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Clinical Observation of TCM Constitution Theory-Based Intervention in the Critical Window of AECOPD

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Abstract: Objective: To observe the efficacy and safety of TCM syndrome differentiation-guided herbal intervention for patients with five constitutions during the high-risk window period of acute exacerbation of chronic obstructive pulmonary disease (AECOPD) based on TCM constitution theory. Methods: A total of 300 AECOPD patients in the high-risk window period (54–66 cases for each constitution) were randomly divided into two groups (150 cases each). The control group received fluticasone furoate/umeclidinium/vilanterol inhalation therapy, while the experimental group was additionally given constitution-specific TCM decoctions (e.g., Erchen Decoction combined with Sanzi Yangqin Decoction for Phlegm-Dampness constitution). The treatment course was 8 weeks with a 6-month follow-up. CAT score, TCM syndrome score, pulmonary function, 6-minute walking distance (6MWD), and levels of CRP and IL-6 were observed. Recurrence and safety indicators were recorded. *Results:* After treatment, all indicators improved significantly in both groups ($p < 0.05$), with the experimental group showing superior improvements in CAT score, TCM syndrome score, FEV1, 6MWD, and inflammatory indicators ($p < 0.01$). The recurrence rate was lower in the experimental group during follow-up ($p < 0.05$). No severe adverse reactions or abnormalities in liver/kidney function were observed in either group. *Conclusion:* TCM syndrome differentiation treatment guided by constitution theory can improve symptoms, quality of life, and pulmonary function, reduce inflammatory levels and recurrence rate in AECOPD patients during the high-risk window period, with good safety.

Keywords: TCM constitution theory; Acute exacerbation of chronic obstructive pulmonary disease (AECOPD); Risk window period

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1. Introduction

Chronic obstructive pulmonary disease (COPD) is a chronic respiratory disease characterized by persistent

respiratory symptoms and airflow limitation, and it is a chronic pulmonary disorder with an extremely high mortality rate [1–3]. This study conducted a prospective clinical trial involving 300 hospitalized AECOPD critical window patients from the Department of Respiratory Medicine to investigate the therapeutic effects of TCM constitution theory-based interventions on exercise tolerance, lung function, inflammatory markers, and TCM symptom scores. The results are reported as follows.

2. Subjects and methods

2.1. Study subjects and grouping

A total of 300 patients in the critical window of AECOPD, identified with TCM constitutions (phlegm-dampness constitution [Tan Shi Zhi], Qi-deficiency constitution [Qi Xu Zhi], yang-deficiency constitution [Yang Xu Zhi], dampness-heat constitution [Shi Re Zhi], and blood-stasis constitution [Yu Xue Zhi]), were enrolled from the Department of Respiratory Medicine at Chengdu Longquanyi District Hospital of Traditional Chinese Medicine between October 2023 and October 2024. Using a random number table method, patients were sequentially assigned to either the treatment group or the control group (150 patients each) based on their order of admission. This study complied with medical ethics requirements and was approved by the Ethics Committee of Chengdu Longquanyi District Hospital of Traditional Chinese Medicine [4–7].

2.2. Diagnostic criteria

The diagnostic criteria for the critical window of AECOPD were established based on the Chinese Expert Consensus on the Diagnosis and Treatment of Acute Exacerbation of Chronic Obstructive Pulmonary Disease and the Chinese Guidelines for the Diagnosis and Management of Community-Acquired Pneumonia in Adults, as follows [8,9]:

2.2.1. Clinical improvement post-treatment

AECOPD patients exhibit significant alleviation of clinical symptoms, but symptoms and lung function have not yet returned to stable-phase levels.

2.2.2. Stable vital signs

(1) Body temperature ≤ 37.0 ℃
(2) Pulse rate ≤ 100 beats/min
(3) Respiratory rate ≤ 24 breaths/min
(4) Systolic blood pressure ≥ 90 mmHg
(5) Ability to eat independently without sleep disruption due to dyspnea.

2.2.3. Adequate oxygenation

Partial pressure of oxygen (PaO_2) ≥ 60 mmHg or peripheral oxygen saturation (SpO_2) ≥ 90% without supplemental oxygen.

2.2.4. Reduced bronchodilator use

Requirement for short-acting β_2-agonists < 6 times within 24 hours.

2.2.5. Clinical stability

Symptoms remain stable for over 24 hours.

2.2.6. Normalized inflammatory markers

White blood cell count < 10×10^9/L and neutrophil ratio ≤ 75%.

2.2.7. No need for intravenous antibiotics

Patients meeting all seven criteria were diagnosed as being in the critical window of AECOPD. TCM Disease Diagnostic Criteria: Based on the TCM Syndrome Diagnostic Criteria for Chronic Obstructive Pulmonary Disease (2011 Edition) and the diagnosis of lung distension (Fei Zhang) in Internal Medicine of Traditional Chinese Medicine:

(1) Chronic and recurrent cough.
(2) Key symptoms including chest and hypochondriac distension, cough with sputum production, shortness of breath or wheezing, severe cases may present palpitations, edema, or cyanosis of the lips.
(3) Triggers, by associated with exposure to external pathogens, overexertion, emotional triggers, or dietary irregularities.

TCM Constitution Classification Criteria: Following the Classification and Determination of TCM Constitutions issued by the China Association of Chinese Medicine, five constitutions were selected.

(1) Phlegm-dampness constitution (Tan Shi Zhi),
(2) Qi-deficiency constitution (Qi Xu Zhi),
(3) Yang-deficiency constitution (Yang Xu Zhi),
(4) Dampness-heat constitution (Shi Re Zhi),
(5) Blood-stasis constitution (Yu Xue Zhi).

2.3. Inclusion criteria

(1) Meet the diagnostic criteria for COPD and currently in the stable phase of the disease;
(2) Meet the diagnostic criteria for lung distension in TCM and satisfy one of the 5 constitution types defined in the TCM constitution classification standard;
(3) Aged 50–80 years, irrespective of gender, with an expected survival period exceeding six months;
(4) Have not participated in any other clinical trials within the past six months and are able to complete all study-required assessments;
(5) Agree to participate and sign the relevant informed consent form.

2.4. Exclusion criteria

(1) Do not meet the diagnostic criteria for COPD;
(2) Have known specific causes of obstructive airway disease, such as bronchial cystic lesions, diffuse bronchiolitis, or obliterative bronchiolitis;
(3) Concurrent pulmonary encephalopathy, shock, coma, or other psychiatric conditions rendering them unable to make autonomous decisions;
(4) Concurrent non-pulmonary infectious diseases, tissue trauma, autoimmune diseases, etc.;
(5) Concurrent severe primary diseases of the liver, kidneys, hematopoietic system, etc., not caused by

COPD;

(6) Concurrent diseases such as tumors or tuberculosis;

(7) Unwilling to participate in the study, unable to complete questionnaires, or unable to accurately recall the history of COPD acute exacerbations.

2.5. Withdrawal and exclusion criteria

(1) Patients taking the Chinese herbal medicine for less than 7 days;

(2) Patients who use other medications outside the study protocol in violation of trial requirements;

(3) Patients with irregular medication adherence or who voluntarily withdraw from the trial;

(4) Patients lost to follow-up or deceased.

2.6. Treatment methods

2.6.1. Control group

Treated with Fluticasone Furoate/Umeclidinium/Vilanterol Inhalation Powder. Usage: Fluticasone Furoate/Umeclidinium/Vilanterol Inhalation Powder (Relvar Ellipta; Manufacturer: Glaxo Operations UK Limited; Approval Number: Import Drug Registration Certificate No. H20190055; Batch Number: DL2F; Specification: 100 μg: 62.5 μg: 25 μg). Administer one inhalation once daily. The treatment course lasted for 8 weeks, with a follow-up period of 6 months after treatment completion.

2.6.2. Treatment group

Received additional traditional Chinese medicine (TCM) treatment based on TCM constitution theory, in addition to the control group treatment.

(1) Phlegm-dampness constitution group

Erchen Decoction combined with Sanzi Yangqin Decoction. Composition: *Pinelliae Rhizoma Praeparatum* 15 g, *Citri Reticulatae Pericarpium* 10 g, Poria 15 g, *Glycyrrhizae Radix et Rhizoma Praeparata* cum Melle 5 g, *Zingiberis Rhizoma Recens* 10 g, P*erillae Fructus* 15 g, *Descurainiae Semen Lepidii Semen* 10 g, *Raphani Semen* 15 g.

(2) Qi-deficiency constitution group

Sijunzi Decoction Composition: *Codonopsis Radix* 15 g, Poria 15 g, *Atractylodis Macrocephalae Rhizoma Praeparatum* 15g, *Glycyrrhizae Radix et Rhizoma Praeparata cum Melle* 5 g, *Astragali Radix* 15 g.

(3) Yang-deficiency constitution group

Sini Decoction. Composition: *Aconiti Lateralis Radix Praeparata* 10 g, *Zingiberis Rhizoma* 10 g, *Glycyrrhizae Radix et Rhizoma Praeparata cum Melle* 5 g, *Epimedii Herba* 15 g, *Morindae Officinalis Radix* 15 g.

(4) Dampness-heat constitution group

Gegen Qinlian Decoction Composition: Puerariae Lobatae Radix 15 g, *Scutellariae Radix* 10 g, *Coptidis Rhizoma* 10 g, *Glycyrrhizae Radix et Rhizoma Praeparata cum Melle* 5 g, Houttuyniae Herba 15 g, Mori Cortex 15 g.

(5) Blood-stasis constitution group

Taohong Siwu Decoction. Composition: *Persicae Semen* 10 g, *Carthami Flos* 10 g, *Rehmanniae Radix*

Praeparata 15 g, *Paeoniae Radix Rubra* 10 g, *Angelicae Sinensis Radix* 10 g, *Chuanxiong Rhizoma* 10 g.

The above TCM herbs were provided by Sichuan Provincial Chinese Herbal Pieces Co., Ltd. as decoction pieces. Administration: One dose daily, decocted in water and taken warm 30 minutes after meals. The treatment course lasted for 8 weeks, with a follow-up period of 6 months after treatment completion.

2.7. Observation indices

2.7.1. TCM syndrome score

A TCM syndrome scoring scale was formulated according to the Criteria for Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine [10]. Symptoms were graded based on severity into four levels: none, mild, moderate, and severe, corresponding to scores of 0, 1, 2, and 3 points respectively. Four primary symptoms were scored: cough, expectoration (sputum production), wheezing, and shortness of breath. Changes in the TCM syndrome scores of patients in both groups before and after treatment were observed.

2.7.2. Pulmonary function testing

Pulmonary function testing was performed on patients by specialized respiratory medicine staff. Changes in the following parameters before and after treatment in both groups were observed: Forced Expiratory Volume in one second (FEV1), Forced Vital Capacity (FVC), and the FEV1/FVC ratio.

2.7.3. Exercise tolerance measurement

The 6-minute walk test (6MWT) was used to measure patients' exercise tolerance. Tests were conducted by specialized respiratory medicine staff. Changes in the 6MWT distance for patients in both groups before and after treatment were observed [11].

2.7.4. Inflammatory factor detection

Fasting venous blood samples were collected from patients' antecubital veins in the early morning. Changes in the levels of inflammatory factors, including Interleukin-6 (IL-6) and high-sensitivity C-reactive protein (hs-CRP), were observed in both groups before and after treatment. Testing was performed by our hospital's central laboratory: IL-6 was measured using Enzyme-Linked Immunosorbent Assay (ELISA), and hs-CRP was measured using immunoturbidimetry.

2.7.5. Dyspnea severity assessment

The COPD Assessment Test (CAT) score was used to assess the severity of patients' dyspnea. A higher score indicates more severe dyspnea. Changes in the CAT scores of patients in both groups before and after treatment were observed [12].

2.7.6. Incidence of exacerbation/relapse

Patients were followed up for 6 months. Cases meeting the diagnostic criteria for an acute exacerbation period were defined as relapses. The acute exacerbation rates were compared between the two groups.

2.7.7. Safety evaluation

Adverse events occurring during treatment in both groups were recorded. Changes in safety indices such as

blood routine tests, liver function, and kidney function were observed. The safety of both treatment regimens was evaluated.

2.8. Statistical methods

Statistical analysis was performed using SPSS software (version 26.0). Continuous variables that were normally distributed are presented as mean ± standard deviation (SD). Comparisons within groups before and after treatment were analyzed using the paired *t*-test. Comparisons between groups were analyzed using the independent samples *t*-test. Continuous variables that deviated from a normal distribution are presented as median and interquartile range [M (P25, P75)]. These were analyzed using non-parametric tests (Mann-Whitney U test for between-group comparisons; Wilcoxon signed-rank test for within-group comparisons). Categorical data are presented as frequencies or percentages and were compared between groups using the Chi-square (χ^2) test. All tests were two-tailed. A p-value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of baseline characteristics between the two groups

The treatment group comprised 150 patients: 80 males and 70 females; age range 51–80 years, mean age 66.12 ± 7.02 years; mean disease duration 11.15 ± 3.05 years; GOLD (Global Initiative for Chronic Obstructive Lung Disease) pulmonary function grades: Grade II: 66 cases, Grade III: 84 cases. The control group comprised 150 patients: 89 males and 61 females; age range 50–79 years, mean age 66.05 ± 5.97 years; mean disease duration 10.36 ± 3.21 years; pulmonary function grades: Grade II: 80 cases, Grade III: 70 cases. Comparisons of baseline characteristics, including gender, age, disease duration, and pulmonary function grade, between the two groups showed no statistically significant differences ($p > 0.05$), indicating comparability.

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

The results presented show that before treatment, there were no statistically significant differences ($p > 0.05$) in the TCM syndrome scores for cough, expectoration (sputum production), wheezing, and shortness of breath between the two groups.

After treatment, both groups showed significant improvements ($p < 0.05$) in the TCM syndrome scores for cough, expectoration, wheezing, and shortness of breath compared to their respective pre-treatment scores. Furthermore, the magnitude of improvement in each TCM syndrome score was significantly greater in the treatment group compared to the control group, with all differences being statistically significant ($p < 0.05$ or $p < 0.01$).

3.3. Comparison of pulmonary function indices between the two groups before and after treatment

The results presented show that before treatment, there were no statistically significant differences ($p > 0.05$) in pulmonary function indices, including FEV1, FVC, and FEV1/FVC, between the two groups.

After treatment, both groups showed significant improvements ($p < 0.05$) in FEV1, FVC, and FEV1/FVC compared to their respective pre-treatment values. Furthermore, the magnitude of improvement in FEV1 was

significantly greater in the treatment group compared to the control group, with a statistically significant difference ($p < 0.05$). However, there were no statistically significant differences between the two groups in the improvement of FVC or FEV1/FVC ($p > 0.05$).

3.4. Comparison of inflammatory markers between the two groups before and after treatment

The results presented show that before treatment, there were no statistically significant differences ($p > 0.05$) in serum levels of high-sensitivity C-reactive protein (hs-CRP) or interleukin-6 (IL-6) between the two groups.

After treatment, serum levels of hs-CRP and IL-6 decreased significantly compared to pre-treatment levels in both groups ($p < 0.05$). Furthermore, the magnitude of reduction (decrease) in serum hs-CRP and IL-6 levels was significantly greater in the treatment group than in the control group, and these differences were statistically significant ($p < 0.01$).

3.5. Comparison of 6MWT distance and CAT scores between the two groups before and after treatment

The results presented show that before treatment, there were no statistically significant differences ($p > 0.05$) in the 6-minute walk test (6MWT) distance or COPD Assessment Test (CAT) scores between the two groups. After treatment, both groups showed significant improvements ($p < 0.05$) in 6MWT distance and CAT scores compared to their respective pre-treatment values. Furthermore, the magnitude of improvement in both 6MWT distance and CAT scores was significantly greater in the treatment group than in the control group, and these differences were statistically significant ($p < 0.05$ or $p < 0.01$).

3.6. Comparison of acute exacerbation incidence between the two groups

The results presented show that all patients completed the 6-month follow-up period. In the control group: There were 62 episodes of acute exacerbation (occurring in 41 patients), resulting in an acute exacerbation incidence rate of 41.3%. Among these exacerbations:18 episodes were mild acute exacerbations that occurred during the treatment period and were resolved with outpatient management. The remaining 44 episodes occurred during the follow-up period. In the treatment group: There were 13 episodes of acute exacerbation (occurring in 13 patients), resulting in an acute exacerbation incidence rate of 8.7%. All exacerbations occurred during the follow-up period. Comparison between groups revealed that the acute exacerbation incidence rate was significantly lower in the treatment group than in the control group, with a statistically significant difference ($p < 0.05$).

3.7. Safety evaluation

During the treatment period, no significant adverse events occurred in either group. Furthermore, safety parameters, including complete blood count (CBC), liver function, and kidney function, remained within normal ranges for all patients.

4. Discussion

Clinically, COPD progresses through distinct phases: the acute exacerbation period, the high-risk window period for exacerbation, and the stable period [13]. The high-risk window period refers to the interval following the

resolution of an acute exacerbation but before achieving stable disease. During this phase, the patient's condition is highly unstable, with a substantial likelihood of recurrent acute exacerbations, which consequently increases hospitalization rates and mortality [14]. While conventional Western medical therapy has not demonstrated a significant ability to halt the progression of COPD in patients, Traditional Chinese Medicine (TCM), guided by its Holistic Concept and the theory of Syndrome Differentiation and Treatment, offers a complementary approach. TCM intervention not only alleviates clinical symptoms and improves quality of life in the short term but also, in the long term, reduces the frequency of acute exacerbations and ameliorates pulmonary structural damage. Thereby, it prevents further disease progression, embodying the fundamental TCM principle of preventing disease before it occurs, preventing deterioration in existing disease, and preventing relapse after recovery.

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Disclosure statement

The authors declare no conflict of interest.

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