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CLINICAL STUDY ON THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE WITH DAMP-TOXIN OBSTRUCTING LUNG SYNDROME USING XUANFEI BAIDU GRANULES COMBINED WITH WESTERN MEDICINE

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Abstract: Objective: To study the clinical efficacy of Xuanfei Baidu Granules combined with Western medicine in the treatment of Damp-Toxin Obstructing Lung Chronic Obstructive Pulmonary Disease (COPD).
Methods: A retrospective analysis was conducted on the data of 124 COPD patients treated at our hospital's respiratory department between July 2021 and March 2024. All patients were diagnosed with Damp-Toxin Obstructing Lung Syndrome. Of these, 64 patients treated with Western medicine alone were designated as the control group, while 60 patients treated with Xuanfei Baidu Granules combined with Western medicine were designated as the study group. The study compared Traditional Chinese Medicine (TCM) syndrome scores, lung function [Forced Expiratory Volume in 1 second (FEV1), Forced Vital Capacity (FVC), FEV1/FVC ratio, Airway Resistance (Raw), Peak Expiratory Flow Rate (PEFR)], 6-minute walk test (6MWT) results, COPD Assessment Test (CAT) scores, inflammation-related indicators [White Blood Cell count (WBC), Neutrophil percentage (NEUT%), Lymphocyte percentage (LYMPH%), Platelet count (PLT), Interleukin-6 (IL-6), Interleukin-17 (IL-17), C-reactive protein (CRP), Procalcitonin (PCT), Connective Tissue Growth Factor (CTGF), Transforming Growth Factor-β1 (TGF-β1)], blood gas analysis indicators [Arterial Oxygen Partial Pressure (PaO2), Carbon Dioxide Partial Pressure (PaCO2), Oxygen Saturation (SaO2), Oxygenation Index (PaO2/FiO2)], clinical efficacy, and adverse reactions between the two groups.
Results: After 5 days of treatment, the control group exhibited significantly higher scores for fever, cough with sputum, dyspnea, wheezing, abdominal distension, constipation, difficulty falling asleep, fatigue, poor appetite, and total TCM syndrome scores compared to the study group, with differences being statistically significant ($P<0.05$). Lung function parameters, including FEV1, FVC, FEV1/FVC ratio, PEFR, and 6MWT results, were significantly lower in the control group compared to the study group, while Raw and COPD CAT scores were significantly higher in the control group. These differences were statistically significant ($P<0.01$). There was no statistically significant difference in WBC counts between the two groups after 5 days of treatment ($P>0.05$). However, NEUT%, LYMPH%, IL-6, IL-17, CRP, PCT, CTGF, and TGF-β1 levels were significantly higher in the control group, while PLT was significantly lower compared to the study group, with differences being statistically significant ($P<0.001$). PaO2, PaCO2, SaO2, and PaO2/FiO2 were all significantly lower in the control group compared to the study group ($P<0.001$). The total effective rate in the control group was 81.25% (52/64), significantly lower than 95.00% (57/60) in the study group, with the difference being statistically significant ($P<0.05$). The adverse reaction rate was 10.94% (7/64) in the control group compared to 6.67% (4/60) in the study group, with no statistically significant difference ($P>0.05$).
Conclusion: The combination of Xuanfei Baidu Granules with Western medicine significantly improves heart and lung function, reduces TCM syndrome scores and inflammation levels, and enhances blood oxygen content and clinical efficacy in patients with damp-heat obstructing the lung type of COPD.
Keywords: Xuanfei Baidu Granules; Damp-heat obstructing the lung syndrome; COPD; Cardio-pulmonary function; Traditional Chinese medicine syndrome scores

1 INTRODUTION

Chronic obstructive pulmonary disease (COPD) is a group of chronic respiratory diseases characterized by persistent airflow limitation, inflammatory responses, and airway hyperreactivity, often accompanied by cough, dyspnea, wheezing, and fever [1]. The primary pathophysiological changes in COPD are ventilation limitation and airway obstruction. Over time, this can lead to complications such as rupture of pulmonary bullae into the pleural cavity, causing spontaneous pneumothorax, or respiratory failure, sleep apnea, and cor pulmonale [2].Clinical treatment of COPD mainly involves anticholinergic bronchodilators, corticosteroid combination formulations, and long-acting or short-acting β2-agonists. These treatments aim to inhibit airway smooth muscle contraction and bronchospasm, improving pulmonary ventilation and gas exchange [3]. However, numerous studies [4-5] have pointed out that such medications, including salbutamol, dexamethasone, and prednisone, may increase the risk of respiratory infections, immune system complications, and even lead to heart failure, myocardial infarction, and arrhythmias over prolonged

use. Additionally, the progression of COPD is influenced by environmental, genetic, and age factors. Thus, reducing the safety risks associated with long-term and regular medication while improving clinical symptoms and preventing acute exacerbations of COPD (AECOPD) remains a key focus in enhancing clinical efficacy.In traditional Chinese medicine (TCM), COPD is categorized under "lung obstruction" and "asthma syndrome," with patients often having a congenital deficiency or chronic lung deficiency. Lung deficiency leads to Qi deficiency, which impairs blood circulation and fluid distribution, causing phlegm accumulation and damp-heat stagnation. This results in blocked blood vessels and stagnant Qi, coupled with a lack of Qi to consolidate the exterior, allowing pathogens to invade and damage fluids, leading to upper respiratory infections and recurrent cough, wheezing, and chest tightness [6]. Therefore, TCM treatment for COPD should focus on "dispersing the lung," "eliminating dampness and heat," and "detoxifying the lung." This study analyzes the efficacy of Xuanfei Baidu Granules combined with Western medicine in treating damp-heat obstructing lung COPD, providing scientific evidence for optimizing combined TCM and Western treatment approaches for this condition.

2 MATERIALS AND METHODS

2.1 Clinical Data

A retrospective review was conducted on 124 COPD patients admitted to the Respiratory Medicine Department of our hospital from June 2023 to June 2024. All patients were diagnosed with the TCM pattern of damp-heat obstructing the lung. Among them, 64 patients receiving only Western medicine were designated as the control group, while 60 patients receiving Xuanfei Baidu Granules combined with Western medicine were designated as the study group.In the control group, there were 37 males and 27 females, aged 41 to 76 years, with an average age of 54.67 ± 7.11 years. The Body Mass Index (BMI) ranged from 19.5 to 32 kg/m², with an average BMI of 24.57 ± 2.32 kg/m². In the study group, there were 34 males and 26 females, aged 43 to 78 years, with an average age of 55.23 ± 6.82 years. The BMI ranged from 19.8 to 31.5 kg/m², with an average BMI of 24.31 ± 2.18 kg/m². There were no statistically significant differences in baseline characteristics between the two groups ($P > 0.05$), indicating comparability.

2.1.1 Western medicine diagnostic criteria[7]

The presence of various symptoms such as wheezing, shortness of breath, cough, sputum production, and chest tightness to varying degrees.Imaging studies, such as lung function tests, chest CT, or X-ray, show findings including increased anteroposterior diameter of the thoracic cavity, sparse peripheral vascular markings in the lung fields, formation of bullae, changes in small airways, and emphysema.Laboratory tests reveal increased white blood cell count (WBC), elevated levels of inflammatory markers or cytokines such as C-reactive protein (CRP) and Interleukin-6 (IL-6).Lung function tests and the COPD self-assessment test (CAT) demonstrate varying degrees of lung function deterioration.

2.1.2 Traditional Chinese medicine diagnostic criteria[8-9]

Diagnosis of "Damp-Heat Obstructing the Lung Syndrome" is based on the presence of 2 primary symptoms and 1 secondary symptom or 1 primary symptom and 2 secondary symptoms, along with specific tongue and pulse signs.Primary Symptoms: Fever, cough with sputum, chest tightness and shortness of breath, wheezing, etc.Secondary Symptoms: Abdominal bloating, constipation, difficulty falling asleep, fatigue, poor appetite, etc.Tongue Signs: Dark red tongue body, yellow and greasy coating, or dry tongue; pulse signs include slippery or rapid pulse or wiry and slippery pulse.

2.1.3 Inclusion criteria

Patients aged 18-80 years old, non-lactating, and non-pregnant women, all of whom signed informed consent forms and received approval from the hospital's ethics committee.No history of nasal, oral, throat, or lung surgery, nor any space-occupying lesions.Patients who meet both the Western medical diagnostic criteria for COPD and the Traditional Chinese Medicine criteria for Damp-Heat Obstructing the Lung Syndrome.No history of systemic glucocorticoid use or antibiotic overuse.

2.1.4 Exclusion criteria

Patients unable to expectorate or those with a large amount of airway secretions requiring intubation.Presence of severe hepatic or renal dysfunction, congenital immune diseases, cardiovascular or cerebrovascular diseases not caused by COPD, active pulmonary tuberculosis, or malignancies.Coexisting with other Traditional Chinese Medicine (TCM) syndromes, laryngeal edema, tracheal polyps, or other conditions affecting ventilation function.Active bleeding tendencies, severe mental disorders, infectious diseases, or consciousness/communication impairments.Patients allergic to the study drugs or their excipients, or those with incomplete clinical and follow-up data.

2.2 Methods

Control Group Treatment:Patients were advised to reduce exposure to risk factors by quitting smoking and alcohol, avoiding dust, irritant gases, and harmful substances, and engaging in moderate exercise. They received back percussion to promote expectoration or nebulized hypertonic saline for sputum clearance. In cases of dyspnea and chest tightness, a semi-recumbent position was recommended. During stable COPD periods, patients received low-flow oxygen therapy at 1-2 L/min. During acute exacerbations of COPD (AECOPD), high-flow humidified oxygen therapy at 6-8 L/min was provided, and non-invasive mechanical ventilation was administered for AECOPD with respiratory failure.For anti-inflammatory and anti-allergic treatment, patients were given budesonide suspension (AstraZeneca Pty Ltd,

approval number H20040624, 2 mg/vial), with a dose of 2 mg per session, twice a day. For severe wheezing and dyspnea, fluticasone propionate nasal spray (Glaxo Wellcome, S.A., approval number H20070265, 50 mcg per spray) was used once daily, with 2 sprays per nostril; if symptoms persisted, the dose was increased to twice daily, with no more than 4 sprays per nostril. Cefoperazone sodium and sulbactam (manufactured by Shanxi Zhendong Taisheng Pharmaceutical Co., Ltd., approval number H20044344, 4 g/tablet) was administered to control respiratory infections, with a dose of 4 g per session, once daily.

Research Group Treatment:In addition to the treatments provided to the control group, the research group received Xuanfei Baidu Granules (manufactured by Shandong Buchang Pharmaceuticals Co., Ltd., approval number C20210003, 10g*2 bags/box), with a dosage of 1 bag per session, twice a day. Both groups were treated continuously for 5 days, with the medication regimen adjusted based on individual conditions. Other bronchodilators or expectorants such as ipratropium bromide, salbutamol, or ambroxol hydrochloride were combined as needed. Adverse reactions in both groups were carefully documented.

2.3 Observational Indicators

2.3.1 TCM syndrome score

A self-made questionnaire was used to evaluate patients' Traditional Chinese Medicine (TCM) syndrome scores before and after 5 days of treatment. The four main symptoms—fever, cough with phlegm, chest tightness with shortness of breath, and wheezing—were scored on a scale of 0 to 6. The five secondary symptoms—abdominal distension, constipation, difficulty sleeping, fatigue, and poor appetite—were scored on a scale of 0 to 3. The higher the total score, the more severe the "damp toxin obstructing the lung" syndrome.

2.3.2 Lung function

Lung function was assessed using several parameters, including Forced Expiratory Volume in 1 Second (FEV1), Forced Vital Capacity (FVC), Airway Resistance (Raw), and Peak Expiratory Flow Rate (PEFR). These measurements were taken using the BK-LFT-I lung function detector (manufactured by Shandong Keboboyue Technology Co., Ltd., registration number Lu Yao Jian Xie Zhun 20180058). The FEV1/FVC ratio was also calculated.

2.3.3 6-Minute Walk Test (6MWT)

The 6MWT was conducted by having patients walk back and forth along a 30-meter corridor at their fastest possible pace. The distance covered in six minutes was used to evaluate cardiopulmonary function. If the patient experienced severe symptoms such as dizziness, chest tightness, or shortness of breath during the test, it was immediately terminated. A shorter walking distance within the six-minute period indicates more severe cardiopulmonary function impairment.

2.3.4 COPD CAT score

Patients were asked to complete the COPD Assessment Test (CAT) after fully understanding the items and their meanings. The assessment covered eight aspects: cough, sputum production, chest tightness, exercise tolerance, daily life activities, outdoor activities, sleep, and energy levels. Each aspect was rated on a scale from 0 to 5, with 0 indicating no impact and 5 indicating a severe impact. The total score ranges as follows:

0–10 points: Indicates that the patient's life is largely normal, but shortness of breath and discomfort may occur during intense activities.

11–20 points: Suggests that COPD has become one of the patient's health issues, with frequent symptoms like coughing, sputum production, and shortness of breath.

21–30 points: Indicates that COPD significantly impacts the patient's life, limiting most activities and causing fear and panic.

30 points: Suggests that COPD has a very severe impact on the patient's life, preventing any activity and making self-care difficult.

2.3.5 Inflammation-related indicators

Inflammation-related indicators were measured using the HwCyte-1026M flow cytometer (Zhejiang Pantide Biotechnology Co., Ltd., Registration No. ZJX20212220112), including white blood cell count (WBC), neutrophil percentage (NEUT%), lymphocyte percentage (LYMPH%), and platelet count (PLT). Additionally, 10ml of venous blood was drawn from patients and centrifuged at 3000r/min for 10 minutes (centrifugal radius of 10cm) to obtain the supernatant. Interleukin-6 (IL-6) and Interleukin-17 (IL-17) levels were detected using the enzyme-linked immunosorbent assay (ELISA) method, while C-reactive protein (CRP) levels were also measured using ELISA. Procalcitonin (PCT), Connective tissue growth factor (CTGF), and Transforming growth factor-β1 (TGF-β1) were detected using immunochromatography. The results were standardized using the URIT-5160 automatic blood cell analyzer (Shanghai Qisheng Medical Instrument Co., Ltd., Registration No. GXZ20162220087).

2.3.6 Arterial blood gas analysis

Arterial blood gas analysis was performed by drawing 5ml of fasting arterial blood from patients and analyzing it with the Kangli blood gas and electrolyte analyzer BG-800A (Wuhan Yijie Xun'an Trading Co., Ltd., Registration No. YX20162220822). The analysis included measurements of arterial partial pressure of oxygen (PaO2), arterial partial pressure of carbon dioxide (PaCO2), and blood oxygen saturation (SaO2). The oxygenation index (PaO2/FiO2) was also calculated, where FiO2 represents the fraction of inspired oxygen.

2.3.7 Clinical efficacy

Clinical Control: Symptoms such as cough and expectoration have mostly disappeared, with a reduction of $\geqslant$95% in TCM syndrome scores.Significantly Effective: Symptoms and signs have significantly improved, with a reduction of

70% to 94% in TCM syndrome scores.Effective: Symptoms and signs have shown some improvement, with a reduction of 30% to 69% in TCM syndrome scores.Ineffective: There is no improvement, or the symptoms and signs have worsened.

2.3.8 Adverse reactions

Such as dizziness, rash, gastrointestinal reactions, etc.

2.4 Statistical Analysis

Data were processed using SPSS version 27.0 statistical software. Categorical data were recorded as "n (%)" and analyzed using the chi-square test; ordinal data were analyzed using the rank-sum test. Continuous data were recorded as "mean ± standard deviation" and analyzed using the t-test. A p-value of <0.05 was considered statistically significant.

3 RESULTS

3.1 Comparison of Traditional Chinese Medicine Syndrome Scores Between the Two Groups

After 5 days of treatment, the control group had significantly higher scores for fever, cough and sputum, breathlessness, wheezing, abdominal distension, constipation, difficulty falling asleep, fatigue, poor appetite, and overall Traditional Chinese Medicine (TCM) syndrome score compared to the study group. The differences were statistically significant (P<0.05), as shown in Table 1.

Table 1 Comparison of TCM Syndrome Scores between the Two Groups ($\bar{x}$ ±s, points)

Item		Control group（n=64）	Research group（n=60）	*t*	*P*
Fever	pre-treatment	3.45±0.78	3.50±0.72	0.370	0.712
	5days-treatment	2.50±0.62*	1.87±0.50*	6.203	<0.001
Cough and sputum	pre-treatment	4.20±0.84	4.23±0.81	0.202	0.840
	5days-treatment	2.17±0.52*	1.57±0.59*	6.017	<0.001
Suffocated and breathless	pre-treatment	4.13±0.72	4.10±0.71	0.233	0.816
	5days-treatment	2.06±0.56*	1.62±0.64*	4.081	<0.001
gasp	pre-treatment	3.86±0.83	3.90±0.84	0.267	0.790
	5days-treatment	2.05±0.45*	1.63±0.64*	4.248	<0.001
Abdominal bloating	pre-treatment	1.72±0.74	1.73±0.63	0.107	0.915
	5days-treatment	0.81±0.56*	0.55±0.59*	2.508	0.014
constipation	pre-treatment	1.64±0.60	1.62±0.49	0.203	0.840
	5days-treatment	0.83±0.55*	0.47±0.50*	3.830	<0.001
Difficulty falling asleep	pre-treatment	1.84±0.51	1.85±0.58	0.102	0.919
	5days-treatment	0.78±0.42*	0.38±0.49*	4.890	<0.001
Lassitude and fatigue	pre-treatment	1.59±0.61	1.57±0.63	0.180	0.858
	5days-treatment	0.70±0.52*	0.28±0.45*	4.795	<0.001
Poor appetite	pre-treatment	1.73±0.60	1.77±0.50	0.402	0.689
	5days-treatment	0.78±0.52*	0.32±0.47*	5.156	<0.001
Total points	pre-treatment	24.17±2.13	24.27±1.64	0.292	0.771
	5days-treatment	12.69±1.42*	8.68±1.42*	15.701	<0.001

Note: Compared with before treatment, *P<0.05.

3.2 Comparison of Pulmonary Function, 6-Minute Walk Test (6MWT), and COPD Assessment Test (CAT) Between the Two Groups

After 5 days of treatment, the control group had significantly lower levels of FEV1, FVC, FEV1/FVC, PEFR, and 6MWT compared to the study group, while Raw and COPD CAT scores were significantly higher in the control group compared to the study group, with all differences being statistically significant (P<0.01), as shown in Table 2.

Table 2 Comparison of Pulmonary Function, 6-Minute Walk Test (6MWT), and COPD Assessment Test (CAT) Between the Two Groups ($\bar{x}$±s)

Item		Control group (n=64)	Research group (n=60)	*t*	*P*
FEV1（L）	pre-treatment	1.09±0.29	1.13±0.31	0.742	0.459
	5days-treatment	1.56±0.28*	2.11±0.35*	9.692	<0.001
FVC（L）	pre-treatment	1.72±0.44	1.69±0.48	0.363	0.717
	5days-treatment	2.13±0.37*	2.62±0.40*	7.086	<0.001
FEV1/FVC（%）	pre-treatment	64.41±13.39	63.85±13.58	0.231	0.818
	5days-treatment	74.33±12.48*	80.92±9.57*	3.284	0.001
Raw（%）	pre-treatment	75.38±7.87	74.60±7.12	0.578	0.565
	5days-treatment	57.49±5.72*	52.16±4.58*	5.704	<0.001
PEFR（L/min）	pre-treatment	3.42±0.78	3.39±0.75	0.218	0.828
	5days-treatment	4.97±1.02*	5.68±1.34*	3.333	0.001
6MWT（m）	pre-treatment	178.45±21.71	176.83±22.05	0.412	0.681
	5days-treatment	267.56±35.83*	314.52±42.16*	6.697	<0.001
COPD CAT（score）	pre-treatment	18.27±4.25	17.68±4.57	0.745	0.458
	5days-treatment	12.14±2.74*	9.32±1.85*	6.672	<0.001

Note: Compared with before treatment, *P<0.05.

3.3 Comparison of Inflammation-Related Indicators Between the Two Groups

There was no statistically significant difference in WBC levels between the two groups (P>0.05); however, after 5 days of treatment, the control group had significantly higher levels of NEUT%, LYMPH%, IL-6, IL-17, CRP, PCT, CTGF, and TGF-β1 compared to the study group, while PLT was significantly lower in the control group than in the study group, with all differences being statistically significant (P<0.001), as shown in Table 3.

Table 3 Comparison of Inflammation-Related Indicators Between the Two Groups ($\bar{x}$±s)

Item		Control group（n=64）	Research group（n=60）	*t*	*P*
WBC（$\times 10^9$/L）	pre-treatment	10.35±1.26	10.29±1.24	0.267	0.790
	5days-treatment	8.20±1.05	8.13±1.02	0.376	0.708
NEUT%	pre-treatment	84.39±7.53	85.06±7.10	0.509	0.612

	5days-treatment	70.24±6.15*	64.50±4.72*	5.802	<0.001
LYMPH%	pre-treatment	47.21±5.57	46.89±5.29	0.328	0.744
	5days-treatment	38.30±4.29*	32.15±3.40*	8.809	<0.001
PLT（$\times10^9$/L）	pre-treatment	74.22±9.85	73.36±10.27	0.476	0.635
	5days-treatment	130.54±15.46*	158.69±17.45*	9.521	<0.001
IL-6（ng/L）	pre-treatment	45.36±7.48	46.57±7.16	0.919	0.360
	5days-treatment	27.21±5.43*	19.45±4.29*	8.792	<0.001
IL-17（ng/L）	pre-treatment	36.29±6.12	37.05±5.43	0.730	0.467
	5days-treatment	18.35±4.40*	13.46±2.72*	7.386	<0.001
CRP（mg/L）	pre-treatment	30.28±6.30	29.75±5.89	0.483	0.630
	5days-treatment	16.43±4.22*	10.69±2.17*	9.430	<0.001
PCT（pg/mL）	pre-treatment	89.36±8.15	90.24±7.49	0.625	0.533
	5days-treatment	30.27±6.56*	22.19±4.35*	8.028	<0.001
CTGF（μg/L）	pre-treatment	214.46±27.28	215.73±26.91	0.261	0.795
	5days-treatment	122.85±19.60*	94.28±17.53*	8.535	<0.001
TGF-β1（pg/L）	pre-treatment	76.28±9.52	75.71±10.14	0.323	0.747
	5days-treatment	47.31±7.12*	39.28±5.57*	6.963	<0.001

Note: Compared with before treatment, *P<0.05.

3.4 Comparison of Arterial Blood Gas Analysis Indicators Between the Two Groups

After 5 days of treatment, the control group had significantly lower levels of PaO2, PaCO2, SaO2, and PaO2/FiO2 compared to the study group, with all differences being statistically significant (P<0.001), as shown in Table 4.

Table 4 Comparison of Arterial Blood Gas Analysis Indicators Between the Two Groups ($\bar{x}$±s)

Item		Control group（n=64）	Research group（n=60）	t	P
PaO_2（mmHg）	pre-treatment	50.83±6.27	51.37±6.05	0.488	0.627
	5days-treatment	85.12±5.19*	89.46±7.10*	3.903	<0.001
$PaCO_2$（mmHg）	pre-treatment	73.25±5.67	73.75±6.21	0.469	0.640
	5days-treatment	85.56±4.43*	93.57±5.26*	9.192	<0.001
SaO_2（%）	pre-treatment	82.59±2.67	83.14±2.49	1.184	0.239
	5days-treatment	90.36±2.68*	96.57±1.54*	15.682	<0.001
PaO_2/FiO_2（mmHg）	pre-treatment	254.78±21.57	253.67±22.16	0.283	0.778
	5days-treatment	322.19±26.45*	365.34±30.58*	8.419	<0.001

Note: Compared with before treatment, *P<0.05.

3.5 Comparison of Clinical Efficacy Between the Two Groups

The overall efficacy rate in the control group was 81.25%, which was significantly lower than the 95.00% efficacy rate in the study group, with a statistically significant difference (P<0.05), as shown in Table 5.

Table 5 Comparison of Clinical Efficacy Between the Two Groups [Case(n%)]

Group	Clinical control	remarkable	effective	In vain	Total effective rate （%）
Control group （n=64）	24	20	8	12	52（81.25）
Research group （n=60）	36	15	6	3	57（95.00）
x^2/z		8.680			5.506
P		0.034			0.019

3.6 Comparison of Adverse Reactions Between the Two Groups

In the control group, there were 2 cases of dizziness, 1 case of rash with itching, 2 cases of nausea and vomiting, 1 case of hoarseness, and 1 case of diarrhea, resulting in an adverse reaction rate of 10.94%. In the study group, there was 1 case of dizziness, 2 cases of nausea and vomiting, and 1 case of palpitations, with an adverse reaction rate of 6.67%. The difference between the two groups was not statistically significant (χ^2=0.699, P=0.403).

4 DISCUSSION

4.1 Current Status of Combined Traditional Chinese and Western Medicine in the Treatment of COPD

Traditional Chinese medicine (TCM) considers that lung distension often occurs as a secondary condition following chronic pulmonary diseases such as chronic cough and asthma. This condition arises when lung Qi stagnates internally for an extended period, failing to disseminate and descend, which leads to the chest becoming distended and full. This results in symptoms such as palpitations, chest tightness, breathlessness, and even dizziness, blurred vision, and cyanosis of the lips and nails[10]. This understanding is consistent with Western medical theories of COPD. Prolonged progression of COPD can also lead to various complications such as cardiovascular diseases, osteoporosis, and lung cancer[11]. The persistent obstruction of the airways creates a vicious cycle, where Qi deficiency impairs the transformation and transportation of fluids and nutrients, affecting the kidneys, spleen, and stomach. Consequently, the protective Qi and blood are compromised, making the condition prone to relapse. COPD commonly affects the elderly and is often chronic and difficult to cure, so the main clinical approach is to control symptoms and improve ventilation and gas exchange function[12]. However, current research indicates that while Western medicines can improve patients' exercise tolerance and alleviate dyspnea, they frequently cause adverse reactions in the nervous and digestive systems and can lead to drug resistance, especially in patients using opioids or those requiring long-term treatment, which increases the risk of addiction[13-14]. Huang P and colleagues conducted a meta-analysis of 490 COPD patients and found that combined Chinese and Western medicine treatments significantly improved lung function and overall efficacy compared to Western medicine alone, with higher safety, especially in patients with COPD complicated by respiratory failure[15]. The results of this study show that after 5 days of treatment, both the main symptoms, secondary symptoms, and total TCM syndrome scores in the two groups significantly improved. This is attributed to the fact that oxygen therapy can increase blood oxygen saturation and effectively alleviate lung hypoxia, while Western medicines such as budesonide suspension and fluticasone inhalation aerosol stabilize the internal cellular environment, enhance immune function, relieve airway hyperreactivity and inflammation, and relax bronchial smooth muscle, reducing airflow limitation[16-17]. However, the improvement in TCM syndrome scores was more significant in the study group, indicating that the combination of Xuanfei Baidu Granules with Western medicine for treating damp-heat obstructed lung-type COPD can more rapidly control symptoms and enhance patient comfort.

4.2 Clinical Effects of Xuanfei Baidu Granules

Xuanfei Baidu Granules are a traditional Chinese medicine formulation developed based on the classic prescriptions of Ma Xing Shi Gan Decoction, Ma Xing Yi Gan Decoction, Qianjin Weijing Decoction, and Ting Li Da Zao Xie Fei Decoction, as well as clinical experience, specifically targeting lung diseases caused by damp-heat obstructing the lung. This formulation not only transforms dampness and strengthens the Yang, but also disseminates the lung, resolves exterior conditions, clears heat and detoxifies, and expels wind[18]. Therefore, after 5 days of treatment, the study group showed significantly higher levels of FEV1, FVC, FEV1/FVC, PEFR, and 6MWT compared to the control group, and had lower Raw and COPD CAT scores. This indicates that Xuanfei Baidu Granules can markedly improve exercise

endurance and cardiopulmonary function in COPD patients, reduce airway resistance, and enhance the lung tissue's self-ventilation and gas exchange function. However, a bibliometric analysis[19] has shown that while there are certain achievements in the clinical and bioinformatics research of Chinese medicine formulations, the molecular mechanisms remain unclear. Moreover, even for the same damp-heat obstructed lung-type COPD, there is considerable individual variability. Directly using Chinese medicine granules may lose the advantage of adjusting prescriptions based on symptoms, which limits the effectiveness of traditional medicine. Therefore, for patients with multiple pulmonary diseases or acute symptoms, it is essential to adjust the treatment plan based on the drug response and control of clinical symptoms and signs to optimize individualized treatment as much as possible.

Xuanfei Baidu Granules are composed of over ten traditional Chinese medicinal herbs. Among them, Ephedra primarily alleviates the five zang organs (pathogenic factors) and regulates the protective qi, expels cold and heat, and when combined with Gypsum, it can disseminate the lung, relieve asthma, and promote diuresis to reduce swelling[20]. The dried Atractylodes rhizome (processed with bran) dries dampness, strengthens the spleen, and resolves cold, and when used with Agastache and Artemisia annua, it is effective for symptoms caused by damp-heat obstructing the lung, such as fever, fatigue, reduced appetite, and disturbed lung qi or reversed qi flow[21]. According to the "Compendium of Materia Medica," Japanese knotweed and Verbena help to drain dampness, resolve jaundice, invigorate blood, and dispel stasis. When used with Coix seed and Reed root, they not only promote the smooth flow of qi and blood but also strengthen the spleen and stomach, clear heat, and transform phlegm. Additionally, Perilla seed, bitter Apricot kernel, and Citrus reticulata peel are effective in stopping cough, relieving asthma, and generating fluids. Together, the formulation performs the functions of disseminating the lung, transforming dampness, and detoxifying, which helps to clear obstructed lung qi and drain internal damp-heat[22-23]. Moreover, network pharmacology has demonstrated that bitter Apricot kernel, Licorice, and Japanese knotweed possess anti-inflammatory, antibacterial, and antiviral properties, effectively inhibiting pathogen proliferation. Reed root contains vitamins A, C, B2, various minerals, and organic acids, which reduce harmful substances and toxins' irritation to the respiratory mucosa, alleviate airway hyperreactivity, and decrease the frequency of asthma, cough, and sputum production[24-25]. Therefore, Xuanfei Baidu Granules significantly enhance the patient's immunity, suppress inflammation-related factor secretion, and reduce respiratory and pulmonary infections.

4.3 Mechanism of Xuanfei Baidu Granules Combined with Western Medicine in the Treatment of Damp-Heat Obstructing the Lung in COPD

Clinical research indicates that the progression and control of damp-heat obstructing the lung type of COPD are related to multiple inflammatory mechanisms. Neutrophils can release arachidonic acid, which, under the action of enzymes, generates thromboxanes, prostaglandins, eosinophil chemotactic factors, fibrinolysin, and coagulation factors. These substances significantly affect vascular caliber and permeability, leading to inflammation and pain, and impacting the coagulation function of tissues and organs[26]. Additionally, leukotrienes secreted by neutrophils play a stronger role than histamine in allergen-mediated nasal allergic reactions and can exacerbate respiratory symptoms during COPD progression[27]. LYMPH% is usually associated with the severity of viral and bacterial infections and is an important indicator of the patient’s immune status[28]. IL-6 is a multifunctional cytokine that can induce the liver to produce acute-phase proteins such as CRP, complement C3, fibrinogen, and serum amyloid A (SAA), and stimulate endothelial cells to produce IL-8 and intercellular adhesion molecule-1 (ICAM-1). This mediates various inflammatory and immune pathways, increases vascular permeability and inflammatory exudate, and promotes disease development[29]. Niu WH et al.[30] established a molecular docking model and analyzed the chemical components of Xuanfei Baidu Granules and other traditional Chinese medicine formulas for damp-heat obstruction. They found that the active compounds in these herbs can interact directly with IL-6, thereby reducing inflammation and promoting patient recovery through a negative feedback mechanism.

IL-17 not only induces the synthesis and secretion of various inflammatory mediators such as IL-6, IL-1β, and TNF-α by epithelial cells, endothelial cells, and fibroblasts, but it also adapts the immune response by regulating cytokine production[31]. For example, IL-17 enhances local and systemic Th2 cell responses through its IL17RA and IL17RB receptors, activating the JAK2-STAT5A pathway, leading to immune dysregulation and exacerbation of local inflammation[32]. CTGF is closely related to tissue fibrosis, and TGF-β1 is involved in the dynamic balance of cell growth, differentiation, apoptosis, and immune function[33]. After 5 days of treatment, NEUT%, LYMPH%, IL-6, IL-17, and CRP were significantly lower in the study group compared to the control group. This can be attributed to the following mechanisms[34-35]: (1) Cefoperazone-sulbactam is primarily used to treat respiratory, skin, and tissue infections caused by sensitive bacteria, and it has a strong inhibitory effect on β-lactamases produced by most Gram-negative bacteria. Combined with other bronchodilators and Xuanfei Baidu Granules, it can significantly downregulate the expression of inflammatory factors and restore immune and inflammatory balance; (2) Western medicine treatment not only rapidly controls symptoms but also effectively inhibits the release of inflammatory mediators by neutrophils, enhances ciliary movement in the airways, and promotes the expulsion of irritants; (3) The core pathogenesis of damp-heat obstructing the lungs involves pathogenic factors entering the body, generating phlegm and dampness that obstructs the lungs. By expelling damp-heat from the lungs with Xuanfei Baidu Granules, the balance of Qi and blood is restored, enhancing the metabolism of nutrients and promoting the nourishment of organs and consolidation of the defensive Qi, thereby reducing the risk of lung fibrosis or substantial damage. Consequently, after 5 days of treatment, PCT, CTGF, and TGF-β1 were significantly lower in the study group. Moreover, the

improvement in blood gas indicators in the study group was also superior to that in the control group. This suggests that the combination of Xuanfei Baidu Granules and Western medicine significantly reduces the incidence of hypoxemia and the hypoxic damage to vital organs such as the heart, brain, and lungs.

5 SUMMARY

In summary, the combination of Xuanfei Baidu Granules and Western medicine for treating damp-heat obstructing the lungs type of COPD significantly improves patients' cardiopulmonary function and increases blood oxygen levels, thereby alleviating airflow limitation and symptoms such as cough. This treatment also reduces Traditional Chinese Medicine (TCM) syndrome scores and inflammation levels, enhancing clinical efficacy. However, this study has limitations, including a short treatment duration, and the long-term safety, feasibility, and recurrence of symptoms after treatment remain unknown. Additionally, given the complex etiology and diverse syndromes of COPD, the clinical application of Xuanfei Baidu Granules still has certain limitations. Future clinical studies need to incorporate extensive data to further explore its value.

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CONFLICT OF INTEREST

The authors have no relevant financial or non-financial interests to disclose.

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