ability. It is a good clinical medicine for early ONFH, treating both symptoms and root causes, and is worthy of continuing to excavate its scientific connotation and clinical promotion.

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