

CLINICAL RESEARCH

## **Therapeutic Effect of Traditional Chinese Medicine Decoction Combined with Cetirizine on Allergic Rhinitis of Kidney-Yang Deficiency Type**

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### **Abstract**

**Objective** To explore the therapeutic effect of traditional Chinese medicine decoction combined with cetirizine on allergic rhinitis (AR) of kidney-Yang deficiency type. **Methods** A total of 96 patients with AR of kidney-Yang deficiency type treated in our hospital from Jul. 2014 to Jun. 2018 were selected and randomly divided into the Western medicine group (n=32), traditional Chinese medicine group (n=32) and combined Chinese and western medicine group (n=32) according to the random number table method, the patients of three groups were orally administrated cetirizine, warming Yang and tonifying Qi and treating sneezing decoction, and the combination of warming Yang and tonifying Qi and treating sneezing decoction and cetirizine, respectively. The total clinical effective rate, visual analog scale (VAS) scores before and after treatment, rhinoconjunctivitis quality of life questionnaire (RQLQ), TCM syndrome scores, and adverse effects were compared among the three groups. **Results** The total effective rate of the combined Chinese and Western medicine group was significantly higher than that of the Western medicine group and the traditional Chinese medicine group ( $P<0.05$ ); After treatment, VAS, RQLQ and TCM syndrome scores of each group were significantly lower than those before treatment ( $P<0.05$ ). The VAS, RQLQ and TCM syndrome scores in the combined Chinese and Western medicine group were significantly lower than those in the Western medicine group and the traditional Chinese medicine group ( $P<0.05$ ); There was no significant difference in the incidence of adverse reactions between the traditional Chinese medicine group and the combined Chinese and Western medicine group ( $P>0.05$ ), however, the incidence of adverse reactions in these two groups was significantly lower than that in the Western medicine group ( $P<0.05$ ). **Conclusion** The effect of traditional Chinese medicine decoction combined with cetirizine on AR of kidney-Yang deficiency type was remarkable, and the adverse effects was few, which is worthy of clinical promotion.

## Introduction

Allergic rhinitis (AR) is a chronic disease that often causes patients to experience symptoms such as recurrent sneezing, runny nose, and nasal obstruction, and it can harm human health for a long time, severely affecting the quality of life of patients [1]. At present, clinical Western medical treatment mostly uses antihistamines such as cetirizine to treat AR, although it has achieved some success, there are also many adverse effects. In recent years, traditional Chinese medicine (TCM) has been widely studied in the treatment of AR, and the clinical effects are also getting better and better, and TCM holds that AR is mostly caused by deficiency of kidney-Yang and attack of exogenous evils. When treating this disease, it should be based on warming Yang, tonifying Qi, and diffusing the lung and treating sneezing [2]. Therefore, on the basis of oral administration of cetirizine, this study combined with the warming Yang and tonifying Qi and treating sneezing decoction to explore the therapeutic effect of the combination of warming Yang and tonifying Qi and treating sneezing decoction and cetirizine on AR, hoping to provide a new direction for AR prevention and treatment.

## Clinical data

### Study subjects

96 patients with AR of kidney-Yang deficiency type who treated in our hospital from July 2014 to June 2018 were selected as the study subjects, and the whole patients were randomly divided into the Western medicine group, TCM group and combined traditional Chinese and Western medicine group (32 cases each) using a random number table method. Western medicine group: there were 18 males and 14 females, aged 15-31 years, with a mean age of  $23.1 \pm 7.1$  years and a mean disease duration of  $4.5 \pm 1.2$  years. TCM group: there were 17 males and 15 females, aged 18-35 years, with a mean age of  $22.6 \pm 6.4$  years and a mean disease duration of  $4.3 \pm 1.1$  years. Combined Chinese and Western medicine Group: 14 males and 18 females, aged 17-32 years, with a mean age of  $22.6 \pm 6.4$  years and a mean disease duration of  $4.6 \pm 1.6$  years. Diagnostic criteria:

the diagnosis of Western medicine met the criteria of *the Guidelines for the diagnosis and treatment of allergic rhinitis* revised in 2015 [4], and the diagnosis of TCM met the criteria of kidney-Yang deficiency syndrome of "Bi Qiu" in *Otorhinolaryngology of traditional Chinese Medicine* [5]. Inclusion criteria: patients who met the diagnostic criteria of traditional Chinese and Western medicine, confirmed to be kidney-Yang deficiency type, aged 15-35 years. Exclusion criteria: patients treated with hormonal drugs and immunosuppressive agents in the last 6 weeks, patients with previous history of ear surgery, patients with psychiatric disorders, dysfunction of heart, brain, liver or kidney, and allergic constitution were excluded, and those with incomplete clinical data were excluded. This study was approved by the hospital ethics committee, and the patients and family members signed informed consent forms, and there was no significant difference ( $P > 0.05$ ) in the comparison of various clinical data between the two comparable groups.

## Treatment

### Western medicine group

Cetirizine (Suzhou Dongrui Pharmaceutical Co., Ltd., H19981104) was orally administrated at the dosage of 10 mg once a day for 8 weeks.

### TCM group

Warming Yang and tonifying Qi and treating sneezing decoction: first the following materials were decocted: processed aconite 12 g, fried Atractylodes macrocephala Koidz 15 g, Guizhi 12 g, Poria cocos 15 g, Fructus Xanthii 9 g, fried Radix Paeoniae Alba 15 g, Codonopsis pilosula 20 g, Fangfeng 9 g, Raw Astragalus 30 g, and Zhigancao 10 g. One dose of decoction was prepared a day by decocting the materials twice, then patients took the decoction one time in the morning and one time in the evening for 8 weeks.

### Combined traditional Chinese and Western Medicine Group

On the basis of oral administration of cetirizine

supplemented with the warming Yang and tonifying Qi and treating sneezing decoction treatment, the dosage of warming Yang and tonifying Qi and treating sneezing decoction was the same as that of the TCM group, and the course of treatment was 8 weeks.

#### **Efficacy evaluation criteria**

The grading scale for nasal symptoms was based on the reference in the study by Gong Weiqun et al. Markedly effective: after the total course of treatment, the frequency of sneezing in a row was 3-5 times a day, the frequency of blowing nose was less than 4 times a day, nasal congestion occurred occasionally, and nasal itching occurred intermittently; effective: the frequency of sneezing was 6-10 times in a row, and the frequency of blowing nose was 5-9 times a day. The nasal congestion was between occasional and almost full-day use of mouth breathing. Nasal itching is a kind of ant-walking like feeling, but it is tolerable; ineffective: the frequency of sneezing was more than 11 times in a row, and the frequency of blowing nose was more than 10 times a day, mouth breathing was used nearly full day. And nasal itching was a kind of ant-walking like feeling, which is intolerable. Total effective rate = (well-healed + markedly effective) cases/total cases  $\times$  100%.

#### **Outcome measures**

##### **Visual analog scale (VAS) scores**

The VAS was made into a 10 cm length ruler with a scale of "0-10" on both sides. The two ends of the ruler were "0" and "10" respectively, and the disease degree increased from "0" to "10".

##### **Rhinoconjunctivitis quality of life questionnaire (RQLQ)**

RQLQ scored according to the patient's daily activities, sleep quality, daily behavior, sensory symptoms, emotion and other aspects of the score, and each aspect was given the scores from 0 to 6, a total of 100 scores, the higher the score, the more serious the disease.

##### **TCM syndrome scores for kidney-Yang deficiency**

#### **type**

It was scored according to the criteria of nasal obstruction, nasal itching, runny nose and other symptoms of kidney-Yang deficiency in the kidney-Yang deficiency syndrome scale [7]. Each item was scored on a "0-3" scale, with higher scores indicating more severe disease.

#### **Statistical analysis**

SPSS 17.0 software was used for statistical analysis. The measurement data should be expressed as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ), the comparison was experimented using *t* test, and  $\chi^2$  test was used for comparison of count data,  $P < 0.05$  was considered statistically significant.

#### **Results**

##### **Comparison of clinical total effective rate among the three groups**

There was no significant difference in the total effective rate between the Western medicine group and the TCM group ( $P > 0.05$ ). The total effective rate of the combined Chinese and Western medicine group was significantly higher than that of the Western medicine group and the TCM group ( $P < 0.05$ ), as shown in table 1.

##### **Comparison of VAS, RQLQ, and TCM syndrome scores among the three groups**

Before treatment, there was no significant difference in the VAS, RQLQ, and TCM syndrome scores among the Western medicine, TCM, and combined Chinese and Western medicine groups ( $P > 0.05$ ). After treatment, the VAS, RQLQ, and TCM syndrome scores of each group were significantly lower than those before treatment ( $P < 0.05$ ), and the VAS, RQLQ, and TCM syndrome scores of the combined Chinese and Western medicine group were significantly lower than those of the Western medicine and TCM groups ( $P < 0.05$ ), see Table 2.

##### **Comparison of adverse effects among the three groups**

There was no significant difference in the incidence of

adverse effects between the TCM group and the combined Chinese and Western medicine group ( $P>0.05$ ), but the incidence of adverse effects in these

two groups was significantly lower than that in the Western medicine group ( $P<0.05$ ), which is shown in Table 3.

Table 1 Comparison of clinical total effective rate among the three groups

Group	Cases	Well-healed	Markedly effective	Effective	Ineffective	Total effective rate [n(%)]
Western medicine group	32	2	9	12	9	23 (71.88)
TCM group	32	3	10	12	7	25 (78.13)
Combined Chinese and Western medicine group	32	11	14	6	1	31 (96.88) <sup>ab</sup>

Note: compared with the Western medicine group, <sup>a</sup> $P<0.05$ ; compared with the TCM group, <sup>b</sup> $P<0.05$ .

Table 2 Comparison of scores among three groups (points)

Group	Cases	Time	VAS	RQLQ	TCM syndrome scores
Western medicine group	32	Before treatment	8.15±1.21	68.45±16.38	9.19±0.86
		After treatment	5.97±1.03 <sup>a</sup>	41.26±12.45 <sup>a</sup>	7.21±1.85 <sup>a</sup>
TCM group	32	Before treatment	8.23±1.36	71.42±14.37	8.85±1.12
		After treatment	6.12±0.85 <sup>a</sup>	45.79±10.24 <sup>a</sup>	6.88±2.12 <sup>a</sup>
Combined Chinese and Western medicine group	32	Before treatment	8.04±1.29	70.65±15.92	9.03±1.04
		After treatment	4.21±0.73 <sup>abc</sup>	23.88±9.37 <sup>abc</sup>	4.54±2.26 <sup>abc</sup>

Note: compared with before treatment, <sup>a</sup> $P<0.05$ ; compared with the Western medicine group, <sup>b</sup> $P<0.05$ ; compared with the TCM group, <sup>c</sup> $P<0.05$ .

Table 3 Comparison of adverse effects among the three groups

Group	Cases	Dizziness	Headache	Thirst	Drowsy	Lethargy	Emesia	Incidence of adverse effects [n(%)]
Western medicine group	32	2	2	1	4	3	2	14 (43.75)
TCM group	32	0	0	1	0	0	1	2 (6.25) <sup>a</sup>
Combined Chinese and Western medicine group	32	1	1	0	1	1	1	5 (15.63) <sup>a</sup>

Note: compared with the Western medicine group, <sup>a</sup> $P<0.05$

## Discussion

AR is a common disease that is a noninfectious

inflammatory disorder of the nasal mucosa caused by the release of IgE mediated mediators after allergen

exposure in atopic individuals and by the involvement of multiple immunoactive substances [1]. TCM holds that most of the patients are deficient in kidney-Yang and weak in Weiyang, which can easily lead to wind and cold invasion, long-term deficiency of lung Qi, abnormal Xuanjiang, accumulation of body fluids, and abnormal ventilation of nasal orifice. Therefore, in the treatment of the disease, we should take warming Yang, tonifying Qi, and diffusing the lung and treating sneezing as the basis. In the past, the clinical use of Western medicine in the treatment of AR usually treats the symptoms but not the root cause, which easily leads to the recurrence of the disease. Although fewer adverse effects occur with TCM therapies, the therapeutic effect is not significant enough. In addition, according to the epidemiology of AR, the incidence of the disease showed a significant upward trend [8]. Therefore, to actively explore the ideal scheme for the treatment of AR of kidney-Yang deficiency type has become an important subject of nasopharyngeal research.

In this study, the Western medicine group was administrated with cetirizine, the TCM group was administrated with warming Yang and tonifying Qi and treating sneezing decoction, and the combined Chinese and Western medicine group was administrated with warming Yang and tonifying Qi and treating sneezing decoction combined with cetirizine to compare the three treatment modalities for the treatment of AR of kidney-Yang deficiency type, and the results showed that the total effective rate of the combined Chinese and Western medicine group was significantly higher than that of the Western medicine group and the TCM group. Moreover, the VAS and RQLQ and TCM syndrome scores in the combination group after treatment were significantly lower than those in the Western medicine and TCM groups. Therefore, it can be concluded that warming Yang and tonifying Qi and treating sneezing decoction combined with cetirizine is more effective for the treatment of AR of kidney-Yang deficiency type, the reason for this is that cetirizine is a selective histamine H1 receptor antagonist with high affinity, can inhibit histamine transmission when the organism

is stimulated by antigen in the outside world, and can also activate T cells to improve the body's immune function and limit the production of inflammatory mediators mediated by IgE [9].

And the processed aconite in the warming Yang and tonifying Qi and treating sneezing decoction has the efficacy of reviving yang for resuscitation, tonifying fire and helping yang, and repelling cold and dampness; *Atractylodes macrocephala* Koidz and *Poria cocos* could eliminate dampness, and the combination of the two drugs can help the kidney to remove dampness and detumescence. Guizhi can regulate Ying Qi and Wei Qi, which has the effects of protecting myocardium, dilating blood vessels and inhibiting platelet aggregation; *Fructus Xanthii* has the functions of dispersing lung and dredging nose, removing dampness and relieving pain, and relieving exterior syndrome and inducing diaphoresis. *Radix Paeoniae Alba* has the effects of dewetting and activating blood, it can also harmonize Yin to suppress the body attached to the dryness; Fangfeng could warm and unblock meridians, dispel wind and relieve exterior syndrome, and dredge nasal obstruction and restrain runny nose. *Codonopsis pilosula* can improve blood and Qi deficiency and return the kidney-Qi to normal; *Astragalus* is able to tonify the Qi and strengthen the superficial, strengthen the body resistance to eliminate pathogenic factors, and has anti-inflammatory and anti-allergic effects; *Zhigancao* can reconcile a variety of herbs, which have the effects of adrenocorticotrophic hormone and regulate renal function; and the combination of medicines can achieve the effects of dredging the nose, dispelling dampness, benefiting Qi and warming Yang, and strengthening the body resistance to eliminate pathogenic factors. Therefore, warming Yang and tonifying Qi and treating sneezing decoction combined with cetirizine can strengthen the therapeutic strength for AR of kidney-Yang deficiency type.

Studies have shown that antihistamine therapy for AR has large side effects, which predispose patients to negative effects on the central nervous, digestive, as well as hematological systems [10]. However, the

incidence of adverse effects of TCM in the treatment of AR is relatively low, and the long-term outcome is stable. In this study, the incidence of adverse reactions in the combined Chinese and Western medicine group for the treatment of AR was almost consistent with that in the TCM group, and the incidence of adverse reactions in the combination group was significantly lower than that in the Western medicine group. Thus, it can be seen that the combined treatment of warming Yang and tonifying Qi and treating sneezing decoction and cetirizine can play a role in reducing the adverse effects.

In conclusion, the combination of TCM decoction and cetirizine was highly effective in the treatment of AR of kidney-Yang deficiency type, and the resulting adverse effects were minor in patients after treatment, which deserves to be promoted clinically.

#### **Declaration of conflict-of-interest**

The authors declare no conflict-of-interest.

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