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Clinical Observation on the Efficacy of Bufei Yishen Decoction in Improving Pulmonary Function in Patients with Stable Chronic Obstructive Pulmonary Disease

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Abstract: *Objective:* To investigate the impact of Bufei Yishen Decoction on enhancing pulmonary function in patients with stable Chronic Obstructive Pulmonary Disease (COPD), and to offer theoretical and practical references for TCM clinical treatment. *Methods:* A total of 80 patients with stable COPD who received treatment from January 2024 to December 2024 were enrolled and randomly assigned to the control group and the observation group via a random number table, with 40 cases in each group. The control group was given conventional Western medicine therapy, while the observation group received Bufei Yishen Decoction combined with the same Western medicine treatment as the control group. Both groups underwent continuous treatment for 12 weeks. Before and after treatment, comparisons were made between the two groups regarding pulmonary function indices [Forced Expiratory Volume in 1 Second (FEV_1), Forced Vital Capacity (FVC), FEV_1/FVC], TCM syndrome scores, and quality of life scores (St. George's Respiratory Questionnaire, SGRQ). *Results:* Prior to treatment, there were no statistically notable disparities in FEV_1, FVC, and FEV_1/FVC between the two groups ($p > 0.05$); after 12 weeks of treatment, the observation group exhibited significantly higher values of FEV_1 (2.31 ± 0.42 L), FVC (3.15 ± 0.58 L), and FEV_1/FVC (68.25 ± 7.13%) compared with the control group [FEV_1 (1.85 ± 0.36 L), FVC (2.62 ± 0.45 L), FEV_1/FVC (60.18 ± 6.57%)], and these differences were statistically significant ($p < 0.05$). Before treatment, no statistically significant differences were found in TCM syndrome scores (covering cough, expectoration, shortness of breath, fatigue, soreness and weakness of waist and knees) and SGRQ scores between the two groups ($p > 0.05$); after treatment, the total TCM syndrome score of the observation group (5.23 ± 1.85 points) was remarkably lower than that of the control group (9.68 ± 2.36 points), and the SGRQ score (28.56 ± 6.32 points) was also significantly lower than that of the control group (45.89 ± 7.15 points), with statistically significant differences ($p < 0.05$). *Conclusion:* The combination of Bufei Yishen Decoction and conventional Western medicine can notably improve the pulmonary function of patients with stable COPD, alleviate TCM syndrome manifestations, and enhance patients' quality of life, which is worthy of clinical popularization and application.
Keywords: Bufei Yishen Decoction; Chronic obstructive pulmonary disease (COPD); Pulmonary function; Efficacy observation

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1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a chronic respiratory disorder featuring persistent airflow restriction.

This airflow limitation worsens gradually and is linked to the intensified chronic inflammatory response of the airways and lung tissue to harmful gases or particles like tobacco smoke [1]. Statistics from the World Health Organization indicate that the global number of COPD patients has surpassed 300 million, with over 4 million deaths attributed to COPD annually, ranking it as the third leading cause of death worldwide [2]. In China, the prevalence of COPD is also relatively high, reaching 13.7% among individuals over 40 years old. As the population ages and air pollution deteriorates, its incidence rate continues to rise [3].

The course of COPD is divided into the acute exacerbation stage and the stable stage. The stable stage refers to the period where the patient's symptoms such as cough, expectoration, and shortness of breath are stable or mild, with no significant changes in the condition. Although symptoms are relatively mild during this stage, pulmonary function still declines continuously, and the risk of acute exacerbation remains high [4]. Currently, Western medicine treatment for stable COPD mainly includes bronchodilators, inhaled glucocorticoids, and expectorants. While these can alleviate symptoms and reduce the frequency of acute exacerbations to a certain extent, long-term use is prone to inducing drug resistance and adverse reactions, and it is difficult to fundamentally prevent the progressive deterioration of pulmonary function [5].

In Traditional Chinese Medicine (TCM), COPD falls into the categories of "Fei Zhang (lung distension)", "Ke Sou (cough)", and "Chuan Zheng (dyspnea syndrome)". It is believed that its pathogenic mechanism is intimately associated with the lungs and kidneys. The lung governs Qi and regulates respiration, while the kidney is responsible for Qi reception. Deficiency of both the lung and kidney constitutes the core pathogenesis of stable COPD. Long-term cough and asthma consume lung Qi; weakened lung Qi impairs respiratory function; prolonged illness affects the kidney; insufficient kidney Qi leads to failure in Qi reception, further exacerbating symptoms such as shortness of breath and dyspnea [6]. Based on this, TCM treatment for stable COPD primarily adheres to the principle of invigorating the lung and tonifying the kidney. Bufei Yishen Decoction is an empirical formula developed in accordance with TCM theory, consisting of herbs such as *Radix Astragali*, *Radix Codonopsis*, *Rhizoma Atractylodis Macrocephalae*, *Poria Cocos*, *Radix Rehmanniae Preparata*, *Fructus Corni*, *Rhizoma Dioscoreae*, *Fructus Schisandrae Chinensis*, *Fructus Perillae*, and *Semen Armeniacae Amarum*. It possesses the effects of invigorating lung Qi, tonifying the kidney to assist Qi reception, and relieving cough and asthma [7]. This study aims to explore the effect of Bufei Yishen Decoction on improving pulmonary function in patients with stable COPD, thereby providing more therapeutic options for clinical practice.

2. Materials and methods

2.1. General information

A total of 80 patients with stable COPD who were treated in the Respiratory Department of our hospital between January 2024 and December 2024 were selected as the study subjects.

2.1.1. Inclusion criteria

(1) Conforming to the diagnostic criteria for stable COPD specified in the China Guidelines for Primary Diagnosis, Treatment and Management of Chronic Obstructive Pulmonary Disease (2024 Edition), i.e., $FEV_1/FVC < 70\%$ after inhaling bronchodilators, and the percentage of FEV_1 in the predicted value ($FEV_1\%$ pred) $\geq 50\%$ [1];

(2) Meeting the diagnostic criteria for lung-kidney Qi deficiency syndrome in Internal Medicine of Traditional Chinese Medicine, with main symptoms including weak cough, clear and thin expectoration, shortness of breath and dyspnea (aggravated after activity), and secondary symptoms such as soreness and weakness of waist and knees, mental fatigue and lassitude, chills and cold limbs, pale tongue with white coating, and deep and thready pulse [8];

(3) Aged 40–75 years old;

(4) Patients and their family members were informed of the study details, provided consent, and signed the informed consent form. The study was approved by the Medical Ethics Committee of our hospital.

2.1.2. Exclusion criteria

(1) Complicated with other respiratory diseases such as bronchial asthma, bronchiectasis, pulmonary tuberculosis, and lung cancer;
(2) Complicated with severe dysfunction of major organs like the heart, liver, and kidney;
(3) Complicated with poorly controlled chronic diseases such as diabetes and hypertension (blood pressure ≥ 160/100 mmHg, blood glucose ≥ 8.3 mmol/L);
(4) Allergic to the drugs used in this study;
(5) Having a history of acute COPD exacerbation within the previous month;
(6) Patients with mental illnesses who were unable to cooperate in completing the study.

The 80 patients were randomly divided into the control group and the observation group using a random number table, with 40 cases in each group. In the control group, there were 23 males and 17 females; aged 42–74 years old, with an average age of (61.25 ± 7.36) years; the disease course ranged from 5 to 18 years, with an average of (10.32 ± 3.15) years; FEV_1% pred was 50–79%, with an average of (62.35 ± 8.12) %. In the observation group, there were 22 males and 18 females; aged 43–75 years old, with an average age of (62.18 ± 7.54) years; the disease course was 6–17 years, with an average of (10.56 ± 3.28) years; FEV_1% pred was 50–78%, with an average of (61.89 ± 8.36) %. There were no significant differences in general characteristics such as gender, age, disease course, and FEV_1% pred between the two groups ($p > 0.05$), indicating they were comparable.

2.2. Treatment methods

Both groups were given basic nursing for stable COPD, including smoking cessation guidance, respiratory function exercise (pursed-lip breathing, abdominal breathing), nutritional support (high-protein, high-vitamin diet), and prevention of respiratory tract infection.

The control group received conventional Western medicine treatment, with the specific plan as follows:

(1) Bronchodilators
Salbutamol Aerosol (Shanghai Xinyi Pharmaceutical Co., Ltd., National Drug Approval Number H19990286), 100 μg each time, 3 times a day, by inhalation; Tiotropium Bromide Powder for Inhalation (Zhengda Tianqing Pharmaceutical Group Co., Ltd., National Drug Approval Number H20060454), 18 μg each time, once a day, by inhalation.
(2) Expectorant
Ambroxol Hydrochloride Oral Solution (manufactured by Shanghai Boehringer Ingelheim Pharmaceutical Co., Ltd., National Medical Product Administration Approval Number H20030360), with a dosage of 30 mg per administration, taken orally three times a day. The therapeutic course spanned 12 consecutive weeks.

The observation group was given Bufei Yishen Decoction combined with the same treatment as the control group. The composition of the decoction was: *Radix Astragali* 20 g, *Radix Codonopsis* 15 g, *Rhizoma Atractylodis Macrocephalae* 12 g, *Poria Cocos* 12 g, *Radix Rehmanniae Preparata* 15 g, *Fructus Corni* 12 g, *Rhizoma Dioscoreae* 15 g, *Fructus Schisandrae Chinensis* 10 g, *Fructus Perillae* 10 g, *Semen Armeniacae Amarum* 10 g, *Radix Platycodi* 10 g, and *Radix Glycyrrhizae* 6 g. Modifications: If the patient had severe cough, add *Bulbus Fritillariae Cirrhosae* 10 g and *Radix Stemonae* 12 g; if there was a large amount of sticky sputum, add *Pericarpium Citri Reticulatae* 10 g and *Rhizoma Pinelliae* 10 g; if soreness and weakness of waist and knees were prominent, add *Cortex Eucommiae* 12 g and *Fructus Lycii* 15 g; if the patient had chills and cold limbs, add *Radix Aconiti Lateralis Preparata* 6 g (decocted first) and *Cortex Cinnamomi* 6 g. One dose per day, decocted with water to obtain 400 mL of decoction, taken warmly twice a day in the morning and evening. The treatment duration was 12 consecutive weeks.

2.3. Observation indicators

2.3.1. Pulmonary function indicators

Before treatment and after 12 weeks of treatment, a pulmonary function tester (Jaeger, Germany, Model: MasterScreen PFT) was used to detect FEV_1, FVC, and FEV_1/FVC of patients in both groups. Patients were guided to cooperate correctly before the test, and each test was repeated 3 times, with the best value recorded.

2.3.2. TCM syndrome scores

Referring to the Guiding Principles for Clinical Research of New Chinese Medicines (Trial Implementation), a TCM syndrome scoring standard was formulated [9]. Five main symptoms (cough, expectoration, shortness of breath, fatigue, soreness and weakness of waist and knees) were scored. Each symptom was classified into four grades based on severity: absent (0 points), mild (1–2 points), moderate (3–4 points), and severe (5–6 points). A higher total score indicated more severe TCM syndromes. Patients in both groups were scored before treatment and after 12 weeks of treatment.

2.3.3. Quality of life scores

The St. George's Respiratory Questionnaire (SGRQ) was used to evaluate the quality of life of patients. The questionnaire included 3 dimensions: Symptoms, Activity, and Impact, with a total of 50 items. The total score ranged from 0 to 100 points. A higher score indicated a poorer quality of life [10]. Patients in both groups were scored before treatment and after 12 weeks of treatment.

2.4. Statistical methods

For the purpose of data analysis, the SPSS 26.0 statistical software package was employed. Measurement data were presented in the form of mean ± standard deviation ($\bar{x} \pm s$): the paired *t*-test was selected to conduct comparisons of relevant indicators within the same group before and after the treatment intervention, and the independent samples *t*-test was adopted for analyzing differences between the two groups. Count data were expressed as percentage rates (%), and the chi-square test was used for comparative analysis. In this study, a *p* value less than 0.05 was regarded as indicating a statistically significant difference.

3. Results

3.1. Comparison of pulmonary function indicators between the two groups before and after treatment

Prior to the initiation of treatment, no statistically meaningful discrepancies were observed in the pulmonary function indices FEV_1, FVC, and FEV_1/FVC between the two study groups ($p > 0.05$). Following 12 weeks of continuous therapeutic intervention, the FEV_1, FVC, and FEV_1/FVC values of both groups demonstrated a significant elevation compared to their respective pre-treatment levels ($p < 0.05$). Moreover, the aforementioned pulmonary function indicators in the observation group were notably higher than those in the control group, and this intergroup difference was confirmed to be statistically significant ($p < 0.05$). Detailed data are presented in **Table 1**.

Table 1. Comparison of pulmonary function indicators between the two groups before and after treatment ($\bar{x} \pm s$)

Group	Case number	Time	FEV_1	FVC (L)	FEV_1/FVC (%)
Control	40	Before treatment	1.62 ± 0.31	2.35 ± 0.42	56.89 ± 6.23
		After treatment	1.85 ± 0.36*	2.62 ± 0.45*	60.18 ± 6.57*
Observation group	40	Before treatment	1.65 ± 0.33	2.38 ± 0.44	57.12 ± 6.35
		After treatment	2.31 ± 0.42	3.15 ± 0.58	68.25 ± 7.13

Note: Compared with before treatment in the same group, *$p < 0.05$; compared with after treatment in the control group, #$p < 0.05$

3.2. Comparison of TCM syndrome scores between the two groups before and after treatment

Before the treatment intervention, there were no statistically significant disparities between the two groups in terms of the scores for individual TCM syndromes (including cough, expectoration, shortness of breath, fatigue, and soreness and weakness of waist and knees) as well as the total syndrome score ($p > 0.05$). After 12 weeks of continuous treatment, the scores of each single syndrome and the total syndrome score in both groups were remarkably reduced compared with their respective pre-treatment levels ($p < 0.05$). Furthermore, the scores of these individual syndromes and the total score in the observation group were significantly lower than those in the control group, and the difference between the two groups was statistically significant ($p < 0.05$). Specific data can be found in **Table 2**.

Table 2. Comparison of TCM syndrome scores between the two groups before and after treatment ($\bar{x} \pm s$, points)

Group	Case number	Time	Cough	Expectoration	Shortness of breath	Fatigue	Soreness and weakness of waist and knees	FEV_1/FVC (%)
Control	40	Before treatment	3.25 ± 1.02	3.18 ± 0.98	3.56 ± 1.12	2.89 ± 0.85	2.65 ± 0.78	15.53 ± 3.25
		After treatment	2.15 ± 0.85*	2.02 ± 0.76*	2.38 ± 0.95*	1.86 ± 0.65*	1.27 ± 0.52*	9.68 ± 2.36*
Observation group	40	Before treatment	3.32 ± 1.05	3.25 ± 1.01	3.62 ± 1.15	2.95 ± 0.88	2.72 ± 0.81	15.86 ± 3.32
		After treatment	1.02 ± 0.56	0.98 ± 0.45	1.15 ± 0.62	0.85 ± 0.42	0.23 ± 0.21	5.23 ± 1.85

Note: Compared with before treatment in the same group, *$p < 0.05$; compared with after treatment in the control group, #$p < 0.05$

4. Discussion

Treatment goals of stable COPD are to relieve symptoms, improve pulmonary function, enhance quality of life, and reduce the number of acute exacerbations [1]. Western medicine treatment mainly aims to control symptoms and delay disease progression, but it is difficult to fundamentally improve the patient's pulmonary function and prognosis. Based on the "holistic concept" and "syndrome differentiation and treatment", TCM has unique advantages in the treatment of stable COPD. By regulating the functions of zang-fu organs, it can achieve the effect of treating both the root and the branch.

In TCM, the core pathogenesis of stable COPD is deficiency of both lung and kidney. The lung is the master of Qi and is responsible for respiration. Long-term cough and asthma consume lung Qi; weakness of lung Qi leads to disorders of the dispersing and descending functions, resulting in symptoms such as cough, expectoration, and shortness of breath. The kidney is the root of Qi and is responsible for Qi reception. The respiratory function of the lung depends on the Qi-receiving function of the kidney. Prolonged illness affects the kidney; deficiency of kidney Qi leads to inability to receive Qi, which further aggravates shortness of breath and dyspnea. In addition, the kidney governs the metabolism of body fluids; kidney deficiency leads to failure of fluid evaporation, which accumulates into phlegm and blocks the airways, worsening the condition [6,8]. Therefore, invigorating the lung and tonifying the kidney is the key treatment method for stable COPD.

From the perspective of modern pharmacology research, many medicinal components in Bufei Yishen Decoction have effects such as improving pulmonary function, anti-inflammation, and anti-oxidation, which provide a scientific basis for its clinical efficacy. Astragalus polysaccharides in *Radix Astragali* can enhance the body's immunity, inhibit the release of inflammatory factors (such as tumor necrosis factor-α, interleukin-6), reduce airway inflammatory response, and at the same time improve the blood perfusion of lung tissue and promote lung tissue repair [11]. *Codonopsis saponins* in *Radix Codonopsis* can enhance the function of respiratory muscles, increase lung ventilation, and improve lung gas exchange

function [12]. Rehmannia polysaccharides in *Radix Rehmanniae Preparata* have anti-oxidation effects, which can scavenge oxygen free radicals, reduce oxidative stress damage of lung tissue, and delay the decline of pulmonary function [13]. Volatile oil components in *Fructus Perillae* and *Semen Armeniacae Amarum* can relax bronchial smooth muscle, relieve airway spasm, and improve airflow limitation [14]. The synergistic effect of these medicinal components jointly promotes the improvement of pulmonary function and the relief of symptoms in patients with stable COPD.

The results of this study showed that after 12 weeks of treatment, the pulmonary function indicators such as FEV_1, FVC, and FEV_1/FVC in the observation group were significantly higher than those in the control group ($p < 0.05$), indicating that Bufei Yishen Decoction combined with conventional Western medicine treatment can more effectively improve the patient's lung ventilation function. This may be because Bufei Yishen Decoction improves the strength and endurance of respiratory muscles, reduces airway inflammation and phlegm obstruction by enhancing the functions of the lung and kidney, thereby improving the ventilation efficiency of the lung [15]. At the same time, the total TCM syndrome score in the observation group was significantly lower than that in the control group ($p < 0.05$), indicating that Bufei Yishen Decoction can effectively alleviate the patient's symptoms such as cough, expectoration, shortness of breath, fatigue, and soreness and weakness of waist and knees. This is consistent with the TCM treatment principle of "invigorating the lung and tonifying the kidney", which fundamentally improves the patient's TCM syndromes by regulating the deficiency of both lung and kidney [16]. In addition, the SGRQ score in the observation group was significantly lower than that in the control group ($p < 0.05$), suggesting that Bufei Yishen Decoction can significantly improve the patient's quality of life. This is not only related to the improvement of pulmonary function and the relief of symptoms, but also may be related to the improvement of the patient's overall physical state and the reduction of psychological pressure [17].

In clinical practice, we also found that Bufei Yishen Decoction has high safety. In this study, no obvious adverse reactions occurred in the observation group, and only 2 patients had mild gastrointestinal discomfort (nausea, abdominal distension). The symptoms were relieved after adjusting the medication time (taken after meals) and did not affect the treatment [18]. This indicates that Bufei Yishen Decoction combined with conventional Western medicine treatment has good safety and is suitable for long-term use in patients with stable COPD.

However, this study also has some limitations:

(1) The sample size was small (80 cases) and it was a single-center study, which may have selection bias. The representativeness and promotion of the research results need to be further verified;

(2) The observation time was short (12 weeks), and the long-term effects of Bufei Yishen Decoction on the patient's pulmonary function, the number of acute exacerbations, and long-term prognosis could not be observed;

(3) In-depth research on the mechanism of action of Bufei Yishen Decoction (such as its effects on airway inflammatory factors and oxidative stress indicators) was not conducted. In the future, further basic experimental research is needed to clarify its mechanism of action;

(4) This study only included patients with stable COPD of lung-kidney Qi deficiency syndrome. The efficacy of Bufei Yishen Decoction in patients with other syndromes (such as phlegm-turbidity obstructing the lung syndrome, lung-spleen Qi deficiency syndrome) has not been observed. In the future, the sample size can be expanded to include patients with different syndromes to further explore the scope of application of Bufei Yishen Decoction.

In conclusion, the combined therapy of Bufei Yishen Decoction and conventional Western medicine in the management of patients with stable COPD yields notable effects: it can remarkably enhance patients' pulmonary function, mitigate the manifestations of TCM syndromes, boost their quality of life, and boasts high safety. Therefore, this therapeutic regimen is deserving of clinical popularization and application. Looking ahead, it is advisable to conduct multi-center clinical studies with large sample sizes and long-term follow-up, integrated with basic experimental research. Such efforts will help further validate the efficacy and safety of this treatment, clarify its underlying mechanism of action, and thereby provide more robust scientific evidence for the TCM-based treatment of stable COPD.

Disclosure statement

The authors declare no conflict of interest.

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