

Clinical Research

Acupuncture combined with pyonex for xerophthalmia

针刺配合揸针治疗干眼症

GAO Hui (高辉)¹, ZHAO Xiao-dong (赵晓东)², MA Guo-juan (马国娟)¹, LI Huan-li (李焕丽)¹,
LIU Huai-dong (刘怀栋)¹

1. Hebei People's Hospital, Shijiazhuang 050051, China; 2. Hebei Provincial Institute of Medical Information (1. 河北省人民医院, 石家庄 050051, 中国; 2. 河北省医学情报研究所)

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First author: GAO Hui (1978-), male, attending physician.

Research field: ophthalmology in traditional Chinese medicine.

E-mail: 239094564@qq.com

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ABSTRACT

Objective To compare the clinical efficacy of acupuncture therapy and acupuncture combined with pyonex in treatment of xerophthalmia. **Methods** Eighty-eight xerophthalmia patients were randomly divided into group A (periocular acupuncture) and group B (acupuncture combined with pyonex). The treatment was conducted once a day, twelve days were one course of treatment, and two courses were needed in total. The changes of symptom score of eyes, Schirmer I test (SIT) and break-up time (BUT) of patients in the two groups before and after treatment were observed. **Results** The symptom score of eyes (8.36 ± 2.54 vs. 5.36 ± 2.65), SIT (5.82 ± 4.61 vs. 8.33 ± 4.24) and BUT (5.92 ± 2.03 vs. 6.78 ± 2.46) of patients in the two groups after treatment were improved when compared with those before treatment. The total effective rate of group B was superior to that of group A (86.3% vs. 63.6%) (all $P < 0.05$). **Conclusion** The efficacy of acupuncture combined with pyonex in treatment of xerophthalmia is significant, which can effectively improve the symptoms of xerophthalmia, and is superior to simple periocular acupuncture in terms of SIT and BUT.

KEY WORDS: xerophthalmia; keratoconjunctivitis sicca; acupuncture; pyonex; intradermal needle

Xerophthalmia is a kind of diseases of eyes discomfort and visual dysfunction caused by lacrimal film instability and/ or ocular surface lesion due to the quantity or quality of tear or abnormal fluid dynamics^[1]. The clinical manifestations include eyes drying, foreign body sensation, itching or burning sensation, photophobia, red eye, asthenopia, and etc. Along with the wide application of video terminal products and contact lenses, and increasingly serious environmental pollution, xerophthalmia has an incidence increasing year by year, and attacks more and more young people. In this study, the clinical efficacy of acupuncture therapy and acupuncture combined with pyonex in treatment of xerophthalmia was evaluated through the observation of the two methods in improving symptom score of eyes, Schirmer I test (SIT) and break-up time (BUT) of patients by adopting randomized controlled approach, providing more basis for conventional treatment of

xerophthalmia.

CLINICAL DATA

General data

Eighty-eight patients, 176 eyes in total, who were in the department of ophthalmology outpatient service of Hebei People's Hospital from April 2014 to December 2014 and were diagnosed with xerophthalmia were randomly divided into group A (44 cases, 88 eyes) and group B (44 cases, 88 eyes). All the 88 patients finished the study, and there was no drop-out case. The difference was not statistically significant when compared the gender, age and course of disease between the two groups (all $P > 0.05$), and the result was comparable (Table 1).

Diagnostic criteria

The criteria were established by reference to

Table 1 Comparison of general information of patients with xerophthalmia in the two groups ($\bar{x}\pm s$)

Groups	Patients	Gender (female/male)	Age (years)	Course of disease (years)
A	44	17/27	41.5±8.84	1.18±0.94
B	44	16/28	42.1±7.18	1.21±0.91

Criteria of Diagnosis and Therapeutic Effect of Diseases and Syndromes in Traditional Chinese Medicine issued by State Administration of Traditional Chinese Medicine^[2]. ① Patients with one or more subjective symptoms including eyes drying, foreign body sensation, photophobia, burning sensation, asthenopia, and etc.; ② SIT<10 mm/5 min; ③ BUT<10 s. Patients conforming to all the three items were diagnosed with xerophthalmia. Xerophthalmia was classified into three types according to ophthalmology of traditional Chinese medicine^[3]: (1) lung *yin* insufficiency: eyes drying and discomfort, less tear, easy asthenopia, blurred vision, normal white of the eye or slight hyperemia of the conjunctiva, and fine spot on dark of the eye, concurrent with dry cough, dry throat, constipation, thin and white tongue coating, less fluid, thready pulse and weakness; (2) spleen and stomach damp-heat: eyes drying and dull pain, light hyperemia of the conjunctiva, miliary vesicles inside the eyelid, weigh down of eyelid, concurrent with sticky sensation in the mouth and bad breath, constipation and dark urine, yellow and greasy tongue coating, and soggy and rapid pulse; (3) liver-kidney *yin* deficiency: eyes drying and photophobia, frequent blink, dim eyesight, light red of white of the eye, concurrent with soreness and weakness of waist and knees, dizziness and tinnitus, profuse dreaming, red tongue, less fluid, thin tongue coating and thready pulse.

Inclusive criteria

① The patients conforming to the above diagnostic criteria of xerophthalmia and syndrome differentiation of traditional Chinese medicine; ② with age from 18 to 70 years old; ③ drug withdrawal for two or more weeks; ④ voluntarily accepting and persisting in treatment, and signing informed consent form.

Exclusive criteria

① The patients with eye diseases such as conjunctiva disorder, keratopathy, obstruction of lacrimal passage and severe trachoma; ② within six months after ophthalmologic operation; ③ patients with combined dry mouth, dry skin and joint sore, who were considered as sjogren syndrome; ④ patients with combined severe primary diseases such as diseases

of heart, liver, kidney and hematopoietic system, or mental disorder; ⑤ suspicion or determination of drug abuse; ⑥ pregnant and lactating women; ⑦ patients concurrent with other severe diseases or patients not suitable for acupuncture and moxibustion; ⑧ patients accepting other methods to treat xerophthalmia at the same time. Patients conforming to one of the above criteria were excluded.

Removing criteria

① The patients terminating treatment due to fainting during acupuncture treatment or other adverse effects caused by acupuncture; ② patients terminating treatment due to other non-treatment factors.

METHODS

Group A

Bǎihuì (百会 GV 20), Chéngqì (承泣 ST 1), Cuánzhú (攒竹 BL 2), Fēngchí (风池 GB 20), Tàiyáng (太阳 EX-HN 5) and Sīzhúkōng (丝竹空 TE 23) were selected as main acupoints. Disposable sterile acupuncture needles (0.30 mm×40 mm filiform needle) were applied at GB 20 and ST 1, and 0.25 mm×25 mm filiform needles were applied at other acupoints. At ST 1, the needle was inserted into skin perpendicularly without twirling, *deqi* was obtained; slight twirling and lifting and thrusting were conducted at TE 23, and the needle was retained after needling sensation was obtained; BL 2 was inserted upwards to Jīngmíng (睛明 BL 1) with the depth of about 80% of the length of needle; at other acupoints, *deqi* was obtained. The needle was retained for 30 min. The treatment was conducted once a day, twelve days were one course of treatment, and two courses were needed. Two days were free from treatment between two courses.

Group B

Acupoint selection and acupuncture manipulation were the same as Group A. Pyonex therapy was combined with acupuncture. Sānyīnjiāo (三阴交 SP 6), Zúsānlǐ (足三里 ST 36), Nèiguān (内关 PC 6) and Tàichōng (太冲 LR 3) were selected as main acupoints. Combined acupoints: ① lung *yin* insufficiency: Fèishū (肺俞 BL 13) and Hégǔ (合谷 LI 4); ② spleen and stomach damp-heat: Píshū (脾俞 BL 20) and Fēnglóng (丰隆 ST 40); ③ liver-kidney *yin* deficiency: Gānshū (肝俞 BL 18) and Shènsū (肾俞 BL 23).

Seirin pyonex (SEIRIN CORPORATION), with the diameter of 0.2 mm, and length of 0.3–1.5 mm, was applied. 0.2 mm×1.5 mm pyonex was

adopted at SP 6, ST 36 and ST 40, and 0.2 mm × 0.9 mm pyonex was adopted at PC 6, LR 3, LI 4, BL 20, BL 18 and BL 23. Pyonex was withdrawn after embedment for three days, and was embedded again on the next day at the same acupoint. After embedment for four times, two days were free from embedment, and embedment for another four times was conducted.

Observational indices

(1) Symptom score of xerophthalmia

Five common symptoms were scored by reference to *Guidelines of Clinical Research on Chinese New Herbal Medicine*^[4], the sum of results was the aggregate score of symptoms. The five symptoms included eyes drying, foreign body sensation, asthenopia, burning sensation and photophobia. Both eyes were evaluated according to the severity of symptom. The grades of eyes drying included mild (2 points), moderate (4 points) and severe (6 points), and the scores of other symptoms were 1, 2 and 3 points. The proposed scoring standard was seen in Table 2.

(2) BUT > 10 s was normal.

(3) SIT < 10 mm indicated that reflection secretion decreased.

All the above examinations were finished by professional personnel of ophthalmology.

Efficacy criteria

The efficacy criteria were established by reference to *Guidelines of Clinical Research on Chinese New Herbal Medicine*. Symptom efficacy index = [(symptom score before treatment – symptom score after treatment) / symptom score before treatment] × 100%.

Markedly effective: after treatment, clinical symptoms improved obviously, symptom efficacy index > 70%, and SIT and BUT were normal. Effective: after treatment, clinical symptoms improved, symptom

efficacy index was 30%–70%, and SIT and BUT was improved. Ineffective: symptom efficacy index < 30%, and all the indices were not improved.

Statistical analysis

Data were analyzed by adopting SPSS17.0 statistical package, and measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$); measurement data conforming to normal distribution were analyzed through *t*-test, and the ones not conforming to normal distribution were analyzed through non-parametric test; enumeration data were analyzed by *chi*-square test or rank sum test.

RESULTS

Comparison of improvement of single symptom of xerophthalmia patients in the two groups before and after treatment (Table 3)

There was no difference between the two groups in occurrence rate of symptom before treatment ($P > 0.05$); after treatment, the symptoms, such as foreign body sensation and asthenopia, were improved, and the difference was not significant ($P > 0.05$). Group B was superior to group A in other symptoms improvement ($P < 0.05$).

Comparison of SIT and BUT of xerophthalmia patients in the two groups before and after treatment

In group A, the differences in SIT and BUT, when compared with those before treatment, were statistically significant after treatment for one month ($P < 0.05$), and each index was improved obviously. In group B, the differences in SIT and BUT, when compared with those before treatment, were markedly statistically significant after treatment for one month ($P < 0.01$), and each index was improved obviously. In the two groups after treatment, the two indices of SIT and BUT in group B were superior to those in group A, and the differences were statistically significant (both $P < 0.05$). The details were shown in Table 4.

Table 2 Scoring standard of the five common symptoms of xerophthalmia

Symptome	Mild	Moderate	Severe
Eyes drying	Eyes drying occasionally	Eyes drying frequently	Unbearable and continuous eyes drying
Foreign body sensation	Foreign body sensation occasionally	Foreign body sensation and blink frequently	Foreign body sensation and blink frequently, tend to rub the eyes
Burning sensation	Burning sensation occasionally	Burning sensation frequently	Happens daily and the eyes sting
Photophobia	Photophobia and intend to squint	Photophobia and squint	Photophobia and not able to open the eyes
Asthenopia	Asthenopia happens occasionally	Shorten watching duration	The eye lid tend to close and could not watch

Table 3 Comparison of scores of single symptom of xerophthalmia patients in the two groups

Items	Group A (n=44)					Group B (n=44)				
	Patients	Markedly effective	Effective	Ineffective	Total effective rate (%)	Patients	Markedly effective	Effective	Ineffective	Total effective rate (%)
Eyes drying	44	10	19	15	65.9	44	14	24	6	86.3 ¹⁾
Foreign body sensation	37	9	14	14	62.1	39	12	16	11	71.9
Burning sensation	34	6	13	15	55.8	41	10	23	8	80.4 ¹⁾
Photophobia	26	7	9	10	61.5	32	11	16	5	84.3 ¹⁾
Asthenopia	25	8	11	6	76.0	31	11	15	5	83.8

Note: compared with the same item in group A, ¹⁾P<0.05.

Table 4 Comparison of SIT and BUT of xerophthalmia patients in the two groups before and after treatment

Groups	Patients	Eyes	SIT (mm)		BUT (s)	
			Before treatment	After treatment	Before treatment	After treatment
A	44	88	3.25±2.32	5.82±4.61 ¹⁾	4.23±1.73	5.92±2.03 ¹⁾
B	44	88	3.41±2.17	8.33±4.24 ²⁾³⁾	4.52±2.11	6.78±2.46 ²⁾³⁾

Notes: compared with that before treatment, ¹⁾P<0.05, ²⁾P<0.01; compared with the group A after treatment, ³⁾P<0.05.

Comparison of clinical efficacy of xerophthalmia patients in the two groups

In group A, the difference in symptom scores of eyes, when compared with that before treatment, was statistically significant after treatment ($P<0.05$), and in group B, the difference in symptom scores of eyes, when compared with that before treatment, was markedly statistically significant after treatment ($P<0.01$). In the two groups after treatment, the symptom scores of eyes in group B were superior to those in group A, and the differences were statistically significant ($P<0.05$). The details were shown in Table 5.

Table 5 Symptom scores of eyes of xerophthalmia patients in the two groups

Groups	Patients	Before treatment	After treatment
A	44	11.25±3.27	8.36±2.54 ¹⁾
B	44	11.61±3.57	5.36±2.65 ²⁾³⁾

Notes: compared with that before treatment, ¹⁾P<0.05, ²⁾P<0.01; compared with group A after treatment, ³⁾P<0.05.

The total effective rate was 63.6% in group A, and 86.3% in group B; according to rank sum test, the difference of efficacy of the two groups was statistically significant ($P<0.05$), indicating that the efficacy of group B was superior to that of group A. The details were shown in Table 6.

DISCUSSION

At present, the incidence of xerophthalmia is on the rise. According to investigation, the incidence of xerophthalmia is 30.05% in Shanghai^[5], and

Table 6 Comparison of clinical efficacy of xerophthalmia patients in the two groups

Groups	Patients	Markedly effective	Effective	Ineffective	Total effective rate (%)
A	44	5	23	16	63.6
B	44	7	31	6	86.3 ¹⁾

Note: compared with that in group A, ¹⁾P<0.05.

27.70% in some community in Shijiazhuang based on sampling survey^[6]. The incidence of xerophthalmia is closely related to the living environment and lifestyle in modern times. The incidence of xerophthalmia may be increasingly high due to aging of population, increasingly serious air pollution, eye operation, long-term ophthalmic administration, popularization of computer and extensive use of contact lenses^[7].

The principle of western medicine treatment for xerophthalmia is to re-establish lacrimal film with normal quality, and relieve eyes discomfort. Tear fluid replacement therapy is the main method which can take effect at the beginning of treatment, but its efficacy cannot be maintained for a long time. Many patients consider that taking eyedrops for a long time can cause other discomforts. While operation may cause greater risk. Therefore, clinical physicians are always looking for a safe and effective therapeutic method.

Xerophthalmia belongs to “white xerotic syndrome” and “dry eye syndrome” in traditional Chinese medicine, which believes that it is most closely related to liver, kidney and spleen. Liver can generate tear fluid, and restrain tear fluid from

overflowing. It was said in *Sùwèn* (《素问》, *Plain Questions*) that “Five kinds of thick fluids are related with the five viscera, and tear is liver fluid.” In CHAO Yuan-fang’s *Zhubing Yuanhou Lun* (《诸病源候论》, *Discussion on Pathogenesis and Syndrome of Diseases*), “Eye is the manifestation of liver, essence of viscera and bowels, confluence of all vessels, and the channel of fluids. If the fluid exhausted, the eyes may be dry and obscure”, which indicated that eyes drying and tear fluid hyposecretion may be related with liver blood deficiency. Kidney is very important in metabolism and distribution of water-humor in human body. Liver-kidney depletion, *yin*-blood insufficiency and eyes malnutrition may cause xerophthalmia. Spleen is the channel of essential *qi* upwards to eyes, spleen *qi* rising can promote and unblock eyes and orifices, spleen-stomach weakness may cause *qi*-blood metaplasia and insufficiency, so that eyes malnutrition may cause xerophthalmia. Therefore, during clinical treatment, acupoint selection is closely related with liver, kidney and spleen.

Acupuncture and moxibustion in treatment of xerophthalmia can protect patients’ visual function, suppress inflammatory response on ocular surface, and restore normal structure and function of ocular surface. Periocular acupoint selection can promote tear secretion, effectively enhance the stability of lacrimal film, and be free of intervention and toxicity of exogenous chemicals. The efficacy is safe and reliable^[8-9]. At present, most xerophthalmia patients are people suffering from asthenopia and menopause women, who need long-term treatment. At one time, “four-acupoint and eight-needle”^[10], established by Mr. PANG Zan-xiang, was applied for treatment clinically; according to observation, this method can improve the symptoms of xerophthalmia effectively, but the efficacy cannot be maintained for a long time. Therefore, pyonex and traditional acupuncture were combined, and scalp “four-acupoint and eight-needle” was applied in periocular acupoint selection, including ST 1, EX-HN 5, BL 2 and GB 20. ST 1 is an intersecting point of foot-*yangming* stomach meridian, *yang* heel vessel and conception vessel, with the functions of scattering wind and quickening the collaterals, and opening the orifices and improving vision. EX-HN 5 can scatter wind and dissipate heat, and clear head and improve vision. BL 2 belongs to the foot-*taiyang* bladder meridian, with the functions of discharging *qi*, and quickening the collaterals and improving vision. GB 20 is an intersecting point of hand-*shaoyang* three energizer meridian, foot-*shaoyang* gallbladder meridian and *yang* link vessel with the functions of unblocking the meridians and

quickening the collaterals, regulating and harmonizing *qi* and blood, scattering wind and dissipating heat, clearing head and opening the orifices, and improving vision and boosting brain. Combined use of the four acupoints can accelerate periocular blood circulation, free and regulate *qi* and blood, and enrich *yin* and clear heat. Acupoint selection with pyonex was performed on the whole body, including ST 36, SP 6, LR 3 and PC 6, which were the four acupoints in body “four-acupoint and eight-needle”. ST 36 is a *he*-sea point of stomach meridian, with the functions of boosting *qi* and fortifying the spleen; SP 6 is an intersecting point of three *yin* meridians of the foot, with the functions of unblocking the meridians and quickening the collaterals, and regulating and harmonizing *yin-yang*. LR 3 is a *shu*-stream point and *yuan*-source point of liver meridian, with the functions of soothing the liver and rectifying *qi*, and invigorating blood and unblocking the collaterals; PC 6 is a *luo*-connecting point of pericardium meridian, with the functions of boosting *qi* and nourishing the blood, and rectifying *qi* and directing counterflow downward. BL 13 and LI 4 were selected for lung *yin* insufficiency to regulate lung *qi*, and unblock the meridians and quicken the collaterals; BL 20 and ST 40 were selected for spleen and stomach damp-heat to remove water-dampness and assist transportation and transformation; BL 18 and BL 23 were selected for liver-kidney *yin* deficiency to soothe the liver and promote gallbladder function, and enrich and nourish kidney *yin*. Combined use of all the acupoints can regulate and harmonize *qi* and blood and the functions of *zang-fu* organs, supplement *qi* and blood and body fluid in eyes. The use of pyonex showed the academic characteristics of “four-acupoint and eight-needle”, and obtained good clinical efficacy in treatment of xerophthalmia.

Pyonex, needle-embedding therapy, is one of the methods of superficial acupuncture. It reduces acupuncture pain by superficial needling but long-term needle retention, prolong the effective time of acupuncture, so as to improve efficacy. It was said in *Plain Questions* that “the one who is good at treating diseases may treat diseases by superficial acupuncture”. Intradermal needling can prevent diseases through superficial acupuncture based on the theory of twelve cutaneous regions. It was also said in *Plain Questions* that “The needle should be inserted into skin when inhaling, *qi* counterflow should be avoided when needling, and needle should be retained until *deqi*”. Needle retention aims to wait *qi* or regulate *qi*, so as to regulate and harmonize *qi* and blood, and balance *yin-yang*. Needle retention should be conducted for a long time for some diseases

so that efficacy can be obtained. With simple operation and without needling sensation, fainting during acupuncture treatment or side effects, pyonex is particularly suitable for patients who need long-term therapy. According to statistics^[1], pyonex has been widely applied in various diseases, including insomnia, hypertension, menstrual irregularities and arthritis, since its improvement in the 1950s. Traditional pyonex has been applied not frequently for the strong discomfort when the thick needle was embedded in skin. Seirin pyonex is a kind of new intradermal needle without pain, and patients can accept it easily. It is used safely and conveniently. Acupuncture combined with pyonex can enhance clinical efficacy relying on the combination of short-term stimulation and long-term needle retention.

According to syndrome differentiation and treatment for xerophthalmia patients, on the basis of periocular acupuncture, individual pyonex treatment for xerophthalmia patients with different symptoms obtained good efficacy. The total effective rate was 63.6% in simple acupuncture group, and is up to 86.3% in acupuncture combined with pyonex group, so were BUT and SIT, which reflected the improvement of the visual function. In conclusion, Acupuncture combined with pyonex in treatment of xerophthalmia can effectively improve symptoms and visual function, with the efficacy superior to simple acupuncture.

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ABSTRACT IN CHINESE

[摘要] 目的：比较针刺疗法和针刺配合揸针疗法治疗干眼症的临床疗效。方法：将88例干眼症患者随机分为A组（眼周针刺）和B组（针刺配合揸针），每天治疗1次，12天为1个疗程，共治疗2个疗程。观察两组患者治疗前后眼部症状积分、泪液分泌试验、泪膜破裂时间的变化。结果：两组患者于治疗后眼部症状积分（ 8.36 ± 2.54 vs. 5.36 ± 2.65 ）、泪膜破裂时间（ 5.92 ± 2.03 vs. 6.78 ± 2.46 ）、泪液分泌试验（ 5.82 ± 4.61 vs. 8.33 ± 4.24 ）均有明显改善，A组总有效率优于B组（63.6% vs. 86.3%，均 $P < 0.05$ ）。结论：针刺配合揸针治疗干眼症疗效显著，可有效改善干眼病症状，在泪膜破裂时间、泪液分泌试验方面优于单纯眼周针刺治疗。

[关键词] 干眼症 角结膜干燥症 针刺 揸针 皮内针