

Clinical Observation on the Combination of Yu Ping Feng San and Olopatadine in the Treatment of Chronic Urticaria

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Abstract: *Objective:* To investigate and analyze the clinical effect of treating patients with chronic urticaria with Yu Ping Feng San combined with olopatadine. *Methods:* The study period was from January 2023 to January 2024, 46 patients diagnosed with chronic urticaria were extracted as assessment samples, which were randomly divided into an observation group ($n = 23$) and a control group ($n = 23$) by using the method of medical record number random drawing. The treatment program for patients in the control group was olopatadine, and the treatment program for patients in the observation group was Yu Ping Feng San combined with olopatadine. The TCM symptom scores, urticaria activity scores (UAS7), itching VAS scores, clinical efficiency, recurrence rate, and incidence of adverse reactions between the two groups were compared. *Results:* The TCM symptom scores of the observation group were lower than those of the control group after treatment ($P < 0.05$); the UAS7 score and itching VAS score of the observation group were lower than those of the control group after treatment ($P < 0.05$); the clinical effective rate of the observation group was higher than that of the control group after treatment, and the recurrence rate was lower than that of the control group ($P < 0.05$); the comparison of the incidence rates of adverse reactions between the two groups did not show any significant difference ($P < 0.05$). *Conclusion:* The treatment effect of patients with chronic urticaria using Yu Ping Feng San combined with olopatadine is remarkable. This combined treatment can relieve the symptoms of Chinese medicine, control the progression of the disease, and reduce the degree of itching, with a lower recurrence rate and higher safety of the medication, which is suitable for popularization and application in healthcare institutions.

Keywords: Yu Ping Feng San; Olopatadine; Chronic urticaria; Clinical efficacy

Online publication: July 18, 2024

1. Introduction

Chronic urticaria is a common clinical skin disease, where patients have a disease duration of more than 6 weeks. The main lesion characteristics of the skin are because of the mucous membrane tissue transient dilation of small blood vessels, significantly increasing in permeability, leading to lesions in the region of the skin to produce limited edema. The etiology of chronic urticaria includes exogenous factors such as drugs, inhalants,

and food, and endogenous factors such as systemic diseases and psychiatric factors. The main symptoms include skin lesions, angioedema, itchy skin, and so on, when the disease triggers, which seriously affects the normal lives of the patients ^[1]. Clinical treatment of chronic urticaria is mostly symptomatic through drugs, such as olopatadine. Olopatadine is an antihistamine that can inhibit the release of histamine and other allergic mediators and relieve symptoms such as edema and itching, but the long-term efficacy is poor and it can cause various kinds of adverse reactions ^[2]. In Chinese medicine theory, chronic urticaria is known as a type of rash, in which the pathogenesis of the disease is the weakness of the spleen and lungs, and the symptoms can be triggered by cold air and irritants on the skin. Yu Ping Feng San is a traditional Chinese medicine formula with medicinal effects on the body surface ^[3]. In this study, 46 cases of chronic urticaria patients were selected to investigate and analyze the clinical effect of Yu Ping Feng San combined with olopatadine treatment.

2. Data and methods

2.1. General information

All matters of this study were reported to the medical ethics committee of the unit for approval, and the study period was from January 2023 to January 2024. A total of 46 cases of diagnosed chronic urticaria patients were taken as assessment samples, which were randomly divided into the observation group ($n = 23$) and the control group ($n = 23$) by utilizing the method of drawing lots of medical record numbers. In the observation group, there were 13 males and 10 females, with an age range of 34–59 years, with 46.58 ± 3.77 mean years, and a disease duration span of 6–15 months, with 10.42 ± 1.69 mean months. In the control group, there were 11 males and 12 females, with an age range of 37–58 years, 46.63 ± 3.75 mean years, and a disease duration span of 6–14 months, with 10.38 ± 1.74 mean months. The general information of the two groups was comparable ($P > 0.05$).

Inclusion criteria: Patients meet the diagnostic criteria for chronic urticaria in the Chinese Urticaria Diagnostic and Treatment Guidelines; no other skin lesions are present; patients know the content and process of the study and sign the informed consent document.

Exclusion criteria: Patients have recent drug treatment or drug allergic reactions; patients have major organ dysfunction; the patient is a pregnant or lactating woman.

2.2. Methods

The treatment program for patients in the control group is olopatadine, which is taken once a day after breakfast and dinner, with a single dose of 5 mg, for a total of 4 weeks.

The treatment program of patients in the observation group was Yu Ping Feng San combined with olopatadine, and the drug program of olopatadine was the same as that of patients in the control group. The drug formula of Yu Ping Feng San is 30 g of *Astragalus*, 20 g of *Atractylodes macrocephala*, 20 g of *Fangfeng*. The physician follows the principle of TCM dialectic treatment to add or subtract the drug formula. For example, if a patient has a wind-cold type condition, they will add herbs such as white peony root (Bai Shao), *Ephedra* (Ma Huang), *Codonopsis* (Dang Shen), raw *Rehmannia* (Sheng Di), raw gypsum (Sheng Shi Gao), *Angelica* (Dang Gui), apricot kernel (Xing Ren), and honey-fried licorice root (Zhi Gan Cao); If the patient has a wind-heat type condition, add Sheng Di Huang (*Rehmannia* root), Dang Gui (*Angelica sinensis*), Jing Jie (*Schizonepeta*), Chan Tui (cicada molt), Ku Shen (*Sophora* root), Sheng Shi Gao (Gypsum), Zhi Mu (*Anemarrhena*), and Zhi Gan Cao (honey-fried licorice). If the patient has a blood deficiency type condition, add Shu Di Huang (*Rehmannia* root), Dang Gui (*Angelica sinensis*), Bai Shao (white peony root), and Zhi Gan Cao (honey-fried licorice). For patients with body deficiency and excessive sweating, add Wu Wei Zi (*Schisandra*). For those with skin

conditions, add Shan Yao (Chinese Yam). If the rash is not developing smoothly, add Fu Ping (duckweeds) and Chan Tui (cicada molt). The patients were given one dose of the above medication daily, one dose consisted of 300 ml of concentrated liquid after decoction, 150 ml was taken in the morning and evening respectively, and the medication was applied for four weeks in total.

2.3. Evaluation criteria

Before treatment and after 4 weeks of treatment, Diagnostic Efficacy Criteria for Chinese Medicine Diseases are referred to evaluate the Chinese medicine symptom scores of edema, wind mass, itching, and skin scratches of the two groups, with a full score of 3 points, and the higher the score is, the more serious the symptom is.

Before treatment and after 4 weeks of treatment, the two groups were evaluated for urticaria activity score (UAS7) and itching VAS score. The UAS7 score items included the diameter and the number of lesions, with a full score of 6, and the higher the score was, the more serious the symptoms were. The higher the itching score, the more severe the itching is.

The clinical efficiency of the two groups after 4 weeks of treatment is evaluated. If the TCM symptom score is reduced by more than 90% after treatment, it will be regarded as very effective; if the TCM symptom score is reduced by 60%–90% after treatment, it will be regarded as effective; and if it does not meet the criteria of effective and very effective, it will be regarded as ineffective. The statistics of the recurrence rate and the incidence of adverse reactions of the two groups are recorded.

2.4. Statistical methods

SPSS23.0 software was used to analyze the research data, with mean \pm SD measurement data for the *t*-test, count data % for χ^2 test, and $P < 0.05$ for the existence of statistical level differences.

3. Results

3.1. Comparison of TCM symptom scores between the two groups

After treatment, the TCM symptom points of the observation group were lower than those of the control group ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of Chinese medicine symptom points between the two groups

Groups	Edema		Vesicles		Itching		Skin scratches	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Observation group ($n = 23$)	2.24 \pm 0.38	0.74 \pm 0.12	2.19 \pm 0.41	0.65 \pm 0.12	2.08 \pm 0.43	0.79 \pm 0.14	2.05 \pm 0.46	0.81 \pm 0.17
Control group ($n = 23$)	2.29 \pm 0.35	1.29 \pm 0.33	2.23 \pm 0.38	1.13 \pm 0.36	2.11 \pm 0.45	1.25 \pm 0.41	2.11 \pm 0.44	1.29 \pm 0.42
<i>t</i> value	0.464	7.512	0.343	6.066	0.231	5.092	0.452	5.081
<i>P</i> value	0.645	0.000	0.733	0.000	0.818	0.000	0.653	0.000

3.2. Comparison of UAS7 score and itching VAS score between the two groups

The UAS7 score and itching VAS score of the observation group were lower than those of the control group after treatment ($P < 0.05$) as shown in **Table 2**.

Table 2. Comparison of UAS7 score and itching VAS score between the two groups

Groups	UAS7 rating		Itching VAS score	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Observation group (<i>n</i> = 23)	5.11 ± 0.57	2.09 ± 0.48	2.05 ± 0.58	0.62 ± 0.11
Control group (<i>n</i> = 23)	5.08 ± 0.64	3.15 ± 0.76	2.09 ± 0.63	1.07 ± 0.35
<i>t</i> value	0.168	5.655	0.224	5.882
<i>P</i> value	0.867	0.000	0.824	0.000

3.3. Comparison of clinical effective rate and recurrence rate between the two groups

The clinical effective rate of the observation group was higher than that of the control group, and the recurrence rate was lower than that of the control group ($P < 0.05$), as shown in **Table 3**.

Table 3. Comparison of clinical effective rate and recurrence rate between the two groups [*n* (%)]

Groups	Very effective	Effective	Ineffective	Overall effective rate	Recurrence rate
Observation group (<i>n</i> = 23)	16	6	1	22 (95.7)	2 (8.7)
Control group (<i>n</i> = 23)	11	6	6	17 (73.9)	8 (34.8)
χ^2				4.212	4.600
<i>P</i> value				0.040	0.035

3.4. Comparison of the incidence of adverse reactions between the two groups

There is no incidence of serious adverse reactions during treatment in both groups. There are two cases of dry mouth and abdominal discomfort in patients in the observation group and one case of abdominal discomfort in the control group, and there is no significant difference in the comparison between the groups ($P > 0.05$).

4. Discussion

Chronic urticaria is a common type of urticaria, with a persistent condition and a relatively complex cause. The main clinical symptoms are wheals and edema. The wheals present are elevated, with temporary lesions that have smooth surfaces and pink color surrounded by a red halo, which can occur in any part of the body. The wheals are mostly itchy, and the edema can be recurring, which affects the patient's work and daily life^[4].

The results of this study show that the clinical effectiveness rate of the observation group is higher than that of the control group, and the recurrence rate is lower than that of the control group, suggesting that patients with chronic urticaria treated with Yu Ping Feng San combined with Olopatadine have a significant positive effect and a lower recurrence rate. Clinical treatment of chronic urticaria is treating the symptoms with drugs. Olopatadine as the second generation of antihistamines, can potently antagonize the histamine H1 receptor, inhibit histamine-related allergic reactions, and then relieve the symptoms of edema and so on. Pharmacological studies have confirmed that olopatadine can also inhibit the synthesis and secretion of allergic chemical mediators such as platelet-activating factor, thromboxane, leukotrienes, and others, and block the actions of eosinophilic granulocytes, thus inhibiting allergic inflammatory reactions^[5]. Olopatadine has a rapid onset of action, which can relieve symptoms such as edema and itching in a short period of time, but the long-term therapeutic effect is not good. The condition of some patients recurs after stopping the drug, and long-term use of the drug is prone to cause dry mouth, drowsiness, and other adverse reactions. In traditional Chinese medicine, chronic urticaria

is a kind of rash, and its pathology is the weakness of the spleen and lungs, emotional disorders, the invasion of external irritants, and so on. The invasion of stagnant external irritants in the body can cause the Ying and Wei to be out of harmony and the imbalance of qi, blood, and yin and yang. This results in the skin not being moistened, which induces the symptoms of edema, itching, and so on ^[6]. In the formula of Yu Ping Feng San, *Astragalus* is sweet and warm in nature, which can replenish the qi of the spleen and lung, and has the effect of fixing the surface and stopping sweating. *Atractylodes macrocephala*, whose main function is to strengthen the spleen and regulate qi, can strengthen the efficacy of astragalus to benefit qi and consolidate the surface. *Fangfeng* can eliminate the irritants invading the body and has the effect of benefiting qi. The combination of the three drugs can achieve the effect of removing the irritants without adverse effects, regulate the qi, nourish the spleen, lungs, and other organs, and effectively remove the pathogenic basis of chronic urticaria. Combined with the treatment of olopatadine, it can have a rapid onset of effect, prolonging the duration of the effect of the drug, effectively removing the lesion, and then obtaining the ideal therapeutic effect ^[7].

The data and information of this study showed that the TCM symptom score of the observation group was lower than that of the control group after treatment, suggesting that the treatment of Yu Ping Feng San combined with olopatadine could alleviate several TCM symptoms. One of the reasons is that olopatadine is an antihistamine that can inhibit many allergic mediators released by mast cells, block H1 receptors, and also inhibit metamorphic reactions, thus relieving symptoms related to chronic urticaria. The duration of efficacy of treatment with olopatadine alone is relatively short, and some patients have recurrent symptoms. In the formula of Yu Ping Feng San, *Astragalus* is the principal medicine, its main effect is to nourish the lungs to achieve the clinical effect of stopping sweating. *Atractylodes macrocephala* belongs to the subject drug, its main effect is to regulate qi and strengthen the spleen, with the combination of astragalus can strengthen the role of regulating and replenishing qi ^[8]. According to traditional Chinese medicine, the invasion of external irritants can induce symptoms related to chronic urticaria, so adding *Fangfeng* to the formula can achieve the clinical effect of expelling the irritants ^[9]. The combination of the three drug components with olopatadine can alleviate a variety of disease symptoms. This study confirmed that the UAS7 score and itching VAS score of the observation group were lower than those of the control group after treatment, suggesting that the treatment of Yu Ping Feng San combined with olopatadine controls the progression of the disease and reduces the degree of itching. Modern pharmacological analysis and research confirm that the formula of Yu Ping Feng San can regulate immunity, inhibit allergic reactions, and have anti-inflammatory and antiviral effects. *Astragalus* can enhance the resistance of the body, inhibit virus-induced cytopathic lesions, protect the liver, and have anti-aging properties. *Atractylodes macrocephala* can regulate immune function and has antibacterial, hepatoprotective, and choleric effects. *Fangfeng* has anti-inflammatory, antipyretic, and analgesic properties, can regulate immunity, inhibit metamorphic reactions, and alleviate a variety of symptoms when combined with other drugs ^[10]. The combined application of olopatadine and Yu Ping Feng San can intervene in the condition in multiple ways to relieve clinical symptoms, and its effect is better than a single Western medicine treatment. In this study, the incidence of adverse reactions in the two groups is not significant. Yu Ping Feng San is made of all-natural ingredients, so no serious adverse reactions occurred after the use of the medication. Olopatadine is a commonly used clinical antihistamine, so the overall safety of the medication is higher, and the combination of the two did not increase the incidence of adverse reactions.

5. Conclusion

In conclusion, the treatment effect of patients with chronic urticaria using Yu Ping Feng San combined with olopatadine is remarkable. This combined treatment can alleviate the symptoms of Chinese medicine, control

the progression of the disease, and reduce the degree of itching, with a lower recurrence rate and higher drug safety, which is suitable for popularizing the use of the drug in healthcare institutions. The number of samples of chronic urticaria patients selected in this study is relatively small, the overall time of the study is short, and a multicenter study has not been implemented, so the specific mechanism of Yu Ping Feng San combined with olopatadine treatment still needs further research.

Disclosure statement

The author declares no conflict of interest.

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