Randomized Parallel Controlled Study of Wenfeizhiluidan in the Treatment of Allergic Rhinitis with Deficiency of Lung Qi and Cold

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Abstract: Objective — To study a randomized parallel control study of allergic rhinitis. Methods — 106 patients with lung Qi deficiency and cold allergic rhinitis treated in the hospital from March 2022 to March 2023 were selected as the study objects. The patients were divided into observation group and control group according to the random parity method. 53 patients in each group took desloratadine, and the observation group took warm lung flow stop for treatment. The clinical effect, the level of inflammatory factors before and after treatment, and the immune function were compared between the two groups. Results — For the observed and control groups, 96.23% was higher than 75.47% (P<0.05). After treatment, the TNSS and RQLQ scores between the observation and control groups were lower (P<0.05). IL-33, TNF-α, and IFN-γ levels were lower in the observed and control groups (P<0.05). IgE, EOS and EOT were higher in observation and control groups (P<0.05). Conclusion — Patients with lung Qi deficiency cold allergic rhinitis after taking warm lung flow Dan treatment, the clinical effect is remarkable, can effectively improve the clinical symptoms of patients, reduce their inflammatory response, improve the immune function of patients, with high clinical application value.

***Keywords*:** pulmonary Qi deficiency cold type, allergic rhinitis, warm lung flow Dan, clinical effect

1. Introduction

Allergic rhinitis is a relatively common clinical otolaryngology disease, which is also called by clinical allergic rhinitis [1]. The incidence of allergic rhinitis is relatively high, and good hair in children, young and middle-aged people, easy to be ignored, but also easy to be missed diagnosis, misdiagnosis. At present, the clinical treatment of allergic rhinitis has western medicine, traditional Chinese medicine treatment. In the treatment of allergic rhinitis by western medicine, we usually take glucocorticoids, H1 receptor blocagent and other symptomatic treatment. Although it can improve the clinical symptoms of patients, it is easy to appear repeatedly, and the clinical effect is not ideal [2]. From the perspective of traditional Chinese medicine, allergic rhinitis belongs to the category of "nose", among which lung Qi deficiency and cold type allergic rhinitis is more common. The clinical effect of warm lung fluid stop Dan in the treatment of lung Qi deficiency and cold allergic rhinitis is remarkable, which can effectively improve a series of clinical symptoms of patients with [3]. Based on this, in order to study the clinical effect of warm lung flow stop Dan treatment on lung Qi deficiency and cold allergic rhinitis, 106 patients from March 2022 to March 2023 were selected and studied, and the curative effect is reported as follows:

2. Data and methods

2.1 Data

A total of 106 patients with allergic rhinitis were selected to the study. Inclusion criteria: (1) met the diagnostic criteria of allergic rhinitis, and the syndrome differentiation type was lung Qi deficiency and cold; (2) the patient had clinical symptoms such as nasal congestion and nasal itching, pale nasal mucosa, swollen mucosa, watery secretions, light tongue, fat / tender tongue, white moss, fine pulse or heavy; (3) the patient was over 18 years old; (4) IgE and EOS positive rate met the experimental requirements; (5) the patient knew the study, voluntarily participated in and signed relevant documents. Exclusion criteria: (1) patients aged <18 years; (2) patients with sinusitis, nasal hemorrhage, asthma and other diseases; (3) patients are allergic to the use of study drugs; (4) patients with severe cardiovascular and cerebrovascular diseases or other organic lesions; (5) patients with pregnancy and lactation; (6) patients with severe malignant tumors and mental disorders. The criteria for removal and shedding: (1) the patient is not treated first according to the doctor's advice; (2) the medical records are not perfect and the efficacy cannot be determined; (3) the patient has serious adverse reactions and clinical treatment cannot be continued. Patients were divided into two groups according to the random parity number method. The established control group with odd numbers of hospitalization numbers and the established group with even numbers of

hospitalization numbers is the observation group. The control group (53 patients): 30 males and 23 females; age 25 to 47 years, mean age (35.56±10.45); disease duration 2-6 years, mean disease duration (3.85±1.56) years. Observation group (53 patients): 28 males and 25 females; age 24 to 48 years, mean (37.12±10.45) years; duration 1-5 years, mean duration (3.91±0.12) years. Comparing the general data between the two groups, the difference was not statistically significant (P>0.05), which was comparable. The study was approved by the medical ethics committee of the hospital.

2.2 Methods

The control group took desloratadine tablets (Hainan Puli Pharmaceutical Co., Ltd.; Chinese drug approved H20020088; size 5mg 24 tablets) once a day, for 14 consecutive days.

The observation group took warm lung stop Dan for treatment, consisting of 12g of ginseng, 10g of mustard, 10 g of platycodon grandiflorum, 20g of cheahiko, 3g of xin, 10g of black plum and 8g of licorice. Decdecocted in water, one dose a day, 200 mL, morning and evening, treated for 14 consecutive days.

2.3 Observation indicators and evaluation criteria

(1) Comparison of the clinical efficacy. If clinical symptoms such as nasal congestion, nasal itching, and runny nose disappear, they are resolved; if clinical symptoms such as nasal congestion, nasal itching, and runny nose are effective; if clinical symptoms such as nasal congestion, they are effective; and if clinical symptoms such as nasal congestion, nasal itching, and so on are not relieved. Total active efficiency = significant efficiency + active efficiency.

(2) Comparison of the clinical symptoms.① The total score of nasal symptoms (TNSS) was used to evaluate the clinical symptoms such as nasal congestion, nasal itching and runny nose, and the subjective score was 0: asymptomatic; 1 point: mild, mild symptoms and easy to pregnancy; 2 points: moderate, the patient's symptoms are obvious, but do not affect the patient's sleep condition and daily life; 3 points: severe, severe symptoms, unbearable, and affect the patient's sleep condition and daily life. The higher the score, the more severe the symptoms, the less severe; ② Quality of life scale (RQLQ) for seven patients, including nasal symptoms, ocular symptoms, daily activities, sleep quality, actual problems, emotional reactions and other symptoms, each 0-15 points. A lower score indicates the better quality of life.

(3) The levels of inflammatory factors. Fasting venous blood was drawn the day before and 14 days after treatment, and interleukin-33 (IL-33), tumor necrosis factor- α (TNF- α), and γ -interferon (IFN- γ) were determined.

(4) Comparison of immune-related indicators. Fasting venous blood was drawn the day and 14 days after treatment, and immune-related indicators including immunoglobulin E (IgE), eosinophils (EOS) and OT (EOT) were determined.

2.4 Statistical method

Data analysis was performed using SPSS 21.0 statistical software for measurement data, t-test for $\bar{x} + s$ comparison between groups; count data were presented as [n (%)] and χ 2 test for comparison between groups. P <0.05 was considered to be statistically significant.

3. Results

3.1 Comparison of the clinical efficacy between the two patient groups

A total of 106 cases were included after excluding the shedding. The observation group recovered 38 cases, 9 cases were effective and 4 cases were effective; in the control group, 23 cases were recovered, 9 cases were effective and 8 cases were effective. The observed and control groups were 96.23% higher than 75.47% (P <0.05). See the data in Table 1 for more details.

Table 1. Comparison of the clinical efficacy between the two groups(n; %)

Group	Recure	Excellence	Effective	Noneffective	Total effective rate
Control group (n=53)	23(43.40)	9(16.98)	8(15.09)	13(24.53)	40(75.47)
Observation group (n=53)	38(71.70)	9(16.98)	4(7.55)	2(3.77)	51(96.23)
χ2 value	-	-	-	-	9.3963
P value	-	-	-	-	0.0022

3.2 Clinical symptoms were compared between the two groups

There was no difference in TNSS and RQLQ scores (P> 0.05); after treatment, TNSS and RQLQ scores between the observation and control groups were lower (P <0.05). See the data in Table 2 for more details.

Table 2. Comparison of the clinical symptoms between the two groups($\bar{x}$±s; score)

	TNSS		RQLQ	
Group	Pretherapy	Post-treatment	Pretherapy	Post-treatment
Control group(n=53)	12.68±4.11	6.85±2.56	73.65±10.44	45.56±7.44
Observation group (n=53)	12.78±3.56	4.12±1.57	73.44±10.56	28.37±6.77
T value	0.1339	6.6181	0.1030	12.4409
P value	0.8937	0.0000	0.9182	0.0000

3.3 Comparison of the inflammatory factor levels between the two groups

Before treatment, IL-33, TNF-α, and IFN-γwere not different (P> 0.05); after treatment, IL-33, TNF-αwere lower in IFN-γbetween observation and control (P <0.05). See the data in Table 3 for more details.

Table 3. Comparison of inflammatory factor levels between the two groups($\bar{x}$±s; ng/L)

Group	IL-33		TNF-α		IFN-γ	
	Pretherapy	Post-treatment	Pretherapy	Post-treatment	Pretherapy	Post-treatment
Control group(n=53)	381.11±20.45	370.55±11.67	73.55±13.54	65.56±8.18	87.56±16.52	55.12±10.43
Observation group (n=53)	380.98±20.46	360.73±9.78	73.14±13.34	41.45±5.45	87.24±16.45	27.17±7.11
T value	0.0327	4.6952	0.1570	17.8572	0.0999	16.1199
P value	0.9740	0.0000	0.8755	0.0000	0.9206	0.0000

3.4 Comparison of immune-related indicators between the two groups

Before treatment, there was no difference in IgE, EOS, and EOT between the two groups (P> 0.05); after treatment, IgE and EOS levels were lower in the observation and control groups (P <0.05). See the data in Table 4 for more details.

Table 4. Comparison of immune-related indicators between the two groups[($\bar{x}$±s)]

	IgE(U/L)		EOS(ng/L)		EOT(ng/L)	
Group	pretherapy	post-treatment	pretherapy	post-treatment	pretherapy	post-treatment
Control group (n=53)	431.74±63.46	325.45±46.95	0.52±0.12	0.35±0.06	87.42±20.69	128.53±30.71
Observation group (n=53)	431.65±63.53	187.01±23.75	0.51±0.13	0.18±0.02	87.52±20.71	208.02±41.12
T value	0.0073	19.1553	0.4115	19.5685	0.0249	11.2758
P value	0.9942	0.0000	0.6816	0.0000	0.9802	0.0000

4. Discussion

Allergic rhinitis is a non-infectious inflammatory disease [4] in the nasal mucosa because the IgE-mediated mediators are released, and it is associated with various immune active cells, inflammatory cytokines, etc. The etiology of the disease is more complex, more than genetic factors, personal constitution, environmental factors and other related. After the disease, patients will appear more obvious nasal congestion, nasal itching, sneezing, runny nose and other clinical manifestations. If not timely intervention of diagnosis and treatment, with the development of the disease. It will lead to complicated sinusitis, asthma and other diseases, and even lead to lung dysfunction, which will bring great impact on patients' daily life and work, and reduce the quality of life of patients [5]. Therefore, timely intervention and effective treatment are needed. At present, the clinical treatment of allergic rhinitis takes more drug treatment to control the clinical symptoms of patients. Desloratadine is the second-generation antihistamine, a first-line therapeutic drug for AR. [6] is recommended clinically and has a rapid effect. Although it has a good effect on improving clinical symptoms such as nasal congestion and nasal itching, it is easy to appear repeatedly after withdrawal, and drug resistance will occur after long-term use, and the clinical effect is not ideal[7].

According to traditional Chinese medicine, the disease of the disease is related to the deficiency of the viscera, and most of the disease is in the lungs. According to its syndrome differentiation and classification, allergic rhinitis can be divided into four types, among which the more common is lung Qi deficiency and cold type of allergic rhinitis. Due to the lack of healthy qi, cou rationale loose, cold invasion of the lungs, resulting in lung loss of publicity, lung Qi deficiency cold, nasal congestion, nasal congestion, runny nose and other symptoms [8]. Therefore, the treatment should be to warm lung scattered cold, stop nose through orifice, Qi solid surface. Warm lung stop Dan has a good effect on the treatment of lung Qi deficiency and cold allergic rhinitis, and the ginseng is Qi tonic medicine, with the effect of replenishing Qi and removing, reinforcing spleen and lung; The mustard has the effect of removing wind evil and relieving surface cold; Platycodon

grandiflorum is a reference medicine, and has the effect to promote the lung and treating nasal cold; and the effect of palliative [9]. From the perspective of modern pharmacology [10], ginseng can nourish the body and enhance the immune function of the body.Vipeta can improve the content of relevant immune indicators in the serum, play pharmacological effects such as anti-inflammatory and analgesic, and then promote the absorption of inflammatory response and restore the immune function of patients. The water-soluble saponin in Platycodon grandiflorum can inhibit cytokines, and then achieve the anti-allergic effect. It contains anti-inflammatory effects, and some of the extracts contain anti-allergic ingredients. It has antibacterial effect and can effectively reduce inflammation. Black plum has an anti-inflammatory effect, while licorice regulates immunity. All medicine together, to achieve the role of lung qi, cold, and drink. In this study, the total response rate of the observation group was higher, and the observation group, TNSS and RQLQ scores were lower, indicating that the treatment of patients with lung deficiency and cold allergic rhinitis was effective, which can effectively improve a series of clinical symptoms and then improve the quality of life of patients. IL-33, TNF-α, IFN-γwill be involved in mediating the allergic reaction in the body, which leads to the aggregation of various immune-related indicators in the nasal mucosa. EOS functions to killing bacteria and is also an extremely important cell during immune and allergic reactions. EOS also releases the contents of the particles, which causes tissue damage and aggravate the progression of inflammation. Compared with the observation group and the control group, IL-33, TNF-α, IFN-γlevels were lower, andIgE, EOS levels were lower, indicating that the treatment of pulmonary Qi deficiency and cold allergic rhinitis could effectively reduce inflammatory response, improve immune indicators, and effectively promote the recovery of patients.

To sum up, patients with lung Qi deficiency and cold allergic rhinitis can effectively relieve a series of clinical symptoms, reduce the inflammatory reaction, and improve the quality of life of patients. The treatment effect is good, which is worth popularizing.

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