

Clinical Study on the Treatment of Moderate Liver Meridian Stagnation-Heat Dry Eye Syndrome with Acupoint Needle Stimulation Combined with “Runmu No.1 Formula” Herbal Nebulization Therapy

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Abstract: *Objective:* To investigate the clinical efficacy and possible mechanism of press-needling combined with the ‘Runmu No. I Formula’ herbal nebulization in the treatment of moderate liver meridian heat-type dry eye, providing a safe and effective treatment option for dry eye patients. *Methods:* A total of 80 patients with dry eye attending the ophthalmology dry eye clinic of our hospital from October 2024 to May 2025 were selected and randomly divided into a control group and an observation group, with 40 patients in each group. The control group received meibomian gland massage combined with conventional artificial tears, while the observation group received press-needling combined with the ‘Runmu No. I Formula’ herbal nebulization on top of the treatment given to the control group. Clinical efficacy, symptom improvement, tear secretion function, and ocular surface damage recovery were observed and compared between the two groups. *Results:* After two weeks of treatment, the intervention group showed significantly better subjective symptoms, tear film breakup time (FBUT), and basic tear secretion test (SIT) results compared to the control group, with statistically significant differences ($P<0.05$), and no adverse reactions were observed. *Conclusion:* Press-needling combined with the ‘Runmu No. I Formula’ herbal fumigation treatment for moderate liver meridian heat-type dry eye can significantly improve patient symptoms, increase tear secretion, prolong tear film breakup time, enhance tear film stability, relieve ocular discomfort, and is safe and effective.

Keywords: Press-needling, Herbal nebulization, Dry eye, Tear secretion.

1. Introduction

Dry eye syndrome is a chronic ocular surface disease characterized by decreased tear film stability, which is essentially an imbalance of the ocular surface microenvironment caused by abnormal tear quality, quantity, or dynamics [1]. According to the “Expert Consensus on the Diagnosis and Treatment of Dry Eye Syndrome (2020 Edition)” [2], the disease is mainly manifested by dry eyes, foreign body sensation, burning sensation, photophobia, and blurred vision, and in severe cases, corneal epithelial defects, ulcers and even perforations may occur. Epidemiological data show that the prevalence of dry eye syndrome in our country has reached 21%-30% [3], and it is showing a trend of younger, which is closely related to factors such as prolonged use of electronic screens and dry environment.

Dry eye syndrome has a significant negative impact on patients’ quality of life. Persistent eye discomfort leads to distraction, decreased work efficiency, and limited daily activities such as reading and driving. Long-term blurred vision may induce psychological problems such as anxiety and depression, forming a vicious cycle of “symptom-psychological-behavioral” [4].

Traditional treatment methods have limitations. Although artificial tears can temporarily relieve symptoms, long-term use may disrupt the microecological balance of the ocular surface and cannot improve the function of the lacrimal glands. In addition, monotherapy is difficult to balance the dual needs of “local symptoms” and “systemic regulation” [5],

resulting in a high recurrence rate.

In recent years, TCM specialty therapies have gradually emerged in the treatment of dry eye syndrome, which can effectively improve patients’ symptoms and complement modern medical therapies. Among them, needle picking and traditional Chinese medicine atomization have attracted much attention because of their unique advantages. As a minimally invasive therapy, acupuncture can regulate eye qi and blood, promote tear secretion, and improve the ocular surface environment by stimulating specific acupuncture points around the eyes [6]. Traditional Chinese medicine nebulization is to turn the decoction of traditional Chinese medicine into tiny particles through the atomization device and directly act on the ocular surface, changing the traditional eye drop treatment method, with fast onset, effectively relieving dry eye symptoms, and reducing the discomfort and hidden dangers caused by dry conjunctiva [7].

The purpose of this study was to investigate the clinical effect of acupuncture combined with “Runmu I Fang” traditional Chinese medicine nebulization in the treatment of dry eye syndrome, and to evaluate the superiority and feasibility of this combination therapy by comparing and observing the efficacy, symptom improvement, tear secretion function and other indicators of the two groups of patients, so as to provide a safer, more effective and more convenient treatment method for patients with dry eye syndrome, and also provide new ideas and basis for the application of traditional Chinese medicine characteristic therapy in the field of ophthalmology.

2. Materials and Methods

2.1 General Information

A total of 80 patients with dry eye, who visited the ophthalmology dry eye clinic of our hospital from October 2024 to May 2025, were selected, all of whom met the diagnostic criteria for dry eye. The patients were numbered in the order of their visits and randomly divided into a control group and an observation group using a random number table, with 40 patients in each group. Statistical analysis using software showed no significant differences between the two groups in terms of gender, age, disease duration, and other related variables ($P>0.05$).

2.2 Diagnostic Criteria

According to the 'Chinese Expert Consensus on Dry Eye: Examination and Diagnosis (2020)' diagnostic criteria for dry eye [2]: if a patient has clinical symptoms such as eye dryness, pain, foreign body sensation, burning, fatigue, etc., and the non-contact tear film breakup time is less than 10 seconds, they can be diagnosed with dry eye.

2.3 Inclusion Criteria

(1) Meet the above diagnostic criteria for dry eye; (2) Age between 16 and 80 years; (3) Normal thinking and expression abilities, able to cooperate with relevant examinations; (4) Sign the informed consent form and agree to participate in the questionnaire survey study.

2.4 Exclusion Criteria

(1) Patients with other serious eye diseases such as ocular trauma, chemical injury to the cornea and conjunctiva, lacrimal gland dysfunction, or incomplete eyelid closure; (2) Patients who have recently used medications that may affect the ocular surface, or those participating in other clinical trials simultaneously; (3) Patients with skin damage around the eyes, or those with a history of needle phobia or adverse reactions to study drugs; (4) Patients with cardiovascular, pulmonary, hepatic, renal, or other systemic diseases, or those with mental disorders.

2.5 Ethical Review

This study was approved by the Ethics Committee of Xi'an Traditional Chinese Medicine Hospital, which issued the 'Ethical Review Comments' with approval number LLSCPJ2024024, and all participants have signed the 'Informed Consent Form'.

3. Treatment Method

3.1 Control Group

Undergo meibomian gland massage once combined with sodium hyaluronate eye drops, 1 drop each time, 4 times daily, for a total of 14 days.

3.2 Observation Group

On the basis of the control group, patients received press-needle treatment combined with nebulization therapy using the traditional Chinese medicine formula "Runmu No. I." Acupoints for press-needling were selected according to the expert consensus on integrated Chinese and Western medicine diagnosis and treatment of dry eye in Sjögren's syndrome in 2024 [8], choosing periocular points such as Jingming, Cuanzhu, and Sibai Kong. Treatment was administered three times a week, with each session retaining the needles for 24 hours. The herbal formula for nebulization consisted of mint 15g, Schizonepeta 12g, dandelion 12g, honeysuckle 12g, mulberry leaf 12g, Siler 12g, cicada slough 10g, and borneol 0.02g (herbal pieces provided by the Pharmacy Department of Xi'an Hospital of Traditional Chinese Medicine). The above herbs were decocted in 500 mL of water until reduced to 200 mL, filtered to remove the residues, and 30 mL of the resulting decoction was placed in a WH-200 ultrasonic nebulizer provided by Guangdong Yuehua Medical Device Co., Ltd. Nebulization inhalation was performed once daily for 20 minutes each time, for a total duration of two weeks.

3.3 Observation Indicators

3.3.1 Subjective Symptom Score: Assessed with reference to the internationally used Ocular Surface Disease Index (OSDI) questionnaire, the survey mainly includes 12 items. Based on the duration of eye discomfort symptoms, each item is scored from 0 to 4: 0 points for no symptoms; 1 point for occasional symptoms, 2–3 times per week; 2 points for symptoms occurring about half of the week; 3 points for symptoms occurring almost daily, causing some impact on daily work and life; 4 points for symptoms occurring continuously every day, severely affecting daily work and life. OSDI score = total score of all answered questions $\times 25 \div$ number of questions answered. Normal: ≤ 12 ; mild dry eye: $> 12-22$; moderate dry eye: $> 22-32$; severe dry eye: $> 32-100$.

3.3.2 Fluorescein tear film break-up time examination (FBUT): In a room with normal temperature, suitable humidity, and low light, use a fluorescein staining strip moistened with saline (Tianjin Jingming New Technology Development Co., Ltd.) for ocular surface staining. Under a slit-lamp cobalt blue light, have the patient blink naturally 2–3 times and then keep their eyes open. Use a stopwatch to record the time until the first black spot appears on the tear film.

3.3.3 Basic tear secretion test (Schirmer I test, SIT): Using standard tear test filter strips (Tianjin Jingming New Technology Development Co., Ltd.), placed in the outer 1/3 of the lower fornix without surface anesthesia, the test is conducted for 5 minutes and the length of wetting on the filter paper is recorded. The length of wetting on the filter paper is proportional to the amount of tear secretion.

3.4 Statistical Methods

To ensure the accuracy of the data, double-entry data input was used, and SPSS 24.0 was applied for statistical analysis. Data are presented as mean \pm standard deviation (SD), and independent sample t-tests were used for analysis. $P<0.05$ indicates a statistically significant difference.

4. Result

4.1 Comparison of Subjective Symptom Scores

A two-week clinical observation was conducted on the intervention group and the control group. A total of 80 patients were included before the intervention. Before treatment, the comparison of OSDI scores between the two groups showed no statistically significant difference ($t = -0.186$, $P = 0.853$). After treatment, the comparison of OSDI scores showed a statistically significant difference ($t = -17.23$, $P = 0.000$), indicating that acupuncture combined with the traditional Chinese medicine fumigation prescription “Runmu No. I” can improve the subjective symptoms of patients with moderate dry eye syndrome of liver and kidney yin deficiency type. See Table 1 for details.

Table 1: Comparison of OSDI Scores Before and After Treatment

Group	Number of cases	Before treatment	After treatment
Intervention group	40	26.45 ± 1.23	18.45 ± 1.02
Control group	40	26.50 ± 1.18	22.50 ± 1.08
<i>t</i>		-0.186	-17.23
<i>P</i>		0.853	0.000

4.2 FBUT, SIT

After two weeks of treatment, comparison between the two groups showed that the intervention group had better improvements in FBUT and SIT than the control group, with the differences being statistically significant ($P < 0.05$). See Table 2 for details:

Table 2: Comparison of FBUT and SIT Scores Before and After Treatment

Group	Before treatment	After treatment	Inter-group comparison		
			<i>t</i>	<i>P</i>	
FBUT	Intervention group	3.50 ± 0.51	8.45 ± 1.02	-17.23	<0.001
	Control group	3.85 ± 0.36	5.50 ± 1.08		
SIT	Intervention group	2.50 ± 0.51	8.45 ± 1.02	-17.23	<0.001
	Control group	3.50 ± 0.51	5.50 ± 1.08		

5. Discussion

Due to aging, smoking, excessive use of electronic devices, and other factors, the incidence of dry eye disease in our country is increasing year by year, bringing a huge economic burden to patients' families and society. Dry eye disease can exacerbate discomfort in the eyes, seriously affecting patients' daily work, life, and quality of life. Moreover, dry eye disease has a high recurrence rate, and repeated treatments also cause considerable mental stress for patients. Xi'an is located in the northwest region, with many sunny days, little rain, a dry climate, high evaporation, and frequent sandstorms, which aggravates the occurrence of dry eye disease [9].

Traditional Chinese medicine clinical techniques have a long history in treating dry eye syndrome, and various therapies have achieved certain therapeutic effects [10]. Press-needle therapy [11], as a minimally invasive TCM method, stimulates acupoints around the eyes to regulate the flow of qi and blood in the eyes, promote tear secretion, and improve microcirculation on the ocular surface. Ultrasonic nebulizers use ultrasonic energy to atomize medicinal liquids into gas containing aerosolized medicinal particles, continuously and evenly acting on the patient's cornea, conjunctiva, and periorbital skin [12]. This allows medicinal ingredients to penetrate ocular tissues more quickly, rapidly relieving clinical symptoms such as eye dryness and foreign body sensation, and enhancing the local concentration and therapeutic effect of the drugs. On this basis, our research group applied press-needle therapy combined with a self-formulated herbal fumigation formula, “Runmu No. 1,” to explore its clinical efficacy in dry eye syndrome due to liver and kidney yin deficiency.

However, in the selection of external Chinese herbal fumigation treatments, there is still no consensus in the academic community. On this basis, our research team has independently formulated the ‘Runmu No. 1’ prescription to explore its clinical effects on liver and kidney yin-deficient

dry eye, further observing its efficacy and investigating its mechanism of action. The chief herbs are dandelion, mint, and honeysuckle to clear heat, detoxify, and improve vision; the deputy herbs are Schizonepeta and mulberry leaf to dispel wind-heat, clear the liver, and enhance vision; the assistant herbs are Ledebouriella root and cicada slough to disperse wind, reduce heat, dissipate films, and improve vision, while the adjuvant herb is borneol to reduce fire, resolve stagnation, clear the orifices, and remove films. When used together, these herbs work to clear the liver, enhance vision, dispel wind, and moisten the lungs.

The research results show that pressing acupuncture combined with the traditional Chinese medicine fumigation formula ‘Runmu No. 1’ can significantly improve patients' subjective symptom scores; for patients, objective measures such as tear film breakup time (FBUT) and Schirmer I test (SIT) also show improvement, increasing tear secretion, prolonging tear film breakup time, improving tear film stability, and alleviating eye discomfort.

This study selected acupressure combined with the traditional Chinese herbal fumigation formula ‘Runmu No.1’ for a two-week intervention treatment for patients. It significantly improved patient symptoms, had a notable short-term effect, and showed no obvious adverse reactions. The treatment is green, safe, and environmentally friendly, improving patients' quality of life while reducing their financial and psychological burdens. However, due to the limitations of the study, the sample size was small, the intervention period was short, and there was no continuous follow-up on the long-term improvement of patients' symptoms. Additionally, there was a lack of laboratory indicators and other measures in the observation of results. These aspects need to be further supplemented and explored in future clinical trials.

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