

CLINICAL RESEARCH

Analysis of the Effect of Jianpi Wenfei Yiqi Prescription and the Effects of Levels of Inflammatory Factors on Allergic Rhinitis Patients

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Keywords

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Abstract

Objective To analyze the effect of Jianpi wenfei yiqi prescription and the effects of levels of inflammatory factors on allergic rhinitis patients.

Methods A total of 98 patients with allergic rhinitis diagnosed at our hospital were selected from Jun. 2018 to Aug. 2019, and they were randomly divided into observation group and control group according to the random number table method. The control group was treated with budesonide combined with loratadine, and the observation group was further treated with Jianpi wenfei yiqi prescription on the basis of the control group. The clinical efficacy, symptom score, inflammatory factor levels and adverse reactions were compared between the two groups.

Results The clinical efficacy, symptom score and inflammatory factor levels in observation group were significantly better than those of control group. There were no significant difference in adverse reactions between the two groups. **Conclusion** The Jianpi wenfei yiqi prescription can improve the clinical efficacy and inflammatory reaction.

Introduction

Allergic rhinitis is a common immune disease, mainly characterized by nasal congestion, nasal itching, sneezing, runny nose, etc. The disease is recurrent [1,2], and currently, patients are usually treated by Western medicine with nonspecific therapy, though

the clinical efficacy is relatively satisfactory, a high recurrence rate still affects patients' prognosis [3]. According to TCM [4], allergic rhinitis belongs to "nasal congestion", which is mostly related to spleen and lung deficiency, in traditional Chinese medicine, strengthening the spleen, tonifying the lung, and

promoting qi is the key to the treatment of patients with allergic rhinitis. In this study, Jianpi Wenfei Yiqi Prescription, a prescription formula of strengthening the spleen, tonifying the lungs and promoting qi) was developed for the treatment of patients with atopic rhinitis, and its therapeutic effects and effects on the levels of inflammatory factors were analyzed, so as to provide a reference for the clinical treatment of atopic rhinitis.

Data and Methods

Clinical Data

Study Subjects

Ninety-eight patients with atopic rhinitis diagnosed in our hospital from June 2018 to August 2019 and meeting the inclusion criteria were selected as the study subjects, and were divided into observation group and control group using random number table method. In the observation group, there were 25 males and 24 females, with the mean age of the patients of 32.28 ± 6.13 years old and the course of the disease of 15.06 ± 3.12 months. In the control group, there were 27 males and 22 females, with the mean age of 32.85 ± 6.36 years old and the course of the disease of 14.98 ± 3.07 years. The study was approved by the Medical Ethics Committee of our hospital, and all the patients voluntarily participated in the study and signed the informed consent form. The differences between the two groups in terms of sex, age, disease duration and other general information were not statistically significant, thus, it was comparable ($P > 0.05$).

Inclusion and exclusion criteria

Inclusion criteria: Clinical diagnosis of allergic rhinitis and diagnosis of congested nose in Chinese medicine; exclusion criteria: Pregnant or lactating women and patients with major organ diseases such as heart, liver, and kidney.

Methods

Patients in the control group were treated with anti-infection, anti-inflammatory and parenteral nutrition support. Those in the observation group were

treated with the following formula on the basis of the control group: 30 g of white lentils, 15 g of Codonopsis pilosulae, 15 g of Coix Seed, 15 g of Chinese yam, 15 g of Rhizoma Atractylodis Macrocephalae, 15 g of Scutellaria baicalensis charcoal, 15 g of Bitter Ginseng, 15 g of Blood and Excess Charcoal, 12 g of Poria Cocos, 9 g of Pericarpium Citri Reticulatae. The prescription was decocted in water to 400 mL, 1 dose/d, taken twice in the morning and evening. All the patients were treated for 8 courses (7 days a course) of treatment.

Observational Indicators

Clinical effectiveness

Patients were evaluated with reference to the symptom integration criteria in "Treatment Guidelines and Recommended Protocols for Allergic Rhinitis" formulated by the Otolaryngology Branch of the Chinese Medical Association. Efficacy index = (total score before treatment - total score after treatment) / total score before treatment $\times 100\%$. Efficacy index $\geq 51\%$ means significantly effective; $21\% \sim 50\%$ means effective, $\leq 20\%$ means ineffective. Total effective rate = (significantly effective) + effective / total number of cases $\times 100\%$.

Main Symptom Points

Visual Analogue Score (VAS) [5] was used to score the four main symptoms of nasal congestion, itchy nose, runny nose, and sneezing, with 0 points for symptomatic and 10 points for severe symptoms.

Inflammatory factor Levels

We collected 5 mL of venous blood from all patients in the fasting state, measured and compared the levels of interleukin-6 (IL-6), IL-8 and IL-10 in the serum of the two groups of patients before and after treatment using enzyme-linked immunosorbent assay.

Incidence of adverse reactions

We compared the occurrence of adverse reactions such as mild panic attacks, mild irritant cough and rash in the two groups of patients.

Statistical Analysis

Statistical analysis was performed using SPSS 20.0, and counting data were compared using χ^2 test, while measurement data were expressed as mean \pm standard deviation ($\bar{x} \pm s$).

Results

Comparison of clinical outcomes between two groups of patients

The overall effective rate of clinical treatment was significantly higher in the observation group than in the control group ($P < 0.05$), as shown in Table 1.

Comparison of major symptom scores between two groups of patients

Before treatment, there was no significant difference in the scores of nasal congestion, nasal itch, runny nose, and sneezing symptoms between the two groups ($P > 0.05$), and after treatment, the scores of both groups were significantly lower than before treatment ($P < 0.05$), with the scores in the observation group greatly lower than the control group ($P < 0.05$), see Table 2.

Table 1 Comparison of clinical outcomes between two groups of patients

Groups	Cases	Significantly effective	Effective	Ineffective	Total effective rate [n(%)]
Observation group	49	38	7	4	45 (91.84)
Control group	49	21	15	13	36 (73.47)
χ^2					5.765
P					<0.05

Table 2 Comparison of major symptom scores between two groups of patients ($\bar{x} \pm s$)

Groups	Cases	Nasal congestion		t	P	Nasal itch		t	P
		Before treatment	After treatment			Before treatment	After treatment		
Observation group	49	5.37 \pm 1.21	0.89 \pm 0.22	25.499	<0.05	6.12 \pm 1.38	0.65 \pm 0.19	27.487	<0.05
Control group	49	5.42 \pm 1.23	2.38 \pm 0.95	13.692	<0.05	6.15 \pm 1.36	2.21 \pm 0.87	17.083	<0.05
t		-0.203	-10.696			-0.108	-12.027		
P		>0.05	<0.05			>0.05	<0.05		

Groups	Cases	Runny nose		t	P	Sneezing		t	P
		Before treatment	After treatment			Before treatment	After treatment		
Observation group		6.89 \pm 1.45	1.08 \pm 0.43	26.891	<0.05	6.54 \pm 1.39	0.96 \pm 0.26	27.622	<0.05
Control group		6.93 \pm 1.49	2.84 \pm 1.05	15.707	<0.05	6.61 \pm 1.41	1.83 \pm 0.77	20.827	<0.05
t		-0.135	-10.858			-0.247	-7.493		
P		>0.05	<0.05			>0.05	<0.05		

Comparison of the levels of inflammatory factors between the two groups of patients.

Before treatment, there was no significant difference in the levels of IL-6, IL-8 and IL-10 between the two

groups ($P>0.05$). After treatment, the levels of IL-6 and IL-8 in both groups were significantly lower than before treatment ($P<0.05$), with the observation group was greatly lower than the control group ($P<0.05$). The IL-10 levels of the patients were noticeably

higher than before treatment ($P<0.05$), and the observation group was significantly higher than the control group ($P<0.05$), see Table 3.

Table 3 Comparison of the levels of inflammatory factors between the two groups of patients ($\bar{x}\pm s$)

Groups	Cases	IL-6 (ng/L)				IL-8 (ng/L)				IL-10 (ng/L)			
		Before treatment	After treatment	<i>t</i>	<i>P</i>	Before treatment	After treatment	<i>t</i>	<i>P</i>	Before treatment	After treatment	<i>t</i>	<i>P</i>
Observation group	49	192.35±21.23	105.23±14.62	23.658	<0.05	172.65±18.35	116.98±12.17	17.698	<0.05	11.35±2.86	18.35±3.42	-10.991	<0.05
Control group	49	189.36±21.45	146.89±17.28	10.793	<0.05	174.28±18.16	138.62±14.25	10.814	<0.05	11.58±2.71	13.54±2.98	-3.406	<0.05
	<i>t</i>	0.694	-12.884			-0.442	-8.083			-0.409	7.423		
	<i>P</i>	>0.05	<0.05			>0.05	<0.05			>0.05	<0.05		

Comparison of the incidence of adverse reactions between the two groups of patients

Two patients in the control group had mild panic attacks, four had mild irritant cough, and one had rash, with an adverse reaction rate of 17.95% (7/39), while three patients in the observation group had mild panic attacks, two had mild irritant cough, and none had rash, with an adverse reaction rate of 12.82% (5/39). There was no statistical significance between two groups ($p<0.05$). After appropriate intervention, all patients' adverse symptoms disappeared and no serious adverse reactions occurred.

Discussion

In recent years, the incidence of allergic rhinitis has increased year by year, and its clinical manifestations are diverse and may cause asthma, sinusitis and other related diseases [6]. Western medicine usually treats allergic rhinitis patients with glucocorticosteroids, but patients tend to develop drug resistance and the long-term effect is unsatisfactory. Chinese medicine

treatment refers to intervention of the disease at multiple levels and targets under the guidance of dialectical medicine to improve patients' clinical symptoms.

According to TCM, allergic rhinitis belongs to the category of "congested nose," which involves the spleen, lungs, and kidneys, and is deficient in nature. The spleen is the source of Qi, and the kidneys are the main source of energy. The spleen and the lungs should be in harmony and balance with each other, so that when the Qi is in abundant state, the nasal aperture is open and the sense of smell will be lively, and the Qi of the nose rises and falls in an orderly fashion. Therefore, the treatment of allergic rhinitis should focus on strengthening the spleen, warming the lungs, promoting Qi, thereby improving the functions of the organs. Jianpi Wenfei Yiqi Prescription consists of astragalus, dahuricae, daidong and other traditional Chinese medicines, among which, astragalus can invigorating Qi for strengthening superficies, bai zhuo can promote Qi and strengthen the spleen, fangfeng

can dispel cold and dredge orifices, and the three used together have the effect of promoting qi and consolidating the superficialities; dahuricae and xin yi can disperse cold and pass the aperture, replenish the spleen and lung; daidong and loofah can dispel cold and pass the aperture, and poria can invigorate spleen and relieve wet; licorice promote Qi. Using these berbes together, the goal of strengthening the spleen and promoting qi, warming the lungs and passing the aperture can be achieved.

The results of this study showed that the clinical effects of patients treated with the Jianpi Wenfei Yiqi Prescription were significantly better than those treated conventionally. According to TCM theory, the nose is located in the upper part of the body, where the nasal aperture is located to clear Yang. In this formula, Pueraria Mirifica is rich in total flavonoids and puerarin, which can relax vascular smooth muscle and have a great inhibitory effect on platelet aggregation and thrombosis; Angelica dahurica and other components can improve the nasal mucosal blood microcirculation, thereby relieving nasal congestion, runny nose and other symptoms; at the same time, the fungus can also promote the absorption of nasal mucosal secretions, improving nasal itching while protecting the nasal mucosa and functions to improve patient clinical outcomes.

Modern pharmacological studies have shown [7] that the puerarin in Pueraria Mirifica can significantly enhance the phagocytosis of macrophages and has the effect of resisting type I allergic reaction; decoction of Angelica dahurica can be anti-inflammatory and antibacterial, moisten the skin; the volatile oil of Pimenta dahurica has strong inhibitory effect on IL-1, phospholipase A2 (PLA2), histamine and other inflammatory mediators; the total saponin in Scutellaria baicalensis can scavenge oxygen free radicals. Strong immunomodulatory effects of all drugs can inhibit the inflammatory response of patients and regulate the serum levels of inflammatory factors in patients. The results of this study indicated that the IL-6, IL-8 and IL-10 levels of patients treated with the prescription were significantly better than those of patients treated with Western medicine,

which also demonstrated the effect of the formula on the inflammatory response of patients with allergic rhinitis. In addition, this study found that the incidence of adverse reactions was not significantly different between patients treated with Jianpi Wenfei Yiqi Prescription and those treated with conventional western drugs, indicating that the prescription is safe in the treatment of patients with atopic rhinitis.

In summary, Jianpi Wenfei Yiqi Prescription can improve the clinical efficacy of patients with atopic rhinitis, regulate the level of inflammatory factors in the body, with high safety and worthy of clinical promotion.

Declaration of conflict-of-interest

The authors declare no conflict-of-interest.

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