

Evidence for Traditional Chinese Medicine in Treating Anterior Uveitis: A Pilot Cohort Study

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Purpose: To explore a viable non-steroid anti-inflammatory therapy in treating anterior uveitis (AU) using Chinese herbal medicine. **Design:** A retrospective cohort study. **Methods:** A total of 55 patients with AU diagnosed who were followed up to two weeks with two treatment groups: 22 patients in steroid alone (group 1) and 33 patients in Chinese Angelica, Gentian & Aloe Formula (Dang Gui Long Hui Wan) with or without (w/o) steroid combined (group 2). Group 2 was further divided into two subgroups: TCM only (n = 8), and TCM with steroid (n = 24). We assessed the changes of anterior chamber cells grading and visual acuity, and compared the recovery rates between two treatment groups. **Results:** A larger reduction in anterior chamber (AC) grading in group 2 was observed than group 1 (p = 0.005). Similarly a significant improvement was observed in visual acuity in group 2 vs. group 1 (p = 0.002). The median time for recovery is 6 and 11 days respectively for group 2 and group 1. The treatment of group 2 increased the recovery rate by 3.90-fold as compared to group 1 (95% CI, 2.07 – 7.36; p < 0.001), whereas the trends of recovery between the subgroups of TCM with and w/o steroid were similar. **Conclusions:** The results are highly consistent to favor the Chinese herbal medicine (Dang Gui Long Hui Wan) with or w/o steroid in terms of various outcomes assessed than steroids alone, also implying its potential application as an anti-inflammation drug for anterior uveitis.

Key words: Traditional Chinese medicine, Anterior uveitis, Dang Gui Long Hui Wan

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Introduction

Uveitis is an inflammatory eye disease, which has been estimated to cause 5 to 10% of blindness worldwide [1]. Anterior uveitis (AU) is the most common form accounting for at least 75% of all cases, followed by posterior uveitis, panuveitis, and intermediated uveitis etc [2,3]. It can be very benign to present with but often can lead to severe complications such as secondary glaucoma, cataract, and macular edema if not treated appropriately [4]. Control of inflammation in uveitis is critical to minimize vision loss.

The mainstay of therapy for AU is steroids, including a topical corticosteroid drop such as prednisolone acetate 1% and often a dilating drop such as cyclopentolate. On occasion, for the treatment of severe AU, local injection of corticosteroid or oral therapy such as prednisone was used. However, the chronic use of these drugs is known to produce various side effects, such as elevated intraocular pressure (IOP) and cystoid macular edema [5-7].

Efforts need to be made to seek therapeutic agents for uveitis that can be used for long-term administration. Some tonic herbs from the traditional Chinese medicine (TCM) pharmacopeia have shown anti-inflammatory effects in ocular disease. It has reported that the patients treated with a combination of prednisone or chlorambucil with TCM herbs have shown improved vision and reduced inflammation in Chinese patients with Vogt-Koyanagi-Harada (VKH) syndrome [8]. However, there is a scarcity of data to assess the effects of traditional Chinese herbal medicine on patients with AU. In this study, we attempted to evaluate the Chinese Angelica, Gentian & Aloe Formula (Dang Gui Long Hui Wan) to treat AU

patients in Taiwan.

Materials and Methods

1. Study Population

This study is an observational retrospective study. Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research. We identified the patients with AU diagnosed between January 01, 2016 and December 31, 2019 at the Universal Eye Center, Tainan, Taiwan, through the recollection of the claims and medical records by the investigators. These patients might have recurrent episodes of AU prior to the starting date of diagnosis; such information has been recorded in the data. A total of 55 patients were included in this study. The study is approved by the Antai-Tian-Sheng memorial Hospital Institutional Review Board at Taiwan, and in accordance with the Declaration of Helsinki. (IRB no: 19-107-B)

The therapy was classed into two groups, treated with steroid only (n= 22; Group 1) and TCM with or without (w/o) steroid (n = 33; Group 2). Group 2 was further divided into two subgroups: TCM only (n = 8), and TCM with steroid (n = 24). Steroid therapy includes Prednicone, 1%Econoprednisolon Plus, 1%Pred-Forte, Delone, 0.1%Viscone, Foxone. TCM herb comprised Chinese Angelica, Gentian & Aloe Formula (Dang Gui Long Hui Wan, herbs of Tian-I Pharmaceutical Co., Ltd. Ministry of Health and Welfare Manufacturing no.009901), oral six pills before meals, three times per day. Each pill (500mg) contains Huangqin 40mg, Danggui 30mg, Huangbo 30mg, Longdan 30mg, Dahuang 30mg, Luhui 25mg, Taoren 20mg, Muxiang 20mg, Sangjisheng 20mg, Zhiziren 20mg, Dilong 20mg, Huanglian 20mg,

Qingdai 14mg, and Fengmi 181mg.

2. Uveitis grading

Symptoms in AU consist of the rapid onset of unilateral pain, photophobia, redness, and watery discharge. AU is preceded by mild ocular discomfort for a few days on some occasions. Visual acuity (VA) could be impaired by AU, depending on the severity of inflammation and the presence of complications. In most cases, the reduction in VA is mild. IOP may be reduced as the result of impairment of aqueous secretion by the ciliary epithelium, or elevated due to a variety of mechanisms, including obstruction of aqueous outflow and therapeutic steroids. Anterior chamber (AC) cells are a dependable indicator of inflammatory activity. Grading (SUN Working Group) is performed by estimating the number of cells in a 1 mm by 1 mm slit beam field, employing adequate light intensity and magnification. Standardization of Uveitis Aqueous flare is the haziness of the normally clear fluid in the anterior chamber, reflecting the presence of protein due to breakdown of the blood-aqueous barrier. It is now thought that in most or all patients the presence of flare indicates active inflammation with a resultant higher risk of complications over the longer

term. Flare may be graded clinically using a slit lamp to assess the degree of interference with the visualization of iris and lens (Table 1) [9].

The patients were followed up to two weeks. The status of recovery is defined as the inflammation level at zero (AC grading = 0).

3. Statistical analysis

In our analysis, the clinical measures of the worse eye for uveitis are presented. The worse eye is defined as the eye with higher AC grade at the baseline. The primary outcome, changes of AC grading in the worse eye at day 7 versus baseline, were compared for the two treatment groups using the two-sample *t*-test. If uveitis was cured prior to day 7, the AC grading on the day of the last visit was used as approximate on day 7. The secondary outcome is the time to recovery. The recovery of the patient refers to AC grading of 0 for the worse eye. Survival analysis, including the log-rank test and Proportional Cox model, was used to compare the recovery rates up to 14 days of follow-up across treatment groups. Kaplan-Meier plot was displayed for recovery estimates for groups. The baseline characteristics of age, gender, AC grades, VA and IOP were compared using the two-sample *t*-test or

Table 1 Standardization of Uveitis Nomenclature. SUN Working Group slit lamp grading of AC cells (1 mm by 1 mm slit beam) and scheme for AC flare.

Grade	AC cells in field	AC flare description
0	<1	None
0.5+	1-5	-
1+	6-15	Faint
2+	16-25	Moderate (iris and lens details clear)
3+	26-50	Marked (iris and lens details hazy)
4+	> 50	Intense (fibrin or plastic aqueous)

chi-square test for continuous and categorical variables respectively. All analyses were conducted using STATA v15. A p-value less than 0.05 is considered to be statistically significant.

Results

Fifty-five patients diagnosed as AU were included in the study, 22 subjects in Group 1 (steroid treatment only) and 33 in Group 2 (TCM with or w/o steroid). The patients were followed up from the baseline for up to 14 days. There were no lost to follow-up. Side effects including abdominal pain, diarrhea and constipation were not observed in the follow-up. All

subjects fulfilled the clinical criteria for anterior uveitis. Baseline demographics and clinical characteristics are shown in Table 2. The baseline characteristics of age, gender, AC grades, visual acuity, and IOP were similar between groups. The average age is 45 years (SD=14.2) and 44 years (SD=16.1) in Group 1 and 2 respectively. 59.1% in Group 1 are males and 58.1% in Group 2. It appears that the largest proportion of patients with AC grading of 4 in both Group 1 (54.55%) and Group 2 (57.58%).

Within 1-week follow-up, there was a larger reduction in AC grading in group 2 (-3.06; 95% confidence interval [CI]: -3.46 to -2.66) than the group 1 (-2.09; 95% CI: -2.67 to -1.51; $p = 0.005$; Table 3).

Table 2 Baseline demographics and clinical characteristics of patients.

	Group 1 Steroid only	Group 2 TCM with or w/o steroid	P-value
N	22	33	
Age(SD), years	45 (14.2)	44 (16.3)	0.896
Age ranges, years	24 - 78	22 - 83	
Male (%)	13 (59.1)	18 (54.6)	0.739
AC grades (%)			
1	1 (4.55)	3 (9.09)	0.261
2	5 (22.73)	10 (30.30)	
3	4 (18.18)	1 (3.03)	
4	12 (54.55)	19 (57.58)	
AC grades (SD)	3.23 (0.97)	3.09 (1.13)	0.645
VA (SD)	0.77 (0.27)	0.68 (0.26)	0.182
IOP (SD), mmHg	24.2 (17.9)	20.0 (12.2)	0.307
*Had steroid medications (%)	7 (31.8)	13 (39.4)	0.567
&Had uveitis in the past (%)	12(54.5)	20 (60.6)	0.655

AC, anterior uveitis; VA, visual acuity; IOP, Intraocular pressure; SD, standard deviation;

* The number of patients who took steroid medication within two weeks before coming to the clinic (the follow-up starting date).

& The number of patients who experienced uveitis in the past one years before coming to the clinic.

For continuous variable, two-sample t-test was conducted to test the mean differences between two groups. For categorical variable, chi-square test was conducted to compare the proportion differences.

Similarly, the proportion of recovery (AC grading of 0) was statistically larger in the group 2 than that in the group 1 (97.0% vs. 45.5%; $p < 0.001$). There was a statistically significant improvement in VA in group 2 (0.19; 0.12 to 0.26) vs. group 1 (0.04, -0.01 to 0.09; $p = 0.002$). Further accounting for age and baseline AC grading in the regression model did not change the conclusion (data not shown). Changes in IOP levels were not significantly different between groups.

In the 2-week follow-up, all recovered in group 2 (100%) and 17 patients (77.2%) in group 1, with the median time for recovery of 6 and 11 days respectively (Table 3). The log-rank test showed significant differences in recovery rates for patients in two groups (Chi-squared =23.55, $p < 0.001$; Table 3). Kaplan-Meier survival curves displayed the recovery rates for patients in two groups, showing a strong trend towards recovery benefit for group 2 (Figure 1A). We also assessed the treatment effects on recovery using

survival analysis. The treatment of group 2 increased the recovery rate by 3.90-fold as compared to group 1 (95% CI, 2.07 – 7.36; $P < 0.001$; Table 4). The conclusion did not change after accounting for age and baseline AC grading (recovery ratio of 4.38, 95% CI, 2.26 – 8.51; $P < 0.001$).

For Group 2, we further divided into two subgroups: TCM only ($n = 8$), and TCM with steroid ($n = 24$). The Kaplan-Meier plots suggested the trends of recovery were similar between these two subgroups (Figure 1B) with the median recovery of 7 and 6 days in TCM only and TCM with steroid group respectively, lower than 11 days for steroid only group. The log-rank test showed that patients treated with TCM only had higher recovery rates than those in steroid only group (Chi-squared = 11.78, p -value = 0.001), whereas similarly to those in TCM with steroid group (Chi-squared = 0.31, p -value = 0.579).

Table 3 Primary outcomes by groups.

Outcome	Group 1 Steroid only (n=22)	Group 2 TCM with or w/o steroid (n=33)	<i>p</i> -value
AC1 - AC0	-2.09 (-2.67 to -1.51)	-3.06(-3.46,-2.66)	0.005
VA1 - VA0	0.04 (-0.01 to 0.09)	0.19 (0.12,0.26)	0.002
IOP1- IOP0	-9.68 (-17.16,-2.20)	-6.0 (-10.24,-1.76)	0.347
#Recovered in 1-week (%)	10 (45.5%)	32 (97.0%)	<0.001
#Recovered in 2-week (%)	17(77.2%)	33 (100%)	<0.001
Median recovery days	11	6	

AC, anterior uveitis; VA, visual acuity; IOP, Intraocular pressure; Two-sample *t*-test or chi-square test was conducted to compare the changes of continuous variables and proportion differences respectively. For the recovered rate in the entire follow-up time (2-week), the log-rank test was performed to test the differences in recovery rates at any time point between two groups (Chi-squared =23.55). Median recovery days were estimated from the Kaplan Meier survival curve.

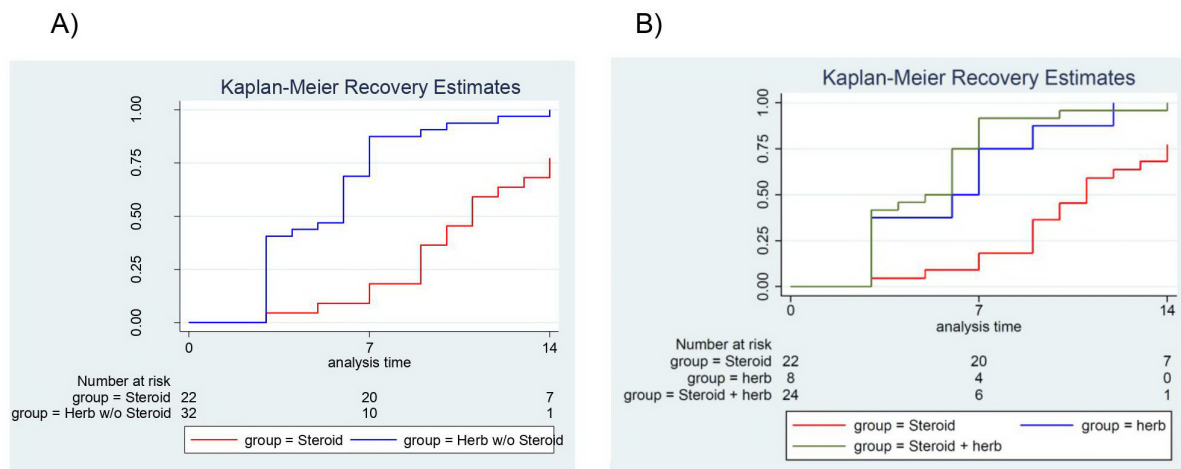


Fig 1 Kaplan-Meier plots of recovery rate for patients by group.

Discussions

To the best of the knowledge, our study is the first study to demonstrate that the ancient liver drugs of Dang Gui Long Hui Wan is effective in treating AU patients. Compared to steroid alone treatment, patients treated with Chinese herb medicine with or w/o steroid showed a significant reduction in inflammation, improved visual acuity and increased recovery estimates.

The option of immunosuppressive therapy is used in the management of patients with ocular inflammatory disorders [7,10,11]. Essentially uveitis practitioners consider the option of immunosuppressive therapy to treat uveitis which is a systemic approach. Currently, available management options for non-infectious AU include corticosteroids or cyclopentolate delivered by periocular or oral routes. Any treatment, including eye drops, may result in adverse effects, for example, transient elevation of IOP in susceptible individuals ('steroid responders') [6,12]. In our study, the effect of the steroid alone was found inferior to the group 2, whereas the trends of recovery between the

subgroups of TCM with and w/o steroid were similar. This result implies the effect of the steroid alone was inferior to the TCM alone suggesting the goal of the complete elimination of active inflammation and, at the same time, decreasing the steroid requirement could be achievable.

Encouraging experience with TCM in treating inflammatory diseases in our study might lead the practitioner to consider its potential application in treating AU. TCM takes a holistic view of the human body [13,14]. The five wheels theory originated from the five phase theories, has still been in usage for the practice of ophthalmology in Chinese Medicine [15]. It classifies the different areas of the eye into five viscera. They are the wind wheel, blood wheel, flesh wheel, Qi wheel, and water wheel, corresponding to the five viscera: liver, heart, spleen, lung, and kidney (Figure 2). The five wheels theory confirms to the ocular anatomy of modern ophthalmology, and could be extended to include the entire eyeball (Figure 3). Many scholars have proposed the matching of modern anatomy of ophthalmology with this five wheels theory. The interpretations of the five wheels theory are largely

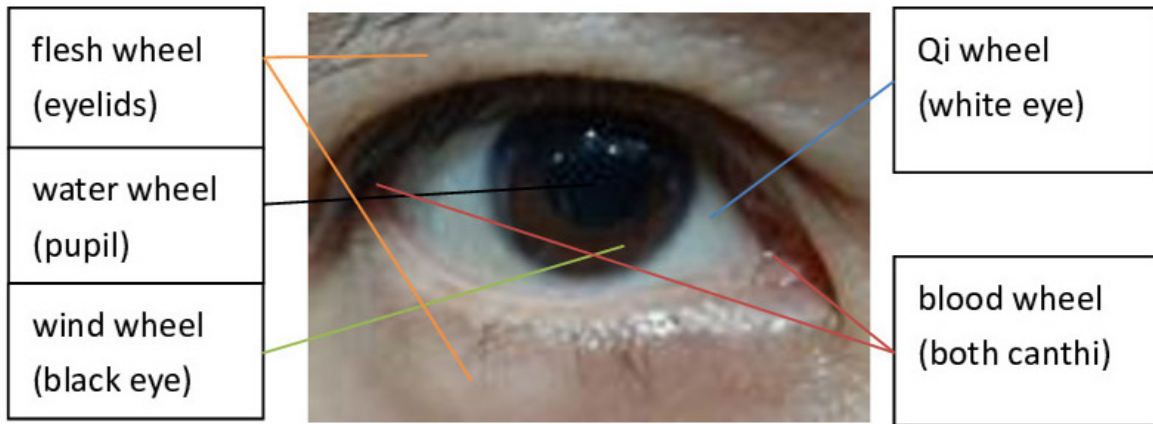


Fig 2 Illustration of the five wheels and corresponding eye components.

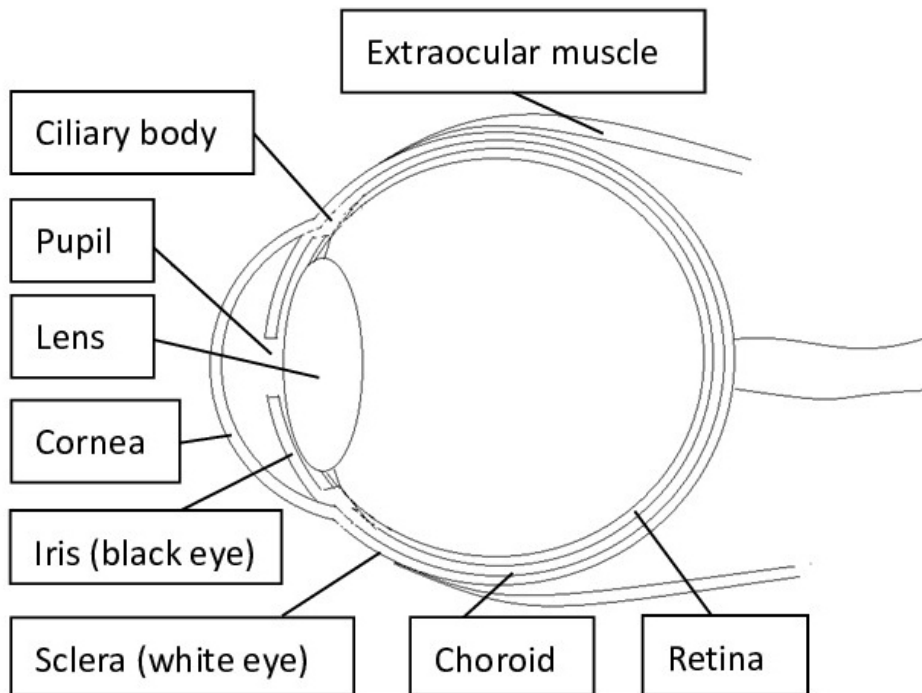


Fig 3 Illustration of the eyeball components by a lateral view.

consistent but their application to the eyes is ambiguous or flawed in some perspectives, for example, most of the researchers advocate that wind wheel is the cornea [16-20]. However, the frontal view of ocular anatomy states that the wind wheel is a black eye, whereas the iris is rich in melanocytes, not the transparent cornea.

This doctrine should be re-examined and reorganized as follows. The wind wheel for the uvea includes the iris, ciliary body and choroid. The blood wheel for the medial and lateral canthi includes the ophthalmic artery and arteriovenous vascular networks in the orbit. The flesh wheel for the upper and lower eyelids includes

the six extraocular muscles. The Qi wheel for the sclera includes the cornea, and finally, the water wheel for the pupil includes the lens and retina [21]. Based on the five wheels theory, it can be inferred that anterior uveitis is anterior inflammation of uvea, linked to the wind wheel corresponding to the liver of viscera from the perspective of TCM.

AU is the most common form of uveitis which has been estimated to cause 5 to 10% of blindness worldwide with a drastic and rapid reduction of vision in one or both eyes, which cannot be quickly reduced without the great bitterness and coldness drugs. The ancient Chinese Angelica, Gentian & Aloe Formula (Dang Gui Long Hui Wan) is formed by many natural great bitterness and coldness herbal drugs (i.e., scutellariae, phellodendron, coptidis) to directly relieve the excess fire in the meridians from the urine and feces. The purpose of the consumption of the ancient Chinese formula is to quench excessive heat, a TCM concept, in the liver manifested by uveal or choroidal inflammation. Numerous Chinese herb formula of the liver, e.g. Shaoyao Qinggan Powder, Qinggan Mingmu Fang, Qinghuo Rougan Mingmu Fang...etc, have been proposed to improve the efficacy in the treatment of acute or chronic uveitis [22-24]. However, Dang Gui

Long Hui Wan is the most effective for uveitis based on our clinical experience.

This study has several limitations. It is a cohort study with small sample size. The limited size of our cohort may reflect in part the difficulty to have patients undergoing Chinese herb treatment. However, despite the small sample size, the results are highly consistent to favor the herbal medicine in terms of various outcomes assessed. Second, patients with the first attack of uveitis or recurrent episodes might have different responses for different treatments.

In our study, we did not restrict the patients based on the new incidence or recurrence episode of AU. Across the groups, it was assured there was no significant difference in the proportions of these two subtypes across groups. The results are highly consistent to favor the Chinese Angelica, Gentian & Aloe Formula (Dang Gui Long Hui Wan) in terms of various outcomes assessed than steroids, also implying its potential application as an anti-inflammation drug for uveitis. Finally, our study is not a randomized trial and further investigation is warranted to confirm our study. A large-scale randomized trial is warranted for further investigation. Even with these limitations, the significant findings of this study should serve

Table 4 Comparing recovery rate differences in 2-week follow-up using Proportional Cox model.

		Recovery Ratio	95% CI	p-value
Model 1	Group 1	1(Ref)		
	Group 2	3.90	2.07 – 7.36	< 0.001
Model 2	Group 1	1(Ref)		
	Group 2	4.39	2.26 – 8.51	< 0.001

Cox proportional hazards regression was conducted to estimate the ratio of recovery in Group 2 vs. Group 1. Model 1 – Univariate Cox model without adjustment for covariates; Model 2 – Cox model adjusted for covariates of age and baseline AC grading. Group 1 – Steroid only; Group 2 – TCM with or w/o steroid.

as a robust pilot data to physicians who are treating uveitis. Although no direct evidence of the therapeutic mechanism is performed here, the results raise the possibility of treating ophthalmic inflammation diseases from traditional nature medicines.

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中醫藥治療眼睛前葡萄膜炎的臨床證據： 病歷回溯性研究

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目的：探討中醫藥作為治療眼睛前葡萄膜炎非類固醇療法之可行性。設計：病歷回溯性研究。方法：共 55 例門診確診為前葡萄膜炎的患者，分為：單純類固醇治療組 22 例（第 1 組）和中藥（當歸龍薈丸）併用或不併用類固醇組合治療組 33 例（第 2 組），第 2 組再進一步分為僅單獨使用中藥（n = 8）和中藥併用類固醇（n = 24）兩個亞組，並觀察追蹤至 2 週。我們評估了眼睛前房發炎細胞數分級和視力的變化，並比較了兩個治療組之間的恢復率。結果：與第 1 組相比，第 2 組的前房細胞分級降低幅度更大（ $p = 0.005$ ）；同樣地第 2 組比第 1 組的視力改善顯著（ $p = 0.002$ ）；第 2 組和第 1 組的中位恢復時間分別為 6 天和 11 天。與第 1 組相比，第 2 組的治療使恢復率提高了 3.90 倍（ $p < 0.001$ ），然而中藥併用和不併用類固醇兩個亞組之間的恢復趨勢幾乎相同。結論：此中藥古方（當歸龍薈丸）併用或不併用類固醇治療眼睛前葡萄膜炎之療效在評估的各項結果均優於單獨使用類固醇者，這也暗示其作為前葡萄膜炎非類固醇消炎藥的潛在應用。

關鍵字：傳統中醫藥、前葡萄膜炎、當歸龍薈丸

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