JTCM 中医杂志 Journal of Traditional Chinese Medicine

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

J Tradit Chin Med 2016 August 15; 36(4): 418-426
ISSN 0255-2922
© 2016 JTCM. All rights reserved.

CLINICAL STUDY

Sugarcane bagasse dietary fiber as an adjuvant therapy for stable chronic obstructive pulmonary disease: a four-center, randomized, double-blind, placebo-controlled study

Liu Miao, Zheng Fengjie, Ni Lei, Sun Yan, Wu Ruohan, Zhang Tianyu, Zhang Jinchao, Zhong Xianggen, Li Yuhang

Liu Miao, Zheng Fengjie, Ni Lei, Sun Yan, Wu Ruohan, Zhang Tianyu, Zhang Jinchao, Zhong Xianggen, Li Yuhang, School of Preclinical Medicine, Beijing University of Chinese Medicine, Beijing 100029, China
Supported by the National Basic Research Program of China: Study on Mechanism of Lung-Intestine Communication in View of the Theory of COPD Treatment Based on Intestine (No. 2009CB522704)
Correspondence to: Prof. Li Yuhang, School of Preclinical Medicine, Beijing University of Chinese Medicine, Beijing 100029, China. liyuhang@bucm.edu.cn
Telephone: +86-10-64287503; +86-15210694921
Accepted: September 21, 2015

Abstract

OBJECTIVE: To evaluate the efficacy and safety of sugarcane bagasse dietary fiber as an adjuvant therapy for improving quality of life in patients with stable chronic obstructive pulmonary disease (COPD).

METHODS: This was a multicenter, randomized, double-blind, placebo-controlled trial. A total of 196 participants were randomized into a trial group (treated with 6 g/day sugarcane bagasse plus conventional treatment, n = 98) and a control group (treated with placebo plus conventional treatment, n = 98). All efficacy analyses were performed according to the intention-to-treat (ITT) principle. A per-protocol analysis set (PPS) was used to analyze the cases that completed the clinical trial with good compliance. The trial period was 30 days, with a 6-month follow-up. Pre- and post-treatment pulmonary symptom scores (cough, sputum, wheezing, and dyspnea) were recorded for both groups. The St. George's Respiratory Questionnaire (SGRQ) and the modified Medical Research Council (mMRC) dyspnea scale were assessed before treatment and at the end of the 6-month follow-up.

RESULTS: The ITT population was 178 and the PPS population was 166. Post-treatment pulmonary clinical symptoms and severity of dyspnea (mMRC and SGRQ evaluation) were significantly improved in both the trial group and the control group (ITT and PPS: $P < 0.05$). However, there was no statistical difference between the two groups in post-treatment pulmonary symptoms and mMRC. There was a greater reduction in the SGRQ subscales of activity, effect and total score in the trial group compared with the control group (ITT and PPS: $P < 0.01$). There was no statistical difference in pre- and post-treatment safety variables in either group.

CONCLUSION: Sugarcane bagasse combined with conventional treatment improved quality of life in patients with stable COPD. Sugarcane bagasse appears to be a safe herbal medicine with potential for treating patients with stable COPD when taken orally as an adjuvant therapy.

© 2016 JTCM.This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/)

Key words: Saccharum; Pulmonary disease, chronic obstructive; Randomized clinical trial; Medicine, Chinese Traditional

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is characterized by constant disruption of airflow into and out of the lungs. COPD induces morbidity and mortality and places a tremendous burden on patients, health-care systems and society.[1] COPD not only disrupts psychological, emotional and social function, but also imposes restrictions on daily activities, and seriously influences patients' health-related quality of life (HRQoL).[2] Based on current trends, COPD is predicted to become the fifth top burden in the world by 2020.[3] Zhong *et al* [4] reported that the prevalence of COPD in China in people 40 years or older was 8.2%, or 43 million based on China's population in 2002-2004.

COPD management is aimed at relieving symptoms, preventing disease progression, treating complications and exacerbations, improving exercise tolerance and health status, and reducing mortality.[5] Therapeutic modalities encompass pharmacologic and non-pharmacologic therapies including oxygen therapy, ventilator support, surgery, and lifestyle changes. Pharmacologic therapy can relieve COPD symptoms, reduce the frequency and severity of exacerbations, and improve exercise tolerance and health status; however, these medications can also cause side effects. For example, anticholinergics can lead to dry mouth, methylxanthines are associated with cardiac arrhythmias,[6] and long-term use of inhaled corticosteroids is related to higher prevalence of hoarseness, oral candidiasis, and skin bruising.[7] Thus, new COPD therapies are needed.

In China, Traditional Chinese Medicine (TCM) is commonly used to treat COPD. The TCM treatment approach is founded on the concept put forth in the ancient classic *Huang Di Nei Jing* that each internal organ has an interrelated organ.[8] Based on this concept, the large intestine is the paired organ of the lung. Thus, one TCM approach widely used in treating lung diseases such as COPD is to promote bowel regularity.

Chinese sugarcane (Saccharum sinense Roxb.) has been used in China as both food and medicine for more than 2000 years. *Ben Cao Gang Mu*, one of the most complete tomes on TCM theory and treatment, reports that sugarcane relaxes the large intestine.[9] Inspired by this, our previous research found that a dietary fiber preparation made from sugarcane bagasse prevented and treated the rat model of COPD.[10]

To verify this new treatment in humans, we undertook a multicenter, randomized, double-blind, placebo-controlled clinical study to evaluate the efficacy and safety of sugarcane bagasse dietary fiber as an adjuvant therapy in patients with stable COPD.

METERIALS AND METHODS

Ethics and trial registration

This trial was conducted according to the guidelines of the Declaration of Helsinki.[11] This trial was registered with the Chinese Clinical Trial Registry (ChiCTR-TRC-09003117), and was approved by the Ethical Research Committee of the Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine (DZMSP20090302). All participants signed informed consent forms, which are on file at the Department of Preclinical Medicine, Beijing University of Chinese Medicine, Beijing, China.

Participants

In this study, 196 out- and in-patients with stable COPD were recruited from November 2009 to February 2013 from four hospitals in China: 58 cases from the Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine (Beijing, 29.6%), 78 cases from Hebei Provincial Hospital of Traditional Chinese Medicine (Shijiazhuang, 39.8%), 40 cases from the Affiliated Hospital of Gansu University of Traditional Chinese Medicine (Lanzhou, 20.4%), and 20 cases from the Affiliated Hospital of Liaoning University of Traditional Chinese Medicine (Shenyang, 10.2%).

Patients were considered eligible if they met all of the following inclusion criteria: (a) diagnosis of COPD (post-bronchodilator FEV_1/FVC less than 70%) based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD; 2007)12 and Chinese Society of Respiratory Diseases;[13] (b) stable COPD; (c) < 80 years old at the time of study commencement; and (d) participating of their own free will after signing an informed consent form. Patients meeting any of the following criteria were excluded from the study: (a) chronic enteritis or diarrhea (> three times/day) with concurrent dizziness and fatigue; (b) intractable constipation and use of stimulant laxatives such as Dahuang (*Radix Et Rhizoma Rhei Palmati*), Fanxieye (*Folium Sennae*), castor oil, or phenolphthalein; (c) severe comorbid disease such as peritonitis, mechanical intestinal obstruction, intestinal stenosis, severe hemorrhoids, hernia, post-colorectal surgery, anal mucosal inflammatory edema, severe anemia, aneurysms, intestinal bleeding or perforation, colorectal cancer, liver cirrhosis, anal fistula, acute cerebral hemorrhage, acute left heart failure, gastrointestinal hemorrhage, acute renal failure, or aplastic anemia; (d) airflow limitation because of bronchiectasis, cystic pulmonary fibrosis, lung cancer, active tuberculosis or other disorders; (e) serious heart, hepatic, renal or hematopoietic diseases; (f) having recently taken immunosuppressant medication; (g) pregnant or breast-feeding; (h) psychiatric or any type of neurological deficit (cognitive impairment or aphasia) that rendered patients unable to understand the nature, scope and possible consequences of the study; (i) digestive obstacles, malnutrition, physical weakness or dehydration; and (j) allergy to the experimental drug.

Participants could withdraw from the study at any time for any reason. Researchers recorded the reasons for withdrawal or early discontinuation, although every

Download English Version:

https://daneshyari.com/en/article/4200902

Download Persian Version:

https://daneshyari.com/article/4200902

Daneshyari.com