



The effective evaluation on symptoms and quality of life of chronic obstructive pulmonary disease patients treated by comprehensive therapy based on traditional Chinese medicine patterns[☆]



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KEYWORDS

Chronic obstructive pulmonary disease;
Tradition Chinese medicine pattern;
Quality of life;
Bu-Fei Jian-Pi granules;

Summary

Objective: To evaluate the efficacy of comprehensive interventions based on the three TCM patterns on symptoms and quality of life of COPD patients.

Design: An open-label, randomized, controlled trial.

Setting: Four hospitals in China.

Intervention: 352 patients were randomly divided into two groups. Patients in the trial group were given conventional Western medicine and Bu-Fei Jian-Pi granules, Bu-Fei Yi-Shen granules and Yi-Qi Zi-Shen granules respectively; patients in the control group were given conventional Western medicine. Data collection was performed at baseline, in the 3rd and 6th month during the treatment period, and the 12th month during the follow-up period.

Abbreviations: COPD, chronic obstructive pulmonary disease; TCM, traditional Chinese medicine; FVC, forced vital capacity; FEV1, forced expiratory volume in one second; FEV1%, FEV1 percentage of predicted value; QOL, quality of life; FAS, full analysis set; PPS, per-protocol analysis set.

[☆] This trial was registered at Chinese Clinical Trial Register, ChiCTR-TRC-11001406.

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Bu-Fei Yi-Shen granules;
Yi-Qi Zi-Shen granules

Outcomes: Symptoms, including cough, sputum, pant, chest tightness, short of breath, lassitude, cyanosis and symptom total score; quality of life, measured by the WHOQOL-BREF questionnaire and adult COPD quality of life questionnaire (COPD-QOL).

Results: Of the 352 patients, 306 fully completed the study. After treatment and follow-up, there were significant differences between two groups in the following: cough, sputum, pant, chest tightness, shortness of breath, lassitude score and symptom total score ($P < .05$); physical, psychological, social and environment domain ($P < .05$) of the WHOQOL-BREF; daily living ability, social activity, depression symptoms and anxiety symptoms domain ($P < .05$) of the COPD-QOL. There were no differences between two groups in cyanosis and adverse events.

Conclusion: Based on the TCM patterns, Bu-Fei Jian-Pi granules, Bu-Fei Yi-Shen granules and Yi-Qi Zi-Shen granules have beneficial effects on symptoms and quality of life of COPD patients. © 2013 Elsevier Ltd. All rights reserved.

Introduction

Chronic obstructive pulmonary disease (COPD) with high prevalence, morbidity, mortality and economic burdens, is a global public health problem.¹ The overall prevalence of COPD in China is 8.2% in individuals 40 years of age or older.² And an estimated 65 million people will die of COPD between 2003 and 2033 in China.³ COPD patients face functional decline and daily life limitations due to the slowly progressive course of breathing discomfort, which can cause dependence, depression, anxiety, and other psychological disturbances overtime.⁴ One of the therapeutic goals for COPD management is to improve symptoms and health-related quality of life (HRQOL).⁵

Chronic airway obstruction and airflow limitation are the key physiological characteristics, and the main symptom is breathlessness, although other symptoms such as lassitude and depression are common.^{6,7} However, in an early or stable state, breathlessness is not obvious and often overlooked by patients and physicians.⁸ In practice the decision to seek medical help is usually determined by the effect of a symptom on a patient's daily life. Therefore, evaluation of the symptom is important to understand health status and to evaluate effects of clinical intervention.⁹ HRQOL is a multidimensional concept that includes physical, psychological and social function and well-being.^{10,11} In the last decade, the evaluation of QOL has been an important outcome measure and assessment tool in COPD research and treatment.¹² Although lung function is often used as an index of COPD severity,⁵ it is not necessarily linked to symptoms, disability or HRQOL; indeed, HRQOL appears more closely linked to the respiratory symptoms than lung function.^{13,14}

The remarkable longevity of traditional Chinese medicine (TCM) for COPD implies its potential advantages.^{15,16} However, there is limited evidence concerning specific symptoms and disease-specific QOL based on comprehensive TCM interventions that responded to the TCM patterns. According to our previous study, there are three common TCM patterns of stable COPD, and there is one specific herbal intervention responding to each pattern.¹⁷ Therefore, a multi-center randomized controlled study had been carried out to evaluate the efficacy of comprehensive interventions based on the three TCM patterns on COPD patients' symptoms and QOL.

Methods

Participants

Patients included should meet the following inclusion criteria: met the diagnostic criteria of COPD;^{7,18} met the TCM pattern criteria of COPD¹⁹ (pattern of lung-spleen qi deficiency, pattern of lung-kidney qi deficiency, pattern of lung-kidney qi and yin deficiency); were stable and met the diagnosis of mild to severe COPD (Global Initiative for Chronic Obstructive Lung Disease, GOLD 1,2,3); aged between 40 and 80 years; no experience in other intervention trials in the previous month; received the treatment voluntarily and signed informed consent. COPD patients were excluded if they had confusion, dementia or any type of mental illness; acute exacerbation of COPD or very severe COPD (GOLD 4); bronchial asthma, or bronchiectasis, or active tuberculosis, pulmonary embolism, or diffuse pan-bronchiolitis; serious diseases such as tumor, heart failure, liver and kidney diseases, or haematopoietic system diseases; allergic to treatment drugs.

Ethical review and entry procedure

The study was approved by the Ethical Research Committees of The First Affiliated Hospital of Henan University of TCM (batch number: YFYKTL2007-1). Patients were enrolled from out-patient department and through open recruitment. Patients were observed in the First Affiliated Hospital of Henan University of TCM, Jiangsu Provincial Hospital of TCM, Henan Provincial People's Hospital and the Affiliated Hospital of Shandong University of TCM. All patients signed informed consent before inclusion.

Sample size

The frequency of acute exacerbation was considered as the primary outcome. From a previous study, the exacerbation frequency decreased by 0.44 times half year,²⁰ then exacerbation frequency decreased at least by 1 time and the standard deviation was 1.5 times/year were assumed to reflect the efficacy of TCM comprehensive interventions. The formulae $((2(\mu_\alpha + \mu_\beta)\sigma^2)/\delta^2)$ was based on a comparison between the equal numbers of a two sample mean. The

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