JTCM
中医杂志
Journal of Traditional Chinese Medicine

Online Submissions: http://www.journaltcm.com
info@journaltcm.com

J Tradit Chin Med 2015 February15; 35(1): 1-10
ISSN 0255-2922

SYSTEMATIC REVIEW

Chinese patent medicine for chronic obstructive pulmonary disease based on principles of tonifying *Qi*, promoting blood circulation by removing blood stasis, and resolving phlegm: a systematic review of randomized controlled trials

Liu Wei, Yang Shuang, Fu Min, Li Jian, Song Yaling, Wei Baolin, Liu Enshun, Sun Zengtao

Liu Wei, Department of Integrated Traditional Chinese and Western Medicine, West China Hospital of Sichuan University, Chengdu 610041, China
Yang Shuang, Fu Min, Li Jian, Song Yaling, Wei Baolin, Liu Enshun, Sun Zengtao, Department of Respiratory Medicine, the Secondary Affiliated Hospital of Tianjin Traditional Chinese Medicine University, Tianjin 300150, China
Supported by International Science & Technology Cooperation Program of China (No. 2011DFA32750)
Correspondence to: Prof. Sun Zengtao, Department of Respiratory Medicine, the Secondary Affiliated Hospital of Tianjin Traditional Chinese Medicine University, Tianjin 300150, China. lovekk_cool@126.com
Telephone: +86-15308095761
Accepted: February 22, 2014

Abstract

OBJECTIVE: To assess the efficacy and safety of Chinese patent medicine (CPM) with the principle of tonifying *Qi*, promoting blood circulation by removing blood stasis, and resolving phlegm (TQ-PBC-RP) in the management of stable chronic obstructive pulmonary disease (COPD).

METHODS: A systematic review of randomized controlled trials (RCTs) identified from electronic databases and print was conducted. RCTs testing CPMs with TQ-PBC-RP against any type of controlled intervention in patients with stable COPD and assessing clinically relevant outcomes were included. Methodological quality was evaluated with the risk of bias tool according to systematic review handbook 5.0.2. Quality of evidence was estimated by the rating approach developed by the Grading of Recommendations, Assessment, Development, and Evaluation Working Group.

RESULTS: Thirteen eligible RCTs with 12 oral CPMs were tested. Significant differences between groups in favor of CPMs were not reported in all trials. Most trials included were deemed to be of low methodological quality with poor evidence quality. Because of large data heterogeneity, statistical pooling was not performed for all outcomes.

CONCLUSION: The effectiveness of CPM in the treatment of stable COPD is not supported by evidence. Currently, evidence from RCTs is scarce and methodologically weak. Considering the popularity of CPMs among patients undergoing COPD, rigorously designed trials are warranted.

Key words: Medicine, Chinese traditional; Pulmonary disease, chronic obstructive; Randomized controlled trial; Review; Reinforcing *Qi*-activating blood; Blood-activating stasis-removing

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a major public health problem, and contributes to enormous economic and social burdens.[1,2] COPD was the fourth-leading global cause of death in 1990[3] but rose to the third by 2010.[4] The burden on patients and society imposed by COPD is more severe in China and

other developing countries.[5,6] Routine Western Medicine (WM) for stable COPD mainly involves inhaled bronchodilators and corticosteroids, which can improve clinical symptoms, but fail to prevent the further decline of lung function and repeated exacerbations. Moreover, inevitable adverse events (AEs) and high costs result in clinical limitations of WM. Therefore, the number of stable COPD patients who fall back on Traditional Chinese Medicine (TCM) as a complementary and alternative treatment is increasing steadily in both China and some other Asian countries.[7]

In the thousands of years before the introduction of WM to China, Chinese people relied on TCM for disease treatment. In modern society, TCM is indispensable for treating COPD, justified through positive evidence from plentiful classic literature, case reports, and clinical trials.[8-11] In TCM theory, the fundamental pathological factors involved in stable COPD are theorized to be *Qi* deficiency, blood stasis, and phlegm turbidity, which can reciprocally result in COPD and mutually infiltrate the lungs.[12-14] Therefore, the principle of tonifying *Qi*, promoting blood circulation by removing blood stasis, and resolving phlegm (TQ-PBC-RP) has been developed to treat each pathogenic factor. Compared with herbal decoctions, proprietary CPMs are more convenient to eat and take along. Many studies have shown promising effects of TQ-PBC-RP CPMs on the improvement of clinical COPD symptoms and quality of life, and reductions in exacerbations and mortalities of COPD. In addition, these CPMs were demonstrated to effectively prevent declining lung function.[15,16]

Many systematic reviews have been conducted to assess the efficacy and safety of TCM in the management of stable COPD.[17] However, no studies have examined CPMs that treat based on specific principles. Therefore, we aimed to assess the efficacy and safety of TQ-PBC-RP CPMs in the treatment of stable COPD. This review is expected to provide more evidence-based information for the clinical use of CPMs.

MATERIALS AND METHODS

Search strategy

The following electronic databases were searched for articles from their individual inceptions to December 31st, 2012: Chinese National Knowledge Infrastructure Database (CNKI), Wanfang Database, Excerpta Medica Database (EMBASE), MEDLINE (PubMed), China Science and Technology Journal Database (VIP), China Biology Medicine disc (CBMdisc), Google Scholar, and Cochrane Collaborative Library.

Search strategies were tailored respectively to comply with each database, and no language restrictions were applied. Search terms included: "chronic obstructive pulmonary disease," "herbal medicine," "Chinese patent medicine," "Traditional Chinese Medicine," and relevant derivatives were used individually or combined. We also contacted authors and manufacturers for more information including unpublished data. Moreover, manual searching for bibliographies of all retrieved trials, relevant peer-reviewed journals, conference proceedings, and unpublished studies was conducted.

Eligibility criteria

To be eligible for inclusion, a trial needed to: (a) involve patients with COPD confirmed by post-bronchodilator spirometry of forced expiratory volume in 1 second (FEV_1) / forced vial capacity (FVC) ratio of < 70% and a FEV_1% of < 80%, in any age, gender, profession, or ethnicity and without severe heart, renal, or hepatic failure; (b) be randomized and controlled, regardless of blinding; (c) include a head-to-head comparison of TQ-PBC-RP CPM in oral administration, combined or not combined with WM, *vs* WM alone, placebo, or no treatment; (d) propose TQ-PBC-RP as prescription principle of CPM used in the trial group and illustrate every single herbal component; (e) report at least one of the following outcomes: primary outcomes: spirometric parameters; total effective rate, defined as a reduction rate of symptom scores (cough, cough-up phlegm, dyspnea, wheezing, or other lung symptoms) ≥ 30% according to the Guiding Principle of Clinical Research on New Drugs of TCM;[18,19] secondary outcomes: quality of life (QoL) score; and adverse events.

Study selection

Duplicate studies resulting from various databases were removed by two reviewers (Song Yaling and Li Jian). The other two reviewers (Liu Wei and Yang Shuang) screened the titles and abstracts of all remaining citations independently to exclude articles that obviously did not satisfy the inclusion criteria and then scrutinized the full text of any article that was deemed to be potentially eligible. Finally, the selection results were discussed together by the four reviewers. Any disagreement about study eligibilities after discussion was resolved by consulting the fifth reviewer (MF).

Data extraction

Data concerning study design, participants, interventions, follow-up, herbal composition, outcomes, and AEs were extracted by two reviewers independently (Liu Wei and Yang Shuang) and checked by a third party (MF). Missing information from one trial[20] was requested by contacting the original author by e-mail. To date, no response has been received. Therefore, it was not included.

Quality assessment

Two reviewers (LW and YS) evaluated the risk of bias of included RCTs separately using a detailed list of quality items recommended by the Cochrane Systematic Review Handbook 5.1.0.[21] Information on method-