



A systematic review and meta-analysis of the herbal formula Buzhong Yiqi Tang for stable chronic obstructive pulmonary disease



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ABSTRACT

Objective: To systematically evaluate the efficacy and safety of Buzhong Yiqi Tang (BZYQT) for stable chronic obstructive pulmonary disease (COPD).

Methods: Three electronic English databases (PubMed, EMBASE and CENTRAL) and four Chinese databases (CBM, CNKI, CQVIP and WFM) were searched from their inception until 30th June 2016. Participants were diagnosed with COPD according to the Chinese Medical Association's COPD diagnosis and treatment guidelines or Global Initiative for Chronic Obstructive Lung Disease (GOLD), and were in stable stage. Randomized controlled trials (RCTs) of oral BZYQT, alone or combined with conventional treatment, compared with conventional treatment alone or plus placebo were included in the review. Clinical improvement and the six-minute walking test (6MWT) were the primary outcome measures. The secondary outcome measures were defined as forced expiratory volume in one second (FEV1), forced vital capacity (FVC), respiratory muscle strength index with maximum inspiratory pressure (MIP), COPD Assessment Test (CAT), and frequency of acute exacerbations. To assess risk of bias the Cochrane, Risk of Bias tool was used, and statistical analysis was performed using RevMan 5.3.0 software.

Results: Sixteen studies (1400 participants) were included. The results of meta-analysis indicated patients receiving BZYQT alone or BZYQT in combination with conventional treatment showed a significant increase in clinical improvement (RR 1.25, 95% CI 1.18 to 1.33, $I^2 = 0\%$), enhanced exercise capacity 6MWT (MD 51.22 m, 95% CI 45.56 to 56.89, $I^2 = 44\%$), improved lung function FVC (L) (MD 0.26 liters, 95% CI 0.18 to 0.33, $I^2 = 37\%$), reduced respiratory muscle fatigue MIP (MD 0.46 liters, 95% CI 0.11 to 0.80, $I^2 = 0\%$), and improved quality of life CAT (MD -2.56 points, 95% CI -3.40 to -1.72, $I^2 = 0\%$) when compared with conventional treatment alone, or plus placebo. BZYQT also showed small but significant improvements in FEV1% and decreased acute exacerbations of COPD. Four studies reported that no adverse events occurred, other studies did not mention adverse events. The finding should be considered with caution because the included studies had methodological shortfalls.

Conclusions: BZYQT improves clinically important outcomes for patients with stable COPD, such as improved clinical symptoms, exercise capacity, lung function and quality of life. Moreover, it has an excellent safety profile. However further evaluation is needed to validate these preliminary findings in high quality RCTs.

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Abbreviations: BZYQT, Buzhong Yiqi Tang; COPD, chronic obstructive pulmonary disease; CENTRAL, Cochrane Central Register of Controlled Trials; CBM, Chinese Biomedical Database; CNKI, China National Knowledge Infrastructure; CQVIP, ChongQing VIP; WFM, Wanfang Medicine Online; RCTs, randomized controlled trials; GOLD, Global Initiative for Chronic Obstructive Lung Disease; 6MWT, six-minute walking test; FEV1, forced expiratory volume in one second; FVC, forced vital capacity; MIP, maximum inspiratory pressure; MCID, minimal clinically important difference; RevMan, Review Manager; MD, mean difference; 95% CI, 95% confidence intervals; TCM, traditional Chinese medicine.

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1. Introduction

With the acceleration of urbanization and industrialization, air pollution is increasingly contributing to airways conditions like chronic obstructive pulmonary disease (COPD). Air pollution and smoking have contributed to approximately 127 million or 10% of people worldwide with COPD.¹ Prevalence is expected to increase and COPD is predicted to be the third leading cause of death by 2030.²

In countries such as China, COPD is treated by combining drug therapies with herbal medicine, referred to as 'integrative medicine'. Recent systematic reviews show that integrative medicine can improve clinical symptoms, quality of life, exercise capacity, reduce respiratory muscle fatigue and frequency of acute exacerbations compared with drug therapy alone.³ Positive effects of integrative medicine have led to an increase in clinical trials on specific herbal medicine combinations, also known as herbal formula.

Experts in Chinese herbal medicine treatment, suggest traditional Chinese medicine (TCM) offers promising advantages to stable COPD,⁴ and studies have shown that herbal medicine (including Chinese medicine and medicinal plants) are effective at relieving COPD symptoms, especially in the stable period.^{5,6}

One promising formula of TCM is Buzhong Yiqi Tang (BZYQT), which was developed by Dongyuan Li, AD 1180–1251.⁷ Since then BZYQT has been widely used in Chinese medicine for several conditions, including respiratory conditions, and is now available in different high quality formulations such as granule, pill, capsule and oral liquid. In Chinese medicine theory, BZYQT is a tonic formula which has the effect of tonifying the middle, replenishing and raising qi. Therefore, it can benefit respiratory and digestive functions. It has reported therapeutic effects in the treatment of stable COPD,⁷ however its full therapeutic and safety profile have not been evaluated systematically. A comprehensive search and analysis of randomized controlled trials was therefore conducted to assess the effect(s) of BZYQT in stable COPD.

2. Methods

2.1. Search strategy

Search of English and Chinese databases was performed. Databases included PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), Chinese Biomedical Database (CBM), China National Knowledge Infrastructure (CNKI), ChongQing VIP (CQVIP), and Wanfang Medicine Online (WFM), from their inception until 30th June 2016.

Terms used to search the databases were divided into three groups: condition (COPD, chronic bronchitis, emphysema, and their synonyms); intervention (Traditional Medicine, Chinese Herbal Drugs, Buzhong Yiqi, sovereign and minister medicinals of BZYQT, and their synonyms), and study type (controlled clinical trial and synonyms) (Table 1). All the search results were downloaded and combined, and duplicates removed.

2.2. Inclusion criteria

Inclusion criteria were: (1) RCTs published in English or Chinese, with or without blinding; (2) participants diagnosed with COPD according to the Chinese Medical Association's diagnosis and treatment guidelines or Global Initiative for Chronic Obstructive Lung Disease (GOLD), with stable COPD and no recent infections, acute exacerbations or emergency hospitalizations; (3) BZYQT was defined as the original formula with the herbs milkvetch root, ginseng, white atractylodes, liquorice root, Chinese angelica, dried tangerine peel, large trifoliate bugbane rhizome, Chinese thorowax root, or a modified form based on BZYQT which need to have at least the sovereign medicinal (milkvetch root) and minister medicinals (ginseng and white atractylodes), administered orally (decoction, powder, liquid, or capsule/pill); Conventional treatments included expectorants, bronchodilators, inhaled corticosteroids, or their combinations. (4) BZYQT was given alone or combined with conventional treatment, and compared with conventional treatment or plus placebo (where the same intervention

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