

Study on Efficacy of Modified Headache Formula I on Patients with Migraine and Its Improvement on Free Radical Disorder

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Abstract: In this study, migraine patients were treated with the addition and subtraction of headache formula I. Compared with conventional Western medicine treatment, under the treatment of this formula, the levels of serum NO and ET-1, SOD, MDA, and migraine attacks in the patients were significantly improved, achieving the goal of improving the symptoms of free radical disorder in patients and helping them recover.

1. Introduction

Migraine belongs to the neurology department in clinical practice. Symptoms of migraine can recur and worsen in patients. If patients do not receive timely treatment, it will directly affect their health, life, and work. There is currently no optimal treatment for migraine in clinical practice. In this study, patients with migraine were treated with headache formula I, and the specific content of the study is described below.

2. Information and Methods

2.1. General Information

70 patients with migraine who were treated in our hospital from August 2022 to August 2023 was selected as the subjects of this study. They were randomly divided into the experimental group and the control group with 35 patients in both groups by using a numerical table. There were 19 male patients and 16 female patients in the experimental group with an age range of 30-65 years old and an average age of (45.86 ± 2.19) years old. And there were 20 male patients and 15 female patients in the control group with an age range of 31-66 years old and an average age of (46.19 ± 1.80) years old. The general information in two groups of patients were compared, and $p > 0.05$.

This study has been approved by the Medical Ethics Committee of our hospital, and all patients have been informed of and been consent to the research content. Inclusion criteria: (1) Patients can follow medical advice for the treatment and have good treatment compliance; (2) Patients are not allergic to the medication used; (3) Patients are not of special types such as ophthalmoplegic migraine or hemiplegic migraine. Exclusion criteria: (1) Patients has cerebrovascular disease; (2) Patients have primary kidney disease; (3) Patients have infectious diseases.

2.2. Methods

Patients in the control group were treated with lomerizine hydrochloride tablets (Manufacturer: Nanjing Changao Pharmaceutical Co., Ltd., National Drug Approval Number: H20050119) with a medication dose of 2mg/time and a medication frequency of 2 times per day. Patients took the medication once in the morning and once in the evening respectively.

On the basis of the control group, patients in the experimental group were treated with modified headache formula I, which included 6g Glycyrrhiza, 6g Scorpion, 6g Asarum, 15g Gastrodia Elata, 3g Scolopendridae, 12g Bombyx Batryticatus, 12g Angelica Dahurica, 10g San Qi, 10g Notopterygium, 10g Saposhnikovia Divaricata, 10g Nepeta Cataria, 10g Eupolyphaga, 10g Typhonium Giganteum, 30g Chuanxiong. If the patient is slightly hot, add 10g of Huangqin and 12g of Chaihu. If the patient has blood deficiency, add 15g of Huangqi. Patients should take one dose twice a day in the morning and evening respectively. Patients in both groups require 12 weeks of treatment.

2.3. Observation indicators

The levels of serum NO and ET-1, SOD, MDA, and migraine attacks in the experimental group were better than those in the control group. The main observation of migraine attacks is the number of headache attacks, duration of each attack, and headache severity score of the patient. The score of headache severity is determined based on *the Diagnosis and Efficacy Standards for Traditional Chinese Medicine Diseases* with a total score range of 0-10 points. A score of 0-1 point indicates no pain, that of 2-4 points indicates mild pain with a maximum of 15 migraine attacks per month and a duration of no more than 24 hours per attack. A score of 5-7 points indicates moderate pain with a range of 15-30 migraine attacks per month and a duration of 24-72 hours per attack, and that of 8-10 points indicates severe pain with migraine attacks exceeding 30 times per month and lasting for more than 72 hours.

2.4. Statistical methods

The research data were analyzed by SPSS 26.0 software, and the measurement data was presented as mean \pm standard deviation. The t-value was used as the research test value. If $p < 0.05$ was obtained, it indicates that there is statistical significance between the research data.

3. Results

3.1. The levels of serum NO and ET-1 of patients in experimental group and control group

The levels of serum NO and ET-1 in the experimental group were lower than those in the control group, $p < 0.05$. The specific research data is shown in Table 1 below.

Table 1: The levels of serum NO and ET-1 of patients in experimental group and control group ($\bar{x} \pm s$)

Group	Case	NO(ng/L)	ET-1(μ mol/L)
Experimental group	35	58.03 \pm 8.91	66.63 \pm 1.69
Control group	35	65.35 \pm 8.28	73.29 \pm 2.35
<i>t</i>	-	10.985	10.869
P	-	0.001	0.001

3.2. The levels of SOD and MDA of patients in experimental group and control group

The level of SOD in the experimental group was higher than those in the control group, but the level of MDA in the experimental group was lower than those in the control group, $p < 0.05$. The specific research data is shown in Table 2 below.

Table 2: The levels of SOD and MDA of patients in experimental group and control group ($\bar{x} \pm s$)

Group	Case	SOD(u/mL)	MDA(nmol/L)
Experimental group	35	107.45±9.13	4.16±1.42
Control group	35	101.76±8.75	5.87±2.95
<i>t</i>	-	11.657	11.568
P	-	0.001	0.001

3.3. Migraine attacks of patients in experimental group and control group

The number of headache attacks, duration of each attack, and headache severity score of patients in the experimental group were lower than that in the control group, $p < 0.05$. The specific research data is shown in Table 3 below.

Table 3: Migraine attacks of patients in experimental group and control group ($\bar{x} \pm s$)

Group	Case	number of headache attacks((times/month))	duration of each attack(h)	headache severity score(point)
Experimental group	35	5.22±0.89	3.26±0.48	1.42±0.23
Control group	35	8.67±1.67	6.27±0.82	2.89±0.32
<i>t</i>	-	9.679	9.858	9.968
P	-	0.001	0.001	0.001

4. Discussion

Migraine is the most common type of disease in clinical practice, maintaining a high number of visits. The pathogenesis is complex, and factors such as diet, spirit, climate, medication, age, genetics, and gender are all associated with such disease. Patients mainly exhibit unilateral or bilateral headaches, and have clinical symptoms such as eye bloating, hallucinations, nausea and vomiting, and emotional instability^[1]. Related clinical studies have shown that when patients have increased cerebral vascular permeability, their serum levels of NO and ET-1 will significantly increase, leading to the formation of edema and more severe ischemia, and finally it leads to the onset of migraine. And relevant studies have also found that the activity and concentration of SOD in platelets of patients with migraine decrease, while the level of MDA increases. This studies indicate that patients with migraine are susceptible to oxidative stress, which then forms a large number of free radicals to attack the cell membrane and ultimately leads to damage to the blood vessel wall^[2].

The main role of lomerizine hydrochloride tablets in clinical practice is to prevent and treat migraine. It can effectively reduce the frequency and frequency of migraine attacks. And when patients experience severe headaches, dizziness, and other discomfort symptoms, lomerizine hydrochloride tablets can help improve symptoms^[3]. Lomelizine is a calcium channel blocker with selective cerebral vasodilation, which can effectively help dilate blood vessels, increase blood supply to the brain, and improve clinical discomfort symptoms. It mainly has good auxiliary and therapeutic effects on patients with dizziness, headache, and neuropathic headache^[4]. Migraine is a type of syncope headache in traditional Chinese medicine, which is related to factors such as blood

stasis, phlegm, dampness, cold, fire, and wind. The principles of treating migraine in traditional Chinese medicine are to dispel weathered phlegm, unblock collaterals and relieve pain, and promote blood circulation and blood stasis^[5]. Headache formula I has a good effect on improving migraine. In the prescription, Typhonium Giganteum and Chuanxiong are used as the main drugs, and Chuanxiong can have the effects of dispelling wind, unblocking collaterals, promoting blood, opening depression, and promoting blood circulation to relieve pain; Typhonium Giganteum can have the effect of clearing meridians and expelling wind and phlegm. The combination of Chuanxiong and Typhonium Giganteum can achieve the effects of clearing meridians, resolving stasis, and dispelling wind and phlegm. At the same time, the use of traditional Chinese medicine such as Gastrodia elata, Notopterygium, Angelica Dahurica, Asarum, Saposhnikovia Divaricata, and Nepeta Cataria in the prescription can effectively enhance the efficacy of the prescription in dispelling wind and relieving pain. Scolopendridae, Scorpion, and Bombyx Batryticatus have strong effects on clearing collaterals, dispelling wind, and resolving phlegm. When used in combination with Chuanxiong and Typhonium Giganteum and these three herbs can alleviate stubborn phlegm and dispel stubborn wind^[6]. San Qi and Eupolyphaga have the effects of dredging collaterals to relieve pain, promoting blood circulation to remove stasis, and dredging collaterals to relieve pain, which can further enhance the efficacy of Chuanxiong in activating blood circulation, relieving pain, and dredging collaterals. Glycyrrhiza can play a moderating role in medicinal prescriptions, and the combination of various drugs can have significant effects on tonifying blood and unblocking collaterals, promoting blood circulation and resolving stasis, dispelling wind and phlegm, and relieving spasms and pain. Modern medicine indicates that Chuanxiong has the effects of promoting blood circulation, sedation, and analgesia, and its extract, sodium ferulate, belongs to a new type of non peptide receptor antagonist that can effectively antagonize the production of endothelin, so that it can achieve the clearance of oxygen free radicals and effectively regulate the serum NO and ET-1 levels of patients. San Qi can not only improve the inflammation status of patients, but also significantly improve their visceral blood and blood function, further enhancing their blood circulation. The results of this study indicate that the serum NO and ET-1 levels of patients in the experimental group are lower than those in the control group. The SOD of patients in the experimental group is higher than that in the control group, and the level of MDA is lower than that in the control group. The number of attacks, duration of each attack, and headache score of patients in the experimental group are all lower than those in the control group, indicating that the efficacy of the experimental group is better than that of the control group.

In summary, treating migraine patients with headache formula I can improve their serum levels, further improve their free radical disorder, alleviate headache symptoms, reduce the frequency and duration of headache attacks, and improve their quality of life.

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