JTCM 中医杂志 Journal of Traditional Chinese Medicine

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J Tradit Chin Med 2017 August 15; 37(4): 522-529
ISSN 0255-2922

RESEARCH ARTICLE

Prescriptions from Traditional Chinese Medicine compared with salbutamol and montelukast for the treatment of pediatric asthma: a randomized controlled trial

Du Hui, Wang Yonghong, Yu Jian, Shi Yumin, Li Suhuan, Sun Wen, Zhang Yiqun, Hu Hong

Du Hui, Wang Yonghong, Yu Jian, Shi Yumin, Li Suhuan, Sun Wen, Zhang Yiqun, Hu Hong, Department of Traditional Chinese Medicine, Children's Hospital of Fudan University, Shanghai 201102, China

Supported by a Major Research Project of Shanghai Traditional Chinese Medicine Three-year Action Plan (No. ZYS-NXD-CC-ZDYJ034), Shanghai Science and Technology Research Program (No. 12401905500) and a Development Project of Shanghai Peak Disciplines-Integrated Chinese and Western Medicine (No. 20150407)

Correspondence to: Prof. Wang Yonghong, Department of Traditional Chinese Medicine, Children's Hospital of Fudan University, Shanghai 201102, China. wyhekyy@126.com
Telephone: +86-18017591038

Accepted: September 21, 2016

Abstract

OBJECTIVE: To compare the effects of a series of Traditional Chinese Medicine (TCM) empirical prescriptions with salbutamol and montelukast (SM) in children with asthma.

METHODS: A total of 182 children with asthma were randomized into the TCM group (n = 97) or SM group (n = 85). Patients in the TCM group were treated with a series of TCM prescriptions, whereas those in the SM group received salbutamol and montelukast; both groups received their respective treatment for 12 weeks. Asthma control, changes in scores of TCM symptom patterns, and asthma symptom control (SC) scores after treatment were compared between the two groups.

RESULTS: A higher percentage of patients in the TCM group had asthma control compared with those in the SM group (91.67% and 76.83%, respectively, P = 0.006). Scores for abnormal feces (P < 0.001), hyperhidrosis (P < 0.001), and tongue appearance (P = 0.001) in the TCM group were significantly better than those in the SM group. However, the total scores of TCM symptom patterns and SC scores did not differ significantly between the two groups (P > 0.05).

CONCLUSION: Compared with salbutamol and montelukast, the TCM prescriptions tested were better for symptom control in children with asthma.

Keywords: Asthma; Albuterol; Feces; Hyperhidrosis; Abnormal tongue presentations; Syndrome differentiation; Chinese medical formula; Randomized controlled trial

INTRODUCTION

Asthma is a relatively common chronic respiratory disease in children. The worldwide annual incidence of pediatric asthma has increased in recent years.[1] If exposed to physical, chemical, or biologic factors, children with asthma are prone to airflow limitation, resulting in recurrent episodes of wheezing, cough, and dyspnea, which are often exacerbated during the night and early morning.[2]

Based on its etiology and pathogenesis, and combined with the experience of the expert Professor Shi Yumin, a series of empirical prescriptions based on Traditional Chinese Medicine (TCM) have been used to treat asthma. Relief from asthma and coughing, the expectoration of phlegm, and cough suppression are the therapeutic principles for asthma during acute exacerba-

tions. For asthma in clinical remission, stimulation of the spleen to remove phlegm, invigoration of *Qi*, and "tonifying" of the kidneys are the therapeutic principles.[3]

We conducted a randomized controlled trial (RCT) to compare the clinical effect of a series of TCM empirical prescriptions with that of salbutamol and montelukast on pediatric asthma. In this way, we wished to encourage use of TCM prescriptions in clinical practice.

MATERIALS AND METHODS

Study design

This study was a single-blinded RCT conducted at the Children's Hospital of Fudan University (Fudan, China). This study protocol was approved by the Ethics Committee of Fudan University (grant number [2013] 065) and was registered on ClinicalTrials.gov (registration number: NCT02341573). This study includes all the information required for CONSORT 2010.

Patients

The study followed diagnostic criteria established in 2008 that were in accordance with the Guideline of Childhood Bronchial Asthma by the Pulmonology Group within the Pediatric Branch of the Chinese Medical Association.[2] A TCM-based symptom pattern was identified according to the Diagnosis and Clinical Effects on Chinese Medical Symptoms by the State Administration of Traditional Medicine.[4] Patients with a pattern meeting the criteria mentioned above for the diagnosis of pediatric asthma and cough-variant asthma and who were aged 3-12 years were enrolled into the study. Asthmatic episodes were catalogued according to the identification of symptom patterns in terms of TCM: a form of phlegm-heat obstructing the lungs or retention of cold fluid in the lungs; lung and spleen deficiencies; deficiency of the kidneys in clinical remission. Patients with congenital diseases of the respiratory system, cancer, immunodeficiency diseases, or cardiovascular diseases were excluded.

Estimation of sample size

The size of the study sample was estimated according to relevant data provided in the literature.[5] We were planning a study of independent cases and controls with one control per case. Previous data suggested that the failure rate among controls is 0.8. If the "true" failure rate for participants was 0.5, then we would need to assess 51 participants in the TCM group and 51 subjects in the salbutamol and montelukast (SM) group to reject the null hypothesis with a probability (power) of 0.9. The probability of a type- I error associated with a test of this null hypothesis was 0.05. We used an uncorrected χ^2 statistic to evaluate this null hypothesis. Given the time limitations for acquiring cases, the percentage of participants lost to follow-up, and the number of dropouts, we assumed that the percentage of participants lost to follow-up would be 15%. Therefore, sample collection was completed when the sample size in each group reached 59 cases.

Implementation of a randomization plan

Patients were grouped according to a random grouping scheme generated by the Excel™ computer program (a simple randomization using the recruitment sequence number as the randomization sequence number) with different treatments for 3 months. According to the single-blinded principle, data were collected by specific physicians in a uniform way, and hospitalized children, children's parents, and data analyst were blinded to the study protocol.

Collection of baseline data

Between March 2013 and December 2014, 182 children with asthma admitted at the Children's Hospital of Fudan University were recruited after obtaining written informed consent. Age, sex, disease course, the scores of TCM symptom patterns, symptom control (SC) scores, and the childhood asthma control test (C-ACT) score were recorded before treatment.

The C-ACT score was obtained according to the childhood asthma control test. The baseline C-ACT score was adopted to evaluate the pre-treatment status of children with asthma. The C-ACT includes separate sections for the parent and child to complete. If the child is too young to answer these questions, this section would be completed by their parent(s).[6]

The scores of TCM symptom patterns were assessed based on the main symptoms: cough, expectoration of phlegm, and wheezing. Secondary symptoms were hyperhidrosis, the appearance of feces, and tongue appearance. Scoring criteria, in accordance with the guiding principles of the clinical research of new TCM drugs[7] were that the: main symptoms were catalogued as "none" (0), "light" (1), "moderate" (2), or "heavy" (3); secondary symptoms were scored as "normal" (0) or "abnormal" (1). Summation of each symptom score was termed the "TCM total score".

SC scores were classified according to the Infantile Bronchial Asthma Prevention and Treatment Guidelines (trial).[8] The main symptoms were daytime and nighttime cough and nasal symptoms, which were based on the guideline mentioned above and relevant studies.[9, 10] Secondary symptoms were wheezing and moist rales, which were classified as "none" (0), "light" (1), "moderate" (2), or "heavy" (3). Summation of each SC score was termed the "SC total score".

Interventions

TCM group: patients received a series of empirical TCM-oriented prescriptions. The initial treatment was Shegan (*Rhizoma Belamcandae*) mixture (hospital preparation; Shanghai Liantang Pharmaceuticals, Shanghai, China; batch number, 20130101) corresponding to an