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Sanfu acupoint herbal patching for stable asthma: A systematic review and meta-analysis of randomised controlled trials

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ABSTRACT

Background: Sanfu acupoint herbal patching (SAHP) is extensively used in people with stable asthma in China. However, the evidence available is scarce. This systematic review aims to evaluate the preventive and therapeutic effect and safety of SAHP in people with stable asthma.
Methods: We searched seven electronic databases for randomised controlled trials (RCTs). The Cochrane risk of bias tool was utilised to evaluate the methodological quality of the included studies and RevMan 5.3 and GRADEpro 3.6.1 were applied to perform data analyses.
Results: A total of 34 RCTs involving 3313 participants were included. The overall methodological quality of the trials was of high risk of bias. SAHP plus conventional therapy (CT) decreased the mean frequency (times per year) of asthma exacerbations compared with CT alone (MD: −1.42; 95% CI: −2.19 to −0.65; 7 RCTs), and similar effect was found for SAHP versus sham SAHP (MD: 0.42; 95%CI: 0.26–0.69; 1 RCT). For lung function (including PEF%, FEV_1% and FEV_1/FVC), SAHP plus CT showed better effect than CT alone, and so did SAHP versus sham SAHP on PEF and PEF%. Adverse effects in the SAHP groups were reported to be mild and well tolerated.
Conclusions: **S**AHP alone or combined with CT appears to be more effective than sham SAHP or CT on reduction of asthma exacerbations, improving lung function, and SAHP seems to be safe. However, the findings should be interpreted with caution due to limitations in trial quality. Further, rigorously designed, large-scale trials are warranted for robust evidence.

Contents

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1. Introduction

Asthma is defined as a chronic airway inflammation with variable expiratory airflow limitation and a history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity.[1] The prevalence of asthma in adults was estimated to be 4.3%, ranging from 0.2% in China to 21.0% in Australia.[2] It's still increasing in many parts of the world from 300 millions up to 400 million by 2025.[3] The burden of asthma is similar to that of diabetes or Alzheimer disease when calculating disability-adjusted life years.[4] Moreover, when the asthma symptoms are uncontrolled, or one or more severe exacerbation happened in last 12 months, this could increase the risk of recurrence of the next exacerbation.[5,6] This vicious circle might increase the risk of asthma related death.[7] Therefore, treatment and management of stable asthma to prevent acute exacerbation are critical.

Currently, conventional therapy (CT) for stable asthma includes pharmacological and non-pharmacological interventions. Pharmacological medications mainly include corticosteroids, beta$_2$-agonists, leukotriene receptor antagonist and sustained-release theophylline for control and relief of asthmatic symptoms. However, inappropriate use of inhaler technique[8] and poor adherence[9] are the major problems. On the other hand, besides the avoidance of exposure to allergens and air pollution, non-pharmacological interventions are often used including allergen immunotherapy, bronchial thermoplasty and vaccines. However, it should take into account the risk of adverse effects, the inconvenience and cost of the prolonged course of the therapy.[1]

In China, the use of acupoint herbal patching (AHP, also called as acupuncture point application therapy) in asthma management was first recorded in *Zhang Shi Yi Tong* in *Qing* Dynasty (1644–1912),[10] and is still in popular use nowadays. As a traditional Chinese medicine (TCM) technique, *Sanfu* AHP (SAHP) is the external application of processed medicinal herbal preparations directly to specific acupuncture points (acupoints), only during the *sanfu* period to produce preventive and/or therapeutic effects. According to the Lunar calendar, *fu* refers to the hottest period of the year between mid-July to mid-August, lasting 30 to 40 days. Each ten days is called one *fu*, and three *fus* are called as *sanfu*. SAHP is a comprehensive intervention that comprises percutaneous absorption of applied herbal extracts, stimulation and regulation of meridians and acupoints.

According to TCM theory, usually, asthma is attributed to lung obstructed by long-retained phlegm. [11] When exogenous pathogenic, improper diet, emotional disturbance, over strain attack patient could make asthma recurrence.[11] TCM also believe lung, spleen and kidney are related to immunology functions; while AHP might regulate these three organs (*Zangfu)* through herbs absorption and meridians stimulation.[12,13] AHP contains herbs with acrid-warm and penetrating flavor which might warm the lung, remove phlegm, facilitate *qi* flow, dissolve masses, dredge the collaterals. Additionally, because *sanfu* is of special significance in TCM when *yang* (a moral connotation of light)[14] in human body is the strongest,[12] it is considered as most effective when AHP is applied during *sanfu* period. A study found that SAHP could reduce the IL-4, and increase IFN-γ significantly which might be the one of the mechanisms of asthma management.[15] A systematic review of six trials published in 2015 showed a positive effect of AHP only on immune outcomes for children with asthma.[16] Another review of 16 RCTs published recently with insufficient searches and mainly focusing on pulmonary function showed encouraging but inconclusive effect. [17]

For this review, we included much larger number of trials (34 RCTs), and evaluated the preventive and therapeutic effect and safety of SAHP alone or in combination with CT for stable asthma, using patient related outcomes such as asthma exacerbations.

2. Methods

This review was prepared according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[18]

2.1. Protocol and registration

The protocol registration number was CRD42015019337 (http://www.crd.york.ac.uk/Prospero).

2.2. Eligibility criteria

We included randomised controlled trials (RCTs) (parallel-group, cross-over or cluster) using SAHP in stable asthma regardless of blinding, publication type or language. Quasi-randomised trials were excluded. Participants included both children and adults with stable asthma (not during exacerbation) regardless of gender, etiology, ethnic, and course of the disease. Interventions included all types of SAHP alone or in combination with conventional therapy (CT) and/or biological agents. CT means that prevention and treatment of stable asthma is based on the Global Strategy for Asthma