Clinical Observation on the Combination of Ear Tip Bleeding and Babao Eye Ointment Ion Introduction in the Treatment of Needle Eye Heat Toxin Obstruction Syndrome

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Abstract: This study aimed to observe the clinical effects of ear tip exofusion combined with Mayinglong Babao eye ointment in the treatment of needle eye conditions. From April 2022 to April 2023, a total of 120 patients (aged 6-25 years) with 120 affected eyes were diagnosed and treated at Ankang Eye Hospital. Using a random allocation method involving sequentially coding, opaque, and sealed envelopes, the patients were divided into an observation group and a control group, with 60 cases in each group. The control group received standard bleeding treatment, while the observation group underwent additional ear tip exofusion. Clinical efficacy, cure time, adverse reactions, and recurrence rates were compared between the two groups. Results showed that the total response rate in the observation group (91.67%) was significantly higher than that in the control group (83.33%) at the same time point (P < 0.05). Additionally, the cure time in the observation group was shorter than that in the control group, with a statistically significant difference (P < 0.05). No adverse events were reported in either group, and there was no statistically significant difference in the recurrence rate between the two groups (all P > 0.05). The combination of ear tip exofusion and Mayinglong Babao eye ointment demonstrated remarkable efficacy in treating needle eye conditions, suggesting its potential as a preferred external treatment option for such conditions, particularly in primary healthcare settings.

Keywords: needle eye; ionic import; ear tip exletting; Chinese medicine; Mayinglong eye cream

1. Introduction

Needle eye, also known as hordeolum, refers to a type of eye condition characterized by boils, redness, itching, and pain on the edge of the eyelid. It often appears as a wheat-shaped nodule and is prone to purulence [1]. The increasing consumption of fatty and sweet foods, coupled with poor dietary habits, has led to accumulation of heat and toxins in the spleen and stomach, resulting in the development of "hot poison obstructing" syndrome associated with needle eye [1]. Clinical manifestations include red and swollen eyelids, heat, pain, palpable hard nodules, prominent swelling in the inner corner of the eye, thirst, and constipation with a red tongue [1]. Currently, clinical treatment using bleeding from ear tips has shown significant efficacy in clearing heat, detoxifying, cooling blood, and reducing swelling [2-3]. Furthermore, needle eye is analogous to palpebral adenitis in Western medicine (commonly known as hordeolum). It can be categorized into internal (infection of the meibomian glands) and external (infection of eyelash hair follicles and their sebaceous or sweat glands) blepharitis. It is generally caused by Staphylococcus infection, with Staphylococcus aureus being the most common pathogen. Severe cases may lead to periorbital cellulitis or cavernous sinus thrombosis [4-5]. Western medicine commonly employs hormones and anti-infective drugs for the treatment of blepharitis.

In this study, the combination of ear tip bleeding and ion introduction was used to effectively treat the aforementioned syndrome, and the findings are detailed in the following report.

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2. Data and methods

2.1. General in Formation

From April 2022 to April 2023, a total of 120 patients aged 6-25 were diagnosed with needle eye and underwent traditional Chinese medicine (TCM) syndrome differentiation. The average age of the patients was 12.56 ± 1.24 years, and the duration of the disease ranged from 1 to 4 days, with an average duration of 2.02 ± 0.35 days. The 120 eyes of these patients were randomly assigned to either the observation or control group, with 60 eyes in each group, using a "sequential coded, radiopaque, and sealed envelopes" method. There were no statistically significant differences (P > 0.05) in the comparison of general data between the two groups, indicating comparability. All participants provided informed consent, and the trial was approved by the Biomedical Research Ethics Branch of Ankang Hospital of Traditional Chinese Medicine.

2.2. Diagnostic Criteria

Diagnostic criteria of traditional Chinese medicine: The diagnosis of needle eye in traditional Chinese medicine follows the standards outlined in the fourth edition of the Traditional Chinese Medicine Ophthalmology, which categorizes patients as exhibiting heat symptoms and aligns with the diagnostic basis, syndrome classification, and curative effect evaluation criteria specified in the industry standard for traditional Chinese medicine syndrome diagnosis effectiveness (ZY/T001.1-94) [1.6]. Clinical manifestations include localized redness and swelling of the eyelid, accompanied by a burning sensation, pain, hardened nodules, prominent red swelling in the eyelid fissure, a red tongue with yellow moss, and a rapid pulse [1.6].

Diagnostic criteria of Western medicine: The diagnosis conforms to the 9th edition of "Ophthalmology," which includes symptoms such as redness, swelling, heat, and pain, external meibomian gland inflammation with swelling and induration, possible ipsilateral lymph node enlargement and tenderness, internal meibomian adenitis with swelling limited to the meibomian gland, and conjunctival congestion and swelling of the eyelid [4].

2.3. Inclusion Criteria and Exclusion Criteria

Inclusion criteria:

- 1) The duration of the disease was less than 3 days.
- ② Patients had a single eye disease with a mass size of less than 5mm, and no more than 2 masses.
- ③ No other drugs were used except for the specified medication.
- 4 Lesions showed no signs of pus or rupture, and there were no other systemic inflammatory reactions.
 - ⑤ Patients completed treatment as prescribed and attended follow-up appointments.

Exclusion criteria:

- ① Patients who had been treated for more than 4 days.
- ②Patients who had received prior treatment or used other medications.
- ③ Presence of coagulation dysfunction.
- 4 Lesions that had developed pus or ruptured.
- ⑤ Patients with redness in both eyes or more than two areas of redness in one eye.

Elimination and dropout criteria:

- 1) Patients who did not complete treatment as prescribed.
- 2) Patients who received treatment with other drugs during the study period.
- ③ Presence of serious adverse reactions or other medical conditions during the course of treatment.

2.4. Treatment Methods

Both the control and observation groups underwent ear tip bleeding treatment, administered once every other day for a total of 3 treatments. The specific procedures were as follows:

- ①Instructed the patient to sit down and identified the ear tip point as the apex of the helix. Gently massaged the area until slight redness and warmth were felt.
- ②Following standard skin disinfection, used a three-edged needle or 1ml syringe needle to induce bleeding at the designated point (approximately 2mm in depth). Around the puncture site, approximately 20 drops of induced bleeding were observed while using a disinfected cotton swab. The first treatment targeted the same ear, with subsequent treatments alternating between ears [7].
 - ③Used a sterilized cotton swab to stop bleeding after the release of blood.
- 4Ensured that the puncture did not cause deep injury to the auricle and maintained aseptic conditions during the procedure $^{[8]}$.

The observation group received treatment using DC iontophoresis with Mayinglong Babao eye ointment (Mayinglong Pharmaceutical Group Co., Ltd., National Drug Approval Number: Z 42021455). The specific procedure involved the following steps:

- ①Application of Mayinglong Babao eye ointment onto gauze, ensuring the gauze was moistened to a moderate degree.
- ②Instructing the patient to gently close their eyes and place the moistened gauze on the eyes before wearing an eye mask.
- ③Initiating a 10-minute session with the multi-functional low-frequency electronic therapeutic instrument manufactured by Xi'an Huya Electronics Co., Ltd., followed by a 5-minute pulse treatment. The power intensity was adjusted based on the patient's tolerance level.
 - **4** Administering the treatment three times a day for 7 days, totaling 3 treatments.

Note: It was emphasized that the gauze should completely cover both eyes to prevent any adverse effects on the patient's skin.

2.5. Observational Indicators

Compare the total clinical response rate of the observation and control groups, as well as compare the clinical efficacy, cure time, adverse reaction, and recurrence rate between the two groups.

Evaluation criteria: refer to the diagnosis and Evaluation of common diseases of Traditional Chinese Medicine issued by the State Administration of Traditional Chinese Medicine establish^[9], cure: redness and swelling dissipate after 4 days of treatment; improvement: redness and swelling decrease after 4 days of treatment; failure: symptoms do not improve after 4 days of treatment, or become pus or rupture after ulceration.^[6] Total response rate = (number of cured + effective) / 100%.

2.6. Statistical Methods

Statistical data were analyzed by SPSS 26.0 statistical software, measurement data were expressed as $(\chi \pm s)$ by t-test; count data was expressed as rate (%) between the two groups χ^2 checkout,P<0.05 was considered to be statistically significant.

Results analysis: The total response rate of the observation group was higher than that of the control group, and the difference was statistically significant (P<0.05), see Table 1; the observation group had the same treatment with the control group (allP<0.05). The observation time was shorter than the treatment group.

Table 1: Comparison of the total clinical response rate in the two groups [n (%)]

group	sample book	cure	laxation	of no avail	Total effective
observation group	60	49	6	5	91.67
control group	60	36	14	10	83.33 ^①

Note: Compared with the control group, ${}^{\odot}P < 0.05$.

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After three months of follow-up, 4 patients relapsed in the observation group, the recurrence rate was 6%, 7 patients relapsed in the control group, and the recurrence rate was 11.6%. The recurrence rate of the observation group was lower than that of the control group (P<0.05).

3. Discussion

The pinicular spot is located in the cellular eyelid, and according to traditional Chinese medicine theory, "the essence is the eye, with the essence of the kidney manifesting in the pupil. The essence of the tendon is the black eye, while the essence of the heart replenishes the venules of the eye. The essence of its spirit is the white eyes, and the essence of muscle is constrained." Subsequently, scholars summarized this concept into the "five wheel theory," which includes the Carlowheel (associated with the spleen and nourishing the muscles), emphasizing the internal-external relationship between the spleen and stomach. As such, diseases related to the meat wheel are often associated with spleen and stomach function. In the Secret room, it is mentioned that "the essence of the viscera is attributed to the spleen, which has an impact on the eye." A healthy diet supports normal spleen and stomach function, thereby benefiting the eyes. Conversely, if diet is poor and results in dysfunction of the spleen and stomach transport, it can contribute to eye disease. Spleen and stomach heat, or disturbance caused by wind and heat, is considered the basic pathogenesis of needle eye. Additionally, a preference for consuming spicy, fatty, and heavy foods, coupled with irregular living habits, may lead to spleen and stomach heat, allowing for the invasion of redness, swelling, heat, pain, and even protrusion of the white eye in the eyelid fissure, thus exhibiting signs of heat and toxin obstruction [12-14].

The clinical manifestations of needle eye can be roughly divided into three stages: initial stage characterized by itching and pain, middle stage with swelling and pain, and later stage with purulent rupture. Redness and swelling subside as the condition improves, but in severe cases, systemic fever, headache, and other symptoms may accompany the disease [15]. The general treatment principle is to promote dissipation when there is no pus present both internally and externally, and to drain pus in cases of purulence. Internal treatment is based on traditional Chinese medicine syndrome differentiation, while external treatment mainly includes the use of eye drops (such as Houttuynia eye drops or antibiotic eye fluid), eye ointment, wet and heat compress (with local cold compress at the initial stage; if the hardening does not soften, local hot compress can be applied to promote blood circulation and aid in inflammation dissipation) [16], application of traditional Chinese medicine preparations, and surgical treatment (patients with pus should undergo incision and drainage) [17]. The external treatment of traditional Chinese medicine for needle eye has been found to be effective, with ear tip bleeding treatment being the most widely used. This treatment aims to clear heat, detoxify, and cool the blood to reduce swelling. According to "LingShu," the ear is the place where the meridians gather, including the foot Yangming stomach meridian, hand Shaoyang Sanjiao meridian, hand Taiyang small intestine meridian, hand Yangming large intestine meridian, foot Taiyang bladder meridian, foot Shaoyin kidney meridian, and foot Shaoyang gallbladder meridian. Qi circulates in these meridians [18-20]. Zhang Jingyue's words state that "three-edge needle bleeding can dispel excess Yang and heat" and that "the nine needles of the Spirit Shu and twelve originals can all achieve detoxification and harmonize qi and blood through bleeding." Ear tip bleeding, as a form of bleeding, also has the effects of detoxification, pain relief, and harmonizing qi and blood [21-22]. Modern studies have shown that the location of the ear tip point is equivalent to the advanced center of the autonomic nerve, promoting blood circulation, improving tissue blood supply and oxygen supply, and exhibiting effects such as reducing fever, anti-inflammation, shock suppression, and analgesia.

Mayinglong Babao eye paste is composed of calcinite, amber, artificial musk, artificial bezoar, pearl, borneol, and borax, which collectively exhibit properties such as clearing heat, reducing redness, alleviating itching, and providing shade [23-24]. It is used to address conditions caused by ocular heat disturbance, including redness, itching, and tearingAmong its components, the herbal medicine has calcinite, which has detoxifying properties and promotes eyesight while removing dampness and promoting the healing of sores. Additionally, bezoar functions in clearing heat and detoxification, reducing swelling and redness. Tauroursodeoxycholic acid, a component of bezoar, enhances the phagocytic function of peripheral blood phagocytes, inhibits late-stage metamorphosis, and exhibits anti-inflammatory, antimicrobial, and tumor growth inhibition effects. Pearl aids in clearing the eyes, detoxifying the muscles, and inducing high tissue fluid permeability to reduce swelling and inflammation. Carnelian disperses internal heat to clear the eyes and alleviate swelling and pain. These three substances collectively contribute to clearing heat, detoxification, and reducing swelling, while also benefiting eyesight and providing shade. Additionally, borneol aids in digestion, breaks blood

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stasis, and disperses, while borax contributes to heat clearance, detoxification, swelling reduction, and acts as a preservative, inhibiting bacterial growth on the skin and mucous membranes. Amber facilitates shock relief, diuresis, blood circulation, and permeates both the viscera and the skin. It contains musk sterone, which helps alleviate pain and swelling. The combination of these ingredients results in significant effects in clearing heat and swelling, detoxification, and dispersion.

The combination of eye cream and direct current (DC) iontophoresis can facilitate the therapeutic effect of drug ingredients by directly delivering them into the body, targeting shallow lesions and exerting a direct influence on the affected areas. This process aids in clearing the local environment, accelerating local blood circulation, and enhancing the efficacy of the drugs. The principle underlying this approach is based on the mutual repulsion of like charges and the attraction of opposite charges within the DC field [25-28]. Iontophoresis has a direct detoxifying and heat-clearing effect on the disease, thereby significantly contributing to the treatment of obstructive heat poison associated with needle eye.

4. Conclusion

This study demonstrates that the combined approach of ear tip bleeding with Mayinglong Babao eye ointment and direct current ion introduction produces more pronounced effects compared to ear tip bleeding alone. Moreover, the synergistic use of traditional Chinese medicine (TCM) exhibits high efficacy, indicating its potential for promotion in clinical practice. Patients can achieve better results when internal and external treatments are combined with oral medications to enhance spleen and stomach function, improve patient constitution, and encourage the development of healthy habits.

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