JTCM
中医杂志
Journal of Traditional Chinese Medicine

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

J Tradit Chin Med 2016 October 15; 36(5): 640-648
ISSN 0255-2922

CLINICAL STUDY

Efficacy and safety of Sancai powder in patients with type 2 diabetes mellitus: a randomized controlled trial

Guo Qiang, Zhang Hengyao, Li Mindian, Zhao Ziyi, Luo Yunlin, Luo Yulei, Cao Wenzhai, Zhao Huan, Zhu Ranran, Lei Xingxing, Chen Huizhen, Gan Huakui, Zuo Zhihuang, Chen Qi, Shi Cuimei, Zhang Xinli, Guo Jian, Zhong Sen, Chen Qiu

Guo Qiang, Zhu Ranran, Lei Xingxing, Chen Huizhen, School of Clinical Medicine, Chengdu University of Traditional Chinese Medicine, Chengdu 610072, China
Zhang Hengyao, Department of Endocrinology, Ningxia Chinese Medicine Research Center, Yinchuan 750021, China
Li Mindian, Department of Cellular and Molecular Physiology, Section of Comparative Medicine and Program in Integrative Cell Signaling and Neurobiology of Metabolism, Yale University School of Medicine, New Haven 06520, USA
Zhao Ziyi, Department of Central Laboratory, Teaching Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu 610072, China
Luo Yunlin, Department of Traditional Chinese Medicine, Dujiangyan Traditional Chinese Medicine Hospital, Dujiangyan 611830, China
Luo Yulei, Diabetes Center, The third Teaching Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu 610015, China
Cao Wenzhai, Medical Department of Cardiology, Zigong First People's Hospital, Zigong 64300, China
Zhao Huan, Medical Department of Neurology, Teaching Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu 610072, China
Gan Huakui, Department of Endocrinology, The First People's Hospital of Neijiang, Neijiang 641000, China
Zuo Zhihuang, Department of Endocrinology, The Central Hospital of Guangyuan, Guangyuan 628000, China
Chen Qi, Department of Endocrinology, Zizhong County Hospital of Traditional Chinese Medicine, Zizhong 641200, China
Shi Cuimei, Department of Endocrinology, Hospital of traditional Chinese Medicine of Xichang, Xichang 615000, China
Zhang Xinli, Department of Endocrinology, Liangshan Hospital of Integrated Traditional and Western Medicine, Xichang 615000, China
Guo Jian, Department of Endocrinology, The Second People's Hospital of Leshan, Leshan 614000, China
Zhong Sen, Medical Department of Infections, Teaching Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu 610072, China
Chen Qiu, Medical Department of Endocrinology, Teaching Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu 610072, China
Supported by Prospective clinical evaluation of Sancai powder in treatment of patients with type 2 diabetes mellitus (No. JDZX2012128)
Correspondence to: Chen Qiu, Medical Department of Endocrinology, Teaching Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu 610072, China. chenqiu1969@163.com; Zhong Sen, Medical Department of Infections, Teaching Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu 610072, China. zhongsen6606@163.com
Telephone: +86-28-87766249
Accepted: March 10, 2016

Abstract

OBJECTIVE: To assess the efficacy and safety of Sancai powder in patients with type 2 diabetes mellitus (T2DM) inadequately controlled with single oral metformin in a randomized controlled trial (RCT).

METHODS: A total of 132 patients with T2DM were enrolled in the study, who only took metformin (500-1000 mg/day) for at least three months and with inadequate glycemic control (7.0% ≤ hemoglobin A1c ≤ 9.0%) in the past three months. The patients stopped taking metformin with lifestyle interventions for three weeks, and 105 patients qualified for the program. They were randomly divided into the Sancai powder group and the metformin group (1500 mg/day). The follow-up period was for 12 weeks. Comparisons of several variables were analyzed.

RESULTS: No significant differences were found between the two groups in hemoglobin A1c (HbA1c), fasting plasma glucose (FPG) and 2 h post-meal glucose (2hPG), although they had decreased significantly ($P < 0.01$). Homeostasis model assessment of beta cell function index was significantly improved in Sancai powder group ($P < 0.01$), and there were significant differences in the changes of homeostasis model assessment of insulin resistance and insulin sensitivity index in the two groups ($P < 0.05$). Sancai powder significantly reduced triglyceride level ($P < 0.05$), although there was no significant difference in the body weight and body mass index in the two groups.

CONCLUSION: In this 12-week study, Sancai powder could significantly reduce hemoglobin A1c, FPG and 2hPG levels, improved beta-cell function and insulin resistance of the T2DM inadequately controlled with metformin.

Key words: Diabetes Mellitus, Type 2; Sancai powder; Metformin; Treatment outcome; Randomized controlled trial

INTRODUCTION

Diabetes mellitus (DM) is a metabolic disease characterized by hyperglycemia as a result of insulin resistance (IR) and beta-cell failure, described as "Xiaoke" in Huang Di Nei Jing[1] in Traditional Chinese Medicine (TCM). The population with diabetes is expected to rise to 439 million.[2] Large-scale epidemiological studies have reported that the estimated prevalence of diabetes in China was 11.6%. Therefore, these findings indicate the importance of diabetes as a public health problem in China.[3]

TCM plays an important role in Chinese health care system,[4] which has advantages in preventing and treating DM, and promotes clinical, scientific research and the development of new drugs, such as Xiaoke Pill (a preparation widely used for diabetes, which contains Chinese herbal medicine and glibenclamide). It can improve the symptoms of diabetes, and has reduction of hypoglycemia risk in diabetes patients.[5] Meanwhile, Chinese herbal medicine Huanglian (*Rhizoma Coptidis*) has great effects in lowering blood glucose, relieving IR and protecting the function of beta-cell.[6] Some studies report that the TCM formula "Fructus Mume" can significantly decrease the fasting and postprandial glucose levels of DM.[7]

Sancai powder formula was created on the basis of three ancient TCM formulas-''San Cai Tang'', Jiao Tai Wan and Fructus Mume The selection of those Chinese herbal medicines for the treatment of diabetes was based on theory of TCM. San Cai, contains three herbal medicine, Tiandong (*Radix Asparagi Cochinchinensis*), Renshen (*Radix Ginseng*), Dihuang (*Rhizoma Rehmanniae*) (heaven, earth and human), and has been used to tonify *Qi* and *Yin* in terms of TCM theory. The preliminary study of our research showed that Sancai powder had the effect of lowering blood sugar, moreover, a single-blind randomized controlled trial was conducted by our team to approve that Sancai powder could effectively improve endothelial dysfunction (ED), insulin resistance (IR), hyperinsulinemia, and the symptoms of mild vascular dementia (VaD).[8] Therefore, this study was conducted to access the efficacy and safety of Sancai powder with the comparison of single oral metformin, which was a first-line anti-diabetic drug applied widely in clinical study.

MATERIALS AND METHODS

Study design

A single-blind randomized controlled trial (RCT) was conducted, and with patients blind to the drug conditions. Trial evaluators were formally trained physicians. Randomization was undertaken by a computer using random number tables for each condition. Allocation of treatment conditions was known to the physicians and nurses who physically administered the drugs to the patients. Sample size was calculated by an inspection level where $\alpha = 0.05$, the power of a test was 0.80, $\delta = 10\%$, and the losing ratio was 10%.

This was a multi-centered, randomized controlled trial, including the screening period, washout period (3 weeks) and follow-up period (12 weeks, follow-up at every 2 weeks). Patients who met the criteria (taking only metformin (500-1000 mg/day) for at least three months, and [7.0% ≤ hemoglobin A1c (HbA1c) ≤ 9.0%] were allowed to enter the washout period. During the washout period, patients stopped taking diabetes drug, and received guidance of diet and exercise according to the 2010 China Type 2 Diabetes Clinical Practice Guidelines.[9] At the end of the washout period, patients still met the inclusion criteria were randomized into the Sancai powder group and the metformin group. Metformin, was used as the control drugs because of its positive safety and efficacy.

Subjects

This trial was sponsored by the Teaching Hospital of Chengdu University of Traditional Chinese Medicine and conducted at 7 centers in Sichuan province, China. This research study was approved by the Institutional Review Board of the Teaching Hospital of Chengdu University of Traditional Chinese Medicine, with all patients and/or their guardians giving signed informed consent. Trial Registration: Chinese Clinical