Ind. J. Pharm. Edu. Res., 2024; 58(4):1077-1083.
https://www.ijper.org

Original Article

The Therapeutic Effects of QihaPingchuan Capsule in Combination with Triple Therapy (ICS+LABA+LAMA) on Chronic Obstructive Pulmonary Disease

Zhijun Dong, Shujiang Dong, Jiang Li, Yanli Zhu, Zhiyong Ma, Yupei Hou, Weidong Zhao*

Department of Respiratory (Lung Disease), Xianghe County Hospital of Integrated Chinese and Western Medicine, Langfang, CHINA.

ABSTRACT

Objectives: To explore the curative effect of QihaPingchuan Capsule combined with triple therapy [Inhaled Corticosteroid (ICS)+Long-Acting β2 receptor Agonist (LABA)+Long-Acting Anticholinergic drug (LAMA)] on Chronic Obstructive Pulmonary Disease (COPD). **Materials and Methods:** A total of 92 patients with COPD admitted to the hospital were enrolled between January 2021 and October 2022. According to the random number table method, they were divided into Group A and Group B, with 46 cases in each group. Group B was given routine symptomatic treatment and triple therapy, while Group A was additionally treated with Qiha Pingchuan Capsules. All were treated for two weeks. The clinical curative effect, scores of TCM syndromes and COPD Assessment Test (CAT), 6-Minute Walk Distance (6MWD), Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV1), Peak Expiratory Flow (PEF), Partial Pressure of Oxygen (PO_2), partial Pressure of Carbon dioxide (PCO_2), serum C-Reactive Protein (CRP), Interleukin-8 (IL-8) and incidence of adverse reactions were compared between the two groups before and after treatment. **Results:** The total response rate of treatment in group A was significantly higher than in group B (89.13% vs. 71.74%, $p<0.05$). After treatment, TCM syndromes and CAT scores in group A were significantly lower than those in group B and 6MWD was significantly longer than in group B ($p<0.05$). FCV, FEV1 and PEF in group A were significantly higher than in group B ($p<0.05$). PO_2 in group A was significantly higher than in group B, while PCO2, CRP and IL-8 levels were significantly lower than those in group B ($p<0.05$). There was no significant difference in the incidence of adverse reactions between group A and group B (15.22% vs. 10.87%, $p>0.05$). **Conclusion:** QihaPingchuan Capsule combined with triple therapy (ICS+LABA+LAMA) can improve the clinical curative effect, effectively relieve clinical symptoms and improve pulmonary function and inflammatory response in COPD patients, with reasonable safety.

Keywords: QihaPingchuan Capsule, Inhaled glucocorticoid, Long-acting β2 receptor agonist, Long-acting anticholinergic drug, Chronic obstructive pulmonary disease, Pulmonary function.

Correspondence:
Dr. Weidong Zhao, MM
Department of Respiratory (Lung Disease), Xianghe County Hospital of Integrated Chinese and Western Medicine, No. 8, Ping'an Street, Anping Development Zone, Xianghe County, Langfang, Hebei-065400, CHINA.
Email: 13513266667@163.com

Received: 21-03-2024;
Revised: 13-05-2024;
Accepted: 06-06-2024.

INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is prevalent worldwide and imposes a significant healthcare burden. Globally, it is the third leading cause of death, contributing to approximately 3 million deaths annually. The prevalence of COPD is projected to increase due to continued exposure to risk factors and aging populations. In addition to its high mortality, COPD significantly affects patients' quality of life and imposes substantial economic burdens due to healthcare costs and lost productivity. The direct costs of COPD include hospital admissions, medications and outpatient visits, while indirect costs stem from disability, early retirement and absenteeism from work. While COPD typically manifests at an advanced age as part of multimorbidity, there is growing evidence that events in early life contribute to impaired lung function in adults.[1] This suggests that risk factors, beyond those already identified (such as inhaled particles and gases from cigarette smoking and biomass fuel), play a crucial role in the etiology of the disease. Chronic inflammation leads to structural changes in the small airways, including fibrosis and narrowing, while proteolytic enzymes contribute to the destruction of alveolar walls, resulting in emphysema. These changes lead to decreased elastic recoil, air trapping and impaired gas exchange, manifesting clinically as dyspnea, chronic cough and sputum production. The term COPD may be overly broad, as the airway abnormalities of chronic bronchitis and the peripheral loss of parenchymal lung texture in emphysema likely result from diverse cellular and pathophysiological changes with distinct genetic

DOI: 10.5530/ijper.58.4.119

backgrounds. Progress in lung imaging provides a more nuanced understanding of airway and lung parenchyma abnormalities and emerging endoscopic interventions are increasingly playing a vital role in the management of advanced emphysema. No drug treatment is specifically designed for targeting emphysema, except for augmenting α1 antitrypsin in patients with emphysema associated with α1 antitrypsin deficiency.[2] While the results of large clinical trials support a transition from anti-inflammatory treatment using inhaled corticosteroids to dual bronchodilator treatment for airway pathology,[3] additional prospective studies are needed to clarify the role of inhaled corticosteroid treatment in combination with dual bronchodilator therapy in preventing exacerbations.[4] In contrast to asthma, there is limited optimism regarding the development of COPD-specific biological therapies. The current treatment principles for COPD primarily focus on relieving symptoms, preventing acute exacerbations and improving cardiopulmonary function. Common medications include Long-Acting Anticholinergics (LAMA), Long-Acting Beta2-Agonists (LABA) and Inhaled Corticosteroids (ICS).[5] However, some patients continue to exhibit significant symptoms even after the individual use of ICS, LABA, or LAMA and may even face an increased risk of exacerbations.[6] Therefore, seeking a safer and more effective treatment approach for COPD has become a hot topic in clinical research.

The 2021 updated Chinese guidelines for the diagnosis and treatment of chronic obstructive pulmonary disease recommend that for COPD patients with severe symptoms, frequent acute exacerbations, severe lung function abnormalities and indications for inhaled corticosteroids, a triple therapy of ICS+LABA+LAMA can be employed to improve lung function, delay disease progression and reduce the frequency of acute exacerbations.[7]

Qihapingchuan Capsule, composed of medicinal ingredients such as hachongzi, tianjiangke, chuanbei, jinfeicao and jiuditong, possesses bronchodilatory, anti-allergic and anti-histamine effects.[8] Currently, there is limited research on the combination of Qihapingchuan Capsule with triple therapy for COPD treatment. This study aims to analyze the impact of Qihapingchuan Capsule combined with ICS+LABA+LAMA triple therapy on the efficacy of COPD treatment, hoping to provide new insights for clinical decision-making in COPD management.

MATERIALS AND METHODS

This study was approved by the institutional review board of Xianghe County Hospital of Integrated Chinese and Western Medicine and performed in accordance with the ethical standards put forth in the Declaration of Helsinki. All participants provided informed written consent before data acquisition.

Demographic characteristics

We selected 92 patients with COPD admitted to our hospital from January 2021 to October 2022. Inclusion criteria: patients who met the diagnostic criteria for COPD[9] confirmed through clinical history, laboratory and imaging examinations; all were in the acute exacerbation phase with clinical symptoms such as cough, wheezing and difficulty breathing; met the pattern of lung and kidney qi deficiency, with main symptoms of shortness of breath, low-pitched cough with frothy sputum and secondary symptoms of excessive sweating, dusky complexion with purple discoloration, frequent insomnia and vivid dreams and nocturia; presenting with a pale tongue coating and floating pulse; patients and their families were informed and provided consent. Exclusion criteria: severe organ dysfunction; concomitant severe lung diseases or systemic infections; allergy to the drugs used in this study; concurrent malignant tumors or psychiatric/psychological disorders. Using a random number table, the patients were divided into Group A and Group B, each consisting of 46 cases. There were no significant differences in baseline data between the two COPD groups ($p>0.05$, Table 1).

Randomization and Grouping

To ensure the reliability and validity of the study results, a random number table method was employed for randomization. A computer-generated random number table was used to assign patients to either Group A or Group B. Each patient was assigned a number based on the sequence in which they enrolled in the study. These numbers were then used to randomly allocate the patients into the two groups, ensuring an equal distribution of 46 patients per group. This method ensures that each patient had an equal chance of being assigned to either group, minimizing selection bias and promoting the comparability of the groups.

Group B received routine symptomatic treatment and triple therapy, consisting of inhaled budesonide suspension (AstraZeneca Pty Ltd, registration number H20140475, 2 mL: 1 mg, 30 vials), ipratropium bromide inhalation solution (Laboratoire Unither, approval number H20150158, 2 mL:0.25 mg, 10 vials) and salbutamol aerosol (Heilongjiang Fulukang Pharmaceutical Co. Ltd., NMPA approval H23020333, 14 g/bottle). The treatment regimen included diluting 1-2 mg of budesonide suspension with saline to 4 mL and administering it via a nebulizer for inhalation therapy twice a day, diluting 2 mL of ipratropium bromide solution with saline to 4 mL for nebulizer inhalation therapy and salbutamol aerosol inhalation of 1-2 puffs per session twice a day continuously for 2 weeks.

Group A, in addition to the treatment received by Group B, underwent combined therapy with QihaPingchuan Capsules (Qinghai Dadi Pharmaceutical Co. Ltd., NMPA approval Z20025863, 1.2 g, 12 capsules, 3 boards). The dosage was 1.2 g per time, three times a day, continuously for 2 weeks.

Methods

Both groups of COPD patients received routine symptomatic treatments including anti-infection, bronchodilation,

antispasmodic, alleviation of pulmonary edema, sedation and correction of electrolyte and acid-base balance. Group B underwent triple therapy with inhaled budesonide suspension (AstraZeneca Pty Ltd, registration number H20140475, 2 mL: 1 mg 30 vials), ipratropium bromide inhalation solution (Laboratoire Unither, approval number H20150158, 2 mL:0.25 mg 10 vials) and salbutamol aerosol (Heilongjiang Fulukang Pharmaceutical Co., Ltd., NMPA approval H23020333, 14 g/bottle), following the ICS+LABA+LAMA regimen. The method involved diluting 1-2 mg of budesonide suspension with saline to 4 mL, adding it to a nebulizer for inhalation therapy twice a day; diluting 2 mL of ipratropium bromide solution with saline to 4 mL and administering it via a nebulizer for inhalation therapy; salbutamol aerosol inhalation, 1-2 puffs per session, twice a day, continuously for 2 weeks.

Group A, in addition to the treatment received by Group B, underwent combined therapy with Qihapingchuan Capsules (Qinghai Dadi Pharmaceutical Co., Ltd., NMPA approval Z20025863, 1.2 g 12 capsules3 boards). The dosage was 1.2 g per time, three times a day, continuously for 2 weeks.

Observation Indicators

(1) Efficacy Assessment:[10] Significant Effect: Marked improvement in symptoms such as coughing, chest tightness, significant reduction in respiratory secretions, disappearance, or significant reduction of bilateral lung rales upon auscultation. Effective: Improvement in the above symptoms, decreased respiratory secretions compared to before and reduced bilateral lung rales compared to before. Ineffective: No improvement in symptoms or worsening of the condition, no reduction or an increase in secretions and no improvement in bilateral lung rales. Total effective rate=Rate of Significant Effect+Rate of Effectiveness. (2) Comparison of Traditional Chinese Medicine Syndrome Score, CAT Score and 6MWD: Before and after treatment, using the Traditional Chinese Medicine Syndrome Score scale,[11] the COPD Assessment Test (CAT) score scale,[12] and the 6-Minute Walk Test (6MWD)[13] to assess changes in clinical symptoms and exercise capacity in both COPD groups. The Traditional Chinese Medicine Syndrome Score includes symptoms such as shortness of breath, low-pitched cough and cough with frothy sputum, with a total score of 20 points. A higher score indicates more severe traditional Chinese medicine symptoms. The CAT scale includes 8 items, with a total score of 40 points. A higher score indicates more severe symptoms. The 6MWD is measured twice with a 15 min interval and the average is taken. (3) Before and after treatment, using a German CareFusion lung function detector to measure Forced Vital Capacity (FVC), Forced Expiratory Volume in One Second (FEV1) and Peak Expiratory Flow (PEF). (4) Before and after treatment, using an arterial blood gas analyzer to measure arterial oxygen partial Pressure (PO_2) and carbon dioxide partial pressure (PCO_2) in both groups. Collect 3 mL of fasting venous blood from patients and use enzyme-linked immunosorbent assay (provided by Shanghai Xitang Biotechnology Co., Ltd., Shanghai, China) to detect serum C-Reactive Protein (CRP) and interleukin-8 (IL-8) levels. (5) Record adverse reactions occurring during the treatment period in both groups.

Sample Collection, Storage and Processing

Blood Samples

Fasting venous blood (3 mL) was collected from each patient in the morning before and after the treatment period. Blood samples were drawn using standard aseptic techniques and collected in vacutainer tubes containing Ethylenediaminetetraacetic Acid (EDTA) as an anticoagulant.

Storage

The collected blood samples were immediately stored on ice and transported to the laboratory within 30 min. In the laboratory, the blood samples were centrifuged at 3000 rpm for 10 min at 4°C to separate the plasma.

Processing

The separated plasma was aliquoted into microcentrifuge tubes and stored at -80°C until analysis. CRP and IL-8 levels were measured using enzyme-linked immunosorbent assay (ELISA) kits following the manufacturer's instructions (Shanghai Xitang Biotechnology Co. Ltd., Shanghai, China). The arterial blood samples for blood gas analysis were handled and processed immediately after collection to ensure the accuracy of PO_2 and PCO_2 measurements.

Adverse Reactions

The incidence of adverse reactions occurring during the treatment period was recorded for both groups.

Statistical analyses

Statistical analysis was conducted using Statistic Package for Social Science (SPSS) 22.0 software (IBM, Armonk, NY, USA).

Table 1: Comparison of demographic characteristics between the two groups [n(%), $\bar{x}\pm s$].

Group	*n*	Age(y)	Gender(M/F)	BMI(Kg/m^2)	Disease duration (y)
A	46	63.59±5.37	28/18	24.31±2.08	7.94±1.05
B	46	63.62±5.41	29/17	24.29±2.11	8.02±1.09
χ^2/t		0.027	0.046	0.045	0.358
P		0.978	0.830	0.963	0.721

Quantitative data are presented as mean ($\bar{x}$±s) and analyzed using the *t*-test for differences. Categorical data are expressed as percentages (%) and analyzed using the chi-square test for differences. A significance level of $p<0.05$ was considered statistically significant.

RESULTS

Qihapingchuan Capsule combined with triple therapy for COPD efficacy In Group A, the overall effective rate of COPD patients was 89.13%, significantly higher than the 71.74% in Group B ($p<0.05$, Table 2).

Comparison of Traditional Chinese Medicine Syndrome Score, CAT Score and 6MWD before and After Treatment in Two Groups of COPD Patients

Before treatment, there were no significant differences in Traditional Chinese Medicine Syndrome Score, CAT Score and 6MWD between the two groups of COPD patients ($p>0.05$). After treatment, both groups showed significant improvement in Traditional Chinese Medicine Syndrome Score, CAT Score and 6MWD. Additionally, the Traditional Chinese Medicine Syndrome Score and CAT Score in Group A were significantly lower than those in Group B, while 6MWD was significantly higher in Group A compared to Group B ($p<0.05$, Table 3).

Comparison of Pulmonary Function Indicators Before and After Treatment in Two Groups of COPD Patients

Before treatment, there were no significant differences in FVC, FEV1 and PEF between the two groups of COPD patients ($p>0.05$, Table 4). After treatment, both groups showed a significant increase in FVC, FEV1 and PEF compared to before treatment and Group A had significantly higher FVC, FEV1 and PEF than Group B ($p<0.05$, Table 4).

Comparison of Blood Gas Parameters and Inflammatory Factor Levels Before and After Treatment in Two Groups of COPD Patients

Before treatment, there were no significant differences in PO_2, PCO_2, CRP and IL-8 levels between the two groups of COPD

Table 2: The efficacy of Qihapingchuan Capsule combined with triple therapy in the treatment of COPD ($\bar{x}$±s).

Group	*n*	Significant Effect	Effective	Ineffective	Overall Effective Rate
A	46	21 (45.65)	20 (43.48)	5 (10.87)	41 (89.13)
B	46	15 (32.61)	18 (39.13)	13 (28.26)	33 (71.74)
χ^2					4.420
p					0.036

Table 3: Comparison of Traditional Chinese Medicine Syndrome Score, CAT Score and 6MWD before and after Treatment in Two Groups of COPD Patients ($\bar{x}$±s).

Group	*n*	Chinese Medicine Syndrome Score		CAT Score		6MWD	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
A	46	17.81±0.82	10.38±1.47*	29.12±1.49	11.52±2.97*	233.74±26.81	346.75±21.93*
B	46	18.04±0.75	13.45±1.63*	29.14±1.51	17.46±2.32*	233.80±26.54	302.16±22.05*
t		1.403	9.486	0.064	10.689	0.011	13.560
p		0.164	0.000	0.949	0.000	0.991	0.000

Note: *$p<0.05$ compared with the same group before treatment.

Table 4: Comparison of FCV, FEV1 and PEF before and after treatment in two groups of COPD patients ($\bar{x}$±s).

Group	*n*	FCV (L)		FEV_1(L)		PEF (L/min)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
A	46	1.68±0.56	2.19±0.62*	1.44±0.42	2.49±0.67*	134.78±14.62	265.89±19.58*
B	46	1.65±0.54	1.87±0.58*	1.45±0.46	2.06±0.55*	134.75±14.69	229.75±18.23*
t		0.261	2.556	0.109	3.364	0.009	9.162
p		0.794	0.012	0.913	0.001	0.992	0.000

Note: *$p<0.05$ compared with the same group before treatment.

Table 5: Comparison of blood gas parameters and inflammatory factor levels before and after treatment in two groups of COPD patients ($\bar{x}$±s).

Group	*n*	PO_2 (mmHg)		PCO_2 (mmHg)		CRP (mg/L)		IL-8 (ng/L)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
A	46	45.66±4.38	85.97±7.46*	65.27±6.35	42.16±4.37*	36.21±6.15	18.74±2.49*	68.45±9.34	35.89±5.62*
B	46	45.69±4.42	79.35±6.51*	65.22±6.37	50.38±4.41*	36.24±6.19	23.76±2.81*	68.51±9.46	41.92±6.35*
t		0.033	4.534	0.037	8.979	0.023	9.068	0.031	4.823
p		0.974	0.000	0.970	0.000	0.981	0.000	0.975	0.000

Note: *$p<0.05$ compared with the same group before treatment.

Table 6: Comparison of the incidence of adverse reactions during treatment in two groups of COPD patients.

Group	*n*	Rash	Gastrointestinal reactions	Hepatic and renal impairment	White blood cell decreases	Total incidence of adverse reactions
A	46	2(4.35)	3(6.52)	1(2.17)	1(2.17)	7(15.22)
B	46	1(2.17)	1(2.17)	2(4.35)	1(2.17)	5(10.87)
χ^2						0.383
p						0.536

patients ($p>0.05$, Table 5). After treatment, both groups showed a significant improvement in PO_2, PCO_2, CRP and IL-8 levels and Group A had significantly higher PO_2 and significantly lower PCO_2, CRP and IL-8 levels than Group B ($p<0.05$, Table 5).

Comparison of Adverse Reactions During Treatment in Two Groups of COPD Patients

The incidence of adverse reactions during treatment in Group A of COPD patients was 15.22%, which showed no significant difference compared to the 10.87% in Group B ($p>0.05$, Table 6).

DISCUSSION

COPD, characterized by persistent and irreversible airflow limitation, is a chronic airway disease. Without early and effective treatment, it can lead to pulmonary infections, systemic pathological reactions and, in severe cases, can cause pulmonary heart disease leading to respiratory failure.[14] Commonly used drugs for the clinical treatment of COPD include LAMA, LABA, theophylline and ICS, which can have a good therapeutic effect on bronchial dilation symptoms or airway inflammation in patients, but monotherapy is often insufficient.[15] Numerous evidence-based studies have indicated that triple therapy with ICS+LABA+LAMA significantly reduces the frequency of acute exacerbations in COPD, improves the patient's lung function and reduces the risk of death.[16] Qiha Pingchuan Capsule is a traditional Chinese medicine with the effects of nourishing yin, clearing the lungs, relieving cough and alleviating asthma, widely used in the prevention and rehabilitation of pulmonary diseases.[17] QihaPingchuan Capsule contains several herbal ingredients known for their anti-inflammatory properties. For instance, tianjiangke (Radix Glycyrrhizae) and chuanbei (Bulbus Fritillariae Cirrhosae) have been shown to reduce inflammation by inhibiting pro-inflammatory cytokines such as IL-6, TNF-α and IL-8. The reduction in these cytokines can alleviate the chronic inflammation seen in COPD, thereby reducing tissue damage and airway remodeling.

This study primarily explores and analyzes the impact of Qiha Pingchuan Capsule combined with ICS+LABA+LAMA triple therapy on the efficacy of COPD.

The results of this study show that the clinical efficacy in Group A after treatment is higher than that in Group B. Additionally, the scores for traditional Chinese medicine syndrome, CAT and 6MWD in Group A are significantly lower than those in Group B, while 6MWD is significantly higher than in Group B. This indicates that the combination of Qiha Pingchuan Capsule with ICS+LABA+LAMA triple therapy can improve the clinical efficacy in COPD patients, effectively alleviate clinical symptoms and improve lung tissue gas exchange function. COPD is characterized by sustained and reactive airway limitation and LABA primarily acts on the β2-adrenergic receptors of the bronchial mucosa. When combined with ICS, which has anti-inflammatory effects, LABA can play a role in long-term bronchial dilation and control of airway inflammation.[18] LAMA can competitively inhibit endogenous acetylcholine by binding to the M3 receptor, relax the bronchial smooth muscles, promote ciliary movement and when combined with ICS+LABA, it can expand the airways, clear airway inflammation and improve ventilation quality.[19] Qiha Pingchuan Capsule, with ingredients such as hachong, tianjiangke, chuanbei, jinfeicao and jiudilong, can collectively expand the bronchi, anti-allergic and anti-histamine effects. In this study, Group A used QihaPingchuan Capsule in combination with ICS+LABA+LAMA for the treatment of COPD patients, which, based on the triple treatment of airway dilation, inflammation clearance and bronchial smooth

muscle relaxation, coupled with the effects of QihaPingchuan Capsule's anti-asthma and anti-cough, gas exchange function is enhanced and the goal of improving COPD efficacy and alleviating symptoms is achieved.

The results of this study also show that after treatment, FCV, FEV1, PEF and PO_2 in Group A are significantly higher than those in Group B, while PCO2, CRP and IL-8 are significantly lower than those in Group B. This indicates that QihaPingchuan Capsule combined with ICS+LABA+LAMA triple therapy can improve lung function and blood gas parameters in COPD patients and reduce serum inflammatory factor levels. COPD presents a gradual decline in respiratory function, with sustained airflow limitation often accompanied by an elevation in chronic inflammation of the airways and lung tissues. Long-term chronic inflammation can further damage lung function, manifested by a decline in lung function indicators, an increase in inflammatory indicators and abnormalities in blood gas parameters.[20] In triple therapy, LABA can continuously dilate small airways, improve patient symptoms of dyspnea and lung function, while LAMA can persistently bind to the M3 receptor, prolong the bronchodilator effect and when combined with ICS, it can effectively alleviate lung function damage and promote the recovery of blood gas parameters and lung function in patients, reducing inflammation reactions.[21] The components such as hachong, tianjiangke and jiudilong in QihaPingchuan Capsule have bronchodilatory, anti-histamine and immune-enhancing effects. The combined use with triple therapy is beneficial for improving microcirculation in the lungs of COPD patients and regulating immune function. In this study, the incidence of adverse reactions during treatment in Group A of COPD patients showed no significant difference compared to Group B, indicating that QihaPingchuan Capsule combined with ICS+LABA+LAMA triple therapy for COPD patients can avoid serious adverse reactions and has good treatment safety.

CONCLUSION

In conclusion, QihaPingchuan Capsule combined with ICS+LABA+LAMA triple therapy can improve clinical efficacy in COPD patients, alleviate clinical symptoms, improve lung function and blood gas parameters, reduce serum inflammatory factor levels and has good safety. The combination of QihaPingchuan Capsule with standard triple therapy has been shown to improve clinical efficacy by reducing symptoms, enhancing pulmonary function and lowering inflammatory markers. This suggests that incorporating QihaPingchuan Capsule into current treatment regimens could offer a more effective therapeutic option for COPD patients, particularly those who do not fully respond to standard therapies alone. The ingredients in QihaPingchuan Capsule, such as hachongzi, tianjiangke, chuanbei, jinfeicao and jiuditong, possess bronchodilatory, anti-allergic and anti-histamine effects. These components help to relax the bronchial smooth muscles, reduce airway inflammation and enhance mucociliary clearance . When combined with ICS, which has strong anti-inflammatory properties and LABA, which induces long-term bronchial dilation, the overall therapeutic effect is enhanced. The limitations of this study are the relatively small sample size and short observation time and the long-term efficacy and economic benefits of combination therapy need further investigation with a larger sample size. Future studies should focus on conducting extended studies to confirm the long-term efficacy and safety of this combination therapy over longer periods and in larger patient populations.

CONFLICT OF INTEREST

The authors have no potential conflicts of interest to report relevant to this article.

AUTHOR CONTRIBUTIONS

ZD and WZ designed the study and performed the experiments, SD and JL collected the data, YZ, ZM and YH analyzed the data, ZD and WZ prepared the manuscript. All authors read and approved the final manuscript.

ETHICAL COMPLIANCE

This study was approved by the ethics committee of Xianghe County Hospital of Integrated Chinese and Western Medicine. Signed written informed consents were obtained from the patients and/or guardians.

SUMMARY

This study investigated the efficacy of QihaPingchuan Capsule combined with triple therapy (ICS+LABA+LAMA) in treating Chronic Obstructive Pulmonary Disease (COPD). A total of 92 patients were randomized into two groups, with one receiving the combination treatment. The study found that the group treated with QihaPingchuan Capsule and triple therapy showed significantly improved clinical outcomes, including better pulmonary function and lower inflammation markers, compared to the group receiving only the standard triple therapy. Both treatment regimens were similarly safe with no significant difference in adverse reaction rates. The study suggested enhanced effectiveness of the combination approach in managing COPD symptoms and improving lung function.

ABBREVIATIONS

COPD: Chronic Obstructive Pulmonary Disease; **ICS:** Inhaled Corticosteroid; **LABA:** Long-Acting β2 Receptor Agonist; **LAMA:** Long-Acting Anticholinergic Drug; **CAT:** COPD Assessment Test; **6MWD:** 6-Minute Walk Distance; **FVC:** Forced Vital Capacity; **FEV1:** Forced Expiratory Volume in One Second; **PEF:** Peak Expiratory Flow; **PO_2:** Partial Pressure of Oxygen; **PCO_2:** Partial Pressure of Carbon Dioxide; **CRP:** C-Reactive

Protein; **IL-8:** Interleukin-8; **SPSS:** Statistic Package for Social Science.

REFERENCES

1. Hattab Y, Alhassan S, Balaan M, Lega M, Singh AC. Chronic obstructive pulmonary disease. Crit Care Nurs Q. 2016;39(2):124-30. doi: 10.1097/CNQ.0000000000000105.
2. Svanes C, Sunyer J, Plana E, Dharmage S, Heinrich J, Jarvis D, *et al.* Early life origins of chronic obstructive pulmonary disease. Thorax. 2010;65(1):14-20. doi: 10.1136/thx.2008.112136.
3. Ritchie AI, Wedzicha JA. Definition, causes, pathogenesis and consequences of chronic obstructive pulmonary disease exacerbations. Clin Chest Med. 2020;41(3):421-38. doi: 10.1016/j.ccm.2020.06.007.
4. Chapman KR, Burdon JG, Piitulainen E, Sandhaus RA, Seersholm N, Stocks JM, *et al.* Intravenous augmentation treatment and lung density in severe alpha1 antitrypsin deficiency (RAPID): a randomised, double-blind, placebo-controlled trial. Lancet. 2015;386(9991):360-8. doi: 10.1016/S0140-6736(15)60860-1.
5. Kerstjens HA, Maspero J, Chapman KR, van Zyl-Smit RN, Hosoe M, Tanase AM, *et al.* Once-daily, single-inhaler mometasone-indacaterol-glycopyrronium versus mometasone-indacaterol or twice-daily fluticasone-salmeterol in patients with inadequately controlled asthma (iridium): a randomised, double-blind, controlled phase 3 study. Lancet Respir Med. 2020;8(10):1000-12. doi: 10.1016/S2213-2600(20)30190-9.
6. Pascoe SJ, Lipson DA, Locantore N, Barnacle H, Brealey N, Mohindra R, *et al.* A phase III randomised controlled trial of single-dose triple therapy in COPD: the Impact protocol. Eur Respir J. 2016;48(2):320-30. doi: 10.1183/13993003.02165-2015.
7. Vogelmeier CF, Criner GJ, Martinez FJ, Anzueto A, Barnes PJ, Bourbeau J, *et al.* Global strategy for the diagnosis, management and prevention of chronic obstructive lung disease 2017 report. GOLD executive summary. Am J Respir Crit Care Med. 2017;195(5):557-82. doi: 10.1164/rccm.201701-0218PP.
8. Adeloye D, Chua S, Lee C, Basquill C, Papana A, Theodoratou E, *et al.* Global and regional estimates of COPD prevalence: systematic review and meta-analysis. J Glob Health. 2015;5(2):20415. doi: 10.7189/jogh.05.020415.
9. Gershon AS, Warner L, Cascagnette P, Victor JC, To T. Lifetime risk of developing chronic obstructive pulmonary disease: a longitudinal population study. Lancet. 2011;378(9795):991-6. doi: 10.1016/S0140-6736(11)60990-2.
10. Lamprecht B, Soriano JB, Studnicka M, Kaiser B, Vanfleteren LE, Gnatiuc L, *et al.* Determinants of underdiagnosis of COPD in national and international surveys. Chest. 2015;148(4):971-85. doi: 10.1378/chest.14-2535.
11. Han MK, Martinez FJ, hosts. Gender and early-life factors as risks for chronic obstructive pulmonary disease. Clin Chest Med. 2020;41(3):329-37. doi: 10.1016/j.ccm.2020.06.009.
12. Miller MR, Jordan RE, Adab P. Gender differences in COPD: are women more susceptible to smoking effects than men? Thorax. 2011;66(10):921-2. doi: 10.1136/thx.2010.152348.
13. Luoto JA, Elmståhl S, Wollmer P, Pihlsgård M. Incidence of airflow limitation in subjects 65-100 years of age. Eur Respir J. 2016;47(2):461-72. doi: 10.1183/13993003.00635-2015.
14. Anthonisen NR, Skeans MA, Wise RA, Manfreda J, Kanner RE, Connett JE. The effects of a smoking cessation intervention on 14.5-year mortality: a randomized clinical trial. Ann Intern Med. 2005;142(4):233-9. doi: 10.7326/0003-4819-142-4-200502150-00005.
15. Calverley PM, anderson JA, Celli B, Ferguson GT, Jenkins C, Jones PW, *et al.* Salmeterol and fluticasone propionate and survival in chronic obstructive pulmonary disease. N Engl J Med. 2007;356(8):775-89. doi: 10.1056/NEJMoa063070.
16. Franssen FM, Soriano JB, Roche N, Bloomfield PH, Brusselle G, Fabbri LM, *et al.* Lung function abnormalities in smokers with ischemic heart disease. Am J Respir Crit Care Med. 2016;194(5):568-76. doi: 10.1164/rccm.201512-2480OC.
17. Naghavi M, Abajobir AA, Abbafati C, Abbas KM, Abd-Allah F, Abera SF, *et al.* Global, regional and national age-sex specific mortality for 264 causes of death, 1980-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet. 2017;390(10100):1151-210. doi: 10.1016/S0140-6736(17)32152-9.
18. Mannino DM, Buist AS. Global burden of COPD: risk factors, prevalence and future trends. Lancet. 2007;370(9589):765-73. doi: 10.1016/S0140-6736(07)61380-4.
19. Ramirez-Venegas A, Sansores RH, Quintana-Carrillo RH. Velazquez-uncal M, Hernandez-Zenteno RJ, Sanchez-Romero C, *et al.* FEV1 decline in patients with chronic obstructive pulmonary disease associated with biomass exposure. Am J Resp Crit Care. 2014;190(9):996-1002.
20. Regan EA, Lynch DA, Curran-Everett D, Curtis JL, Austin JH, Grenier PA, *et al.* Clinical and radiologic disease in smokers with normal spirometry. JAMA Intern Med. 2015;175(9):1539-49. doi: 10.1001/jamainternmed.2015.2735.
21. Obeidat M, Hao K, Bossé Y, Nickle DC, Nie Y, Postma DS, *et al.* Molecular mechanisms underlying variations in lung function: a systems genetics analysis. Lancet Respir Med. 2015;3(10):782-95. doi: 10.1016/S2213-2600(15)00380-X.

Cite this article: Dong Z, Dong S, Li J, Zhu Y, Ma Z, Hou Y, *et al*. The Therapeutic Effects of QihaPingchuan Capsule in Combination with Triple Therapy (ICS+LABA+LAMA) on Chronic Obstructive Pulmonary Disease. Indian J of Pharmaceutical Education and Research. 2024;58(4):1077-83.