# Clinical Observation of Ruyi Jinhuang Powder Combined with Ultrasonic Iontophotosis in the Treatment of Multiple Stye

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Keywords: Ruyi Jinhuang Powder; ultrasonic iontophoresis; stye

Abstract: In order to observe the clinical efficacy of Ruyi Jinhuang Powder combined with ultrasonic iontophotosis in the treatment of multiple stele, 90 patients with multiple stele treated in the ophthalmology department of our hospital from January to June 2023 were randomly divided into the observation group and the control group, 45 cases in each group. The control group was treated with ofloxacin eye ointment, and the observation group was treated with Ruyi Jinhuang Powder combined with ultrasonic iontophoresis on the basis of the control group. The treatment cycle of both groups was 7 days. The clinical efficacy, visual analogue score (VAS) and the changes of tumor size were compared between the two groups to observe and compare the clinical efficacy. And pay attention to the side effects and adverse reactions of patients in the course of treatment. By observing and studying the therapeutic effect of all patients, we found that the total effective rate of the observation group was 88.89%, which was significantly higher than that of the control group (80.00%). After systemic treatment, the visual analogue scale (VAS) scores of both groups decreased significantly, but the decrease was greater in the observation group. In addition, the size of the mass after treatment was compared with that before treatment, and the intra-group comparison: both groups were smaller than that before treatment, the difference was statistically significant. Therefore, we have reached the following conclusion: the combination of Ruyi Jinhuang Powder and ultrasonic iontophoresis in the treatment of multiple stes can effectively help patients relieve pain and promote the elimination of eyelid sclerosis.

# **1. Introduction**

Stye, also known as blepharitis, is an acute suppurative inflammation of the eyelid gland. According to the location of the disease can be divided into internal and external blepharitis. Staphylococcus, especially staphylococcus aureus, is the cause of staphylococcus staphylococcus. Its main symptoms are "redness, swelling, heat and pain" [1], that is, external blepharitis will

indurate the palpebral margin at the root of the eyelashes, and internal blepharitis will mostly indurate in the meibomian gland, and both types of blepharitis will be accompanied by tenderness and other discomfort. According to the clinical symptoms of the disease, it can be classified as "needle eye", "chancre", "soil lesion" and other diseases in traditional Chinese medicine. The etiology and pathogenesis of the disease are mostly caused by wind and heat evil attacking the eyelid directly, causing local vein to remain, or by heat and poison evil attacking the eyelid and causing local pus ulceration [2]. The common syndromes mainly include: wind-heat syndrome, heat-toxicity syndrome and so on. The treatment principle of TCM ophthalmology for this disease is: those who do not develop pus should be treated both internally and externally to promote its dissipation; Those who have become pus should be treated by incision and drainage. Modern medicine mainly uses symptomatic treatment such as antibacterial and anti-inflammatory, local hot compress on the affected area, and surgery if necessary [3]. Common treatment methods mainly include: drug therapy, surgical treatment, physical therapy, vaccination and other treatment methods.

If the treatment is properly applied, the condition will be relieved or cured in about one week. However, it is targeted at patients with recurrent and multiple stes (which can be seen in one eye or both eyes), with several lesions and repeated attacks [4, 5]. The disease of these patients is often prolonged and not healed, and is not suitable for surgical incision treatment. In addition, it can also be seen that patients who are allergic to antibiotics and patients with cicatricial body have limited treatment options, and the above treatment methods cannot fundamentally solve the problem. Therefore, it is necessary to combine the advantages of traditional Chinese and western medicine to explore new conservative and efficient treatment methods in order to reduce patients' treatment pain.

Ruyi Jinhuang Powder, also known as golden powder, is one of the commonly used external drugs in surgery. Ruyi Jinhuang Powder originated from the Original book of Surgery written by Chen Shigong in the Ming Dynasty [6]. It is one of the most classic prescriptions for traditional Chinese medicine surgery, and has high clinical application and research value for treating all surgical diseases such as boils, boils and bruises. Its prescription composition is also the earliest recorded in the Ming Dynasty Chen Shigong "Surgery Authentic": "Ruyi Jinhuang Powder rhubarb, turmeric yellow Baizhi Chen Cang, south star Magnolia trichosanthin, applied a hundred edema of self." "Authentic Surgery" said: "All surgical all stubborn evil swelling poison, handy use, all should be effective, sincere for the sore home good will also." Since ancient times, the "prescription" and "agent" of Ruyi Jinhuang Powder have diversified forms. With the continuous update of scientific research technology, and according to the research summary, the forms of its patent medicine mainly include: powder, paste, gel, black paste, film agent, and cloth agent. In clinic, Ruyi Jinhuang Powder is widely used in traditional Chinese medicine surgery. In modern clinic, it is mainly used in the treatment of skin abscess, positive sore, prostatic hyperplasia, anal fistula, diabetic foot ulcer and other diseases [7, 8]. Especially in the acute phase of infectious diseases have a very good anti-inflammatory analgesic effect.

Ultrasonic iontophage technology is a method of physical promotion of drug penetration through the complete skin by using ultrasonic dynamic force with specific frequency, specific sound intensity and specific pulse switching ratio. It can enable specific drug molecules and ions to obtain directional motion function and move along the propagation direction of sound wave. Ultrasonic action on human body will produce mechanical effect and warm effect. Cavitation effect and radiation pressure effect to enhance skin permeability.

The purpose of this study is to observe the therapeutic effect of Ruyi Jinhuang Powder combined with ultrasonic iontophoresis in the treatment of recurrent and multiple stes that are not suitable for surgical treatment, and to observe the changes in pain degree, secretion volume, redness and swelling dissipation or pus discharge and wound healing during treatment, and to pay attention to whether there will be skin allergies and other adverse reactions during treatment. To evaluate the clinical effect of the therapy comprehensively. The following is reported.

#### 2. Data and methods

#### **2.1. Case selection**

Inclusion criteria: (1)The selected patients had to meet the relevant diagnosis of stye (meibomian gland inflammation) in Ophthalmology; (2) The selected patients must meet the relevant diagnosis of "needle eye" in Chinese Medicine Ophthalmology; (3) After understanding the patient's medical history, the patient was confirmed to be repetitive and multiple styes; (4) The patient has never received any medication or other symptomatic treatment within one week after the onset of the disease; (5) The patients had no other ocular diseases; (6) The patient has the capacity for civil conduct, understands and voluntarily accepts the enrollment treatment after being fully informed. Exclusion criteria: (1) Pregnant and lactating women were not included; (2) Children, the elderly and patients with diabetes were excluded; (3) Patients with severe liver and kidney dysfunction were excluded; (4) Patients who received other drugs or other therapeutic interventions within one week after the onset of illness were excluded; (5) Patients with other ocular diseases were prohibited. (6) Patients with ocular skin damage were prohibited. (7) Patients allergic to drugs were prohibited. (8) Other patients who did not meet the inclusion criteria were prohibited. Exclusion and drop-out criteria: (1) Patients who do not meet the inclusion criteria and cannot abide by the trial protocol must be excluded; (2) Patients with incomplete data were excluded; (3) Patients who withdrew without permission or did not receive the whole treatment were excluded; (4) Patients with serious adverse reactions during treatment were excluded; (5) Patients who could not continue to receive treatment were excluded.

## 2.2. Case data

A total of 90 patients with multiple stes who were treated and treated in the Department of Ophthalmology of our hospital from January to June 2023 were selected as effect subjects, and the patients were divided into control group and observation group by random number table method, with 45 cases in each group. In the observation group, there were 29 males and 16 females, aged 22-59 years, with an average age of  $(43.11\pm5.73)$  years. The course of disease lasted from 1 to 7 days, with an average of  $(4.83\pm1.00)$  days. The sites of disease were as following: 12 cases in the right eye, 16 cases in the left eye, and 17 cases in both eyes. In the control group, there were 31 males and 14 females, aged 21-57 years, with an average age of  $(4.80\pm1.17)$  days. Eye category: 11 cases in the right eye, 19 cases in the left eye and 18 cases in both eyes. There was no significant difference between the two groups in general materials, such as gender, age, duration of disease, and eye classification (P > 0.05).

#### **2.3. Treatment Methods**

Before entering the group, patients in both groups were required to keep the skin of the infected area clean, pay attention to protect the integrity of the skin and prevent skin lesions to avoid further infection. At the same time, patients in both groups were treated with conventional drugs: Ofloxacin eye ointment (Shenyang Xingqi Eye Medicine Co., LTD., National drug approval number H10940177), 3 times a day, 1 drop each time, for 7 days. Observation group was supplemented with Ruyi Jinhuang Powder (self-prepared by the Pharmacy Department of Xi 'an Hospital of Traditional Chinese Medicine) on the basis of the control group, and applied appropriate amount of normal

saline to the skin of the affected eye with gauze, and ultrasonic ion import technology was applied to the affected eye for ultrasonic treatment, 20min each time, once a day. Both groups were evaluated after 7 days of treatment. In addition, patients in the 2 groups were asked to pay attention to light diet in daily life, regular rest and rest, pay attention to eye hygiene, and try to avoid diet and emotional stimulation.

# 2.4. Observation indexes and evaluation criteria of curative effect

The clinical treatment effect, pain changes and eyelid mass size changes of the two groups of patients were compared, and whether adverse reactions occurred during treatment[9]. Efficacy evaluation criteria: It is combined with the criteria for the efficacy of pinocular and blepharitis in the Criteria for the Diagnosis and Efficacy of Diseases of Traditional Chinese Medicine and the criteria for the Diagnosis and Efficacy of Common Diseases (Criteria), and combined with the patient's experience after treatment. (1) Ineffective: After 3 days of treatment, the patients did not meet the above criteria, or the ulcer healed spontaneously, the induration after ulceration did not disappear, the symptoms did not improve or recurred. (2) Effective: After 3 days of treatment, the above clinical symptoms were significantly relieved, the redness and swelling decreased slightly, and the symptoms were reduced or returned to only subcutaneous induration, and the appearance was normal. (3) Cure: After 3 days of treatment, the clinical symptoms disappeared, the local redness, heat, pain and induration subsided, the redness dissipated or the pus was discharged, the wound was smooth, the eyelid of the affected eye had no obvious secretions, and the affected eye returned to normal. Total effective rate in this clinical observation =[(number of cured cases + number of effective cases)]/ total number of cases  $\times 100\%$ .

## 2.5. Statistical Methods

SPSS25.0 statistical software was used to process the data in this study. The measurement data were (x±s) and t test was used. The counting data were expressed as percentage (%) and  $\chi^2$  test was used. P <0.05 was considered statistically significant.

# **3. Results**

# **3.1.** Comparison of clinical efficacy

Comparison of clinical efficacy between the two groups is shown in Table 1. The total effective rate of the observation group was significantly higher than that of the control group (P < 0.05).

group	Ν	cure	effective	no effect	Total effective rate
Observation group	45	23	17	5	40(88.89%) #
Control group	45	20	16	9	36(80.00%)

Table 1: Comparison of clinical efficacy between the two groups

Comparison with control group, #P < 0.05

#### **3.2. Comparison of VAS scores**

Table 2: Comparison of VAS scores before and after treatment in patients with stye in each group

group	Ν	pre-treatment	post-treatment
Observation group	45	7.20±1.19	2.14±0.59*#
Control group	45	7.13±1.95	4.29±1.19*

Compared with this group before treatment, \* P < 0.05. Compared with control group after treatment, #P < 0.05.

Comparison of pain scores before and after treatment between the two groups is shown in Table 2. VAS scores in both groups decreased significantly after treatment, but the decrease was greater in the observation group (P < 0.05).

#### **3.3. Comparison of tumor size**

Comparison of tumor size before and after treatment between the two groups is shown in Table 3. After treatment, the mass decreased in both groups, but the decrease was greater in the observation group (P < 0.05).

group	Ν	pre-treatment	post-treatment
Observation group	45	4.20±1.15	0.19±0.36*#
Control group	45	$4.03 \pm 1.07$	0.49±0.64#

Table 3: Comparison of tumor size before and after treatment in each group (mm)

\*Comparison with control group, P < 0.05. # Compared with the same group before treatment, P < 0.05.

## 3.4. Adverse reaction

There was no obvious adverse reaction between the observation group and the control group during treatment, and the difference was not statistically significant (P > 0.05).

#### **4. Discussion**

Stye, in traditional Chinese medicine, belongs to the categories of "needle eye", "malnutrition", "soil lesion", etc. In traditional Chinese medicine, the needle eye is usually caused by evil visitors of wind and heat attacking the eyelid, or by poor Qi and blood, or by excessive spicy food, heat in the spleen and stomach, upward attack on the eyelid, disorder of ying and wei, and stagnation of qi and blood. It can also be caused by the weakness of the spleen and stomach, the lingering evil is not clear, and the lingering evil is disturbed by the wind [10]. Therefore, the main principles of clinical treatment for the disease are: non-suppurative, internal and external treatment, promote its dissipation; If pus has been festered, cut and discharge pus. Targeted treatment for patients at different stages in the process of disease change and development. And modern medical research shows that staphyletis, that is, blepharitis, the cause of its onset is mostly related to staphylococcus infection, especially staphylococcus aureus infection. Clinically, according to whether the patient has suppuration, ulceration and other conditions, the patient can be selectively given anti-infection treatment or surgical incision drainage treatment. The principle of selecting different treatment methods is similar to that of traditional Chinese medicine.

In addition to receiving standard traditional Chinese medicine or modern medicine treatment, patients usually need to eat a light diet in their daily life, avoid alcohol as much as possible, pay attention to eye hygiene and maintain a happy mood. Most patients will get significantly better about a week after treatment.

Ruyi Jinhuang Powder, as a classic ancient prescription, has undergone historical changes since ancient times, and the composition of prescriptions has also undergone continuous evolution. Its curative effect of clearing heat and detoxification is certain and recognized by the world. After modern medical research clearly shows that the active ingredients in this prescription have clear pharmacological effects, such as analgesia, anti-inflammatory, anti-infection and so on. When used in combination with other anti-inflammatory treatments, serum levels of substance P and inflammatory factors can be reduced more rapidly [11]. In this study, the control group was treated with ofloxacin eye ointment for anti-infection treatment. The observation group was additionally treated with Ruyi Jinhuang Powder and external application, combined with ultrasonic iontophoresis therapy. Under the same conditions, the two groups of patients were standardized for one week of full treatment to observe and compare whether there was a difference in the final efficacy and the size of the difference. Ruyi Jinhuang Powder was first published in "Authentic Surgery". It combines white art with royal medicine rhubarb and yellow cypress, and has the effect of clearing heat and detoxifying. The "three Huangs" in Ruyi Jinhuang Powder can reduce swelling and discharge pus, and the "Magnolia officinale", "Baizhu" and "Tangerine peel" can regulate qi and strengthen spleen, dehydrate and promote Qi, and can be combined with turmeric, "dry lotus grass" and other drugs to reduce swelling and pain, and licorice, and finally achieve the purpose of detoxifying heat, relieving pain and eliminating swelling, regulating qi and strengthening spleen, and diuresis [12, 13].

The ultrasonic iontophage technology, belongs to the scope of physical therapy, the reason is that the therapist uses ultrasonic heating in physical therapy, and through observation, the instrument probe is heated by ultrasonic heating and then massage the treatment site, its effect of promoting drug penetration into the skin is significantly enhanced, therefore, people gradually began to regard it as a boost to enhance the ability of drugs to penetrate the skin. It is also considered to be an enhancer of drug transdermal penetration. Moreover, low frequency ultrasound has stronger penetration promotion effect than high frequency ultrasound, and its penetration promotion effect is better than high frequency ultrasound. The thermal shock, cavitation shock and flow shock caused by it may be related to this law [14-17]. It was found in this study that the efficacy of patients in the observation group was more significant than that in the control group in all aspects and dimensions, such as total effective rate, VAS score, and degree of mass dissipation, and no obvious side effects or adverse reactions occurred in patients in both groups, such as skin allergic rash, skin flushing and even ulceration. The above findings support the conclusion of this study.

To sum up, Ruyi Jinhuang Powder combined with ultrasonic iontophoresis can be considered for the treatment of patients with recurrent, multiple and refractory stye, or other patients who are not suitable for surgical treatment of stele. The combination of the two has significant efficacy, and is superior to the anti-infection treatment of ofloxacin ophthalmic ointment alone. This method can provide a new treatment option for patients with recurrent and multiple stye.

The results of this study indicate that Ruyi Jinhuang Powder combined with ultrasonic iontophoresis has good effect in the treatment of multiple stye, which can effectively reduce the pain of patients, shorten the course of disease and promote the elimination of eyelid mass. The treatment has many advantages such as less pain, fewer side effects, good efficacy, less cost, and no incision without leaving scars, avoiding the impact of eyelid dysfunction, ensuring the eye skin integrity and beauty, etc., is an ideal treatment for patients with stylosis to achieve multiple benefits, worthy of clinical promotion and application.

It is believed that in the future, in the clinical diagnosis and treatment of stye patients, especially patients with multiple stye, this combination treatment program can gradually be familiar and have the opportunity to serve more patients and benefit more patients.

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