

CLINICAL STUDY

Effects on type 2 diabetes complicated with pulmonary tuberculosis: regiment of insulin, isoniazid, rifampicin, pyrazinamide and ethambutol versus the regiment plus *Qi*-boosting and *Yin*-nourishing decoction of Traditional Chinese Medicine

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Abstract

OBJECTIVE: To observe the clinical effect on type 2 diabetes mellitus (T2DM) complicated with pulmonary tuberculosis (TB) of insulin, isoniazid, rifampicin, pyrazinamide and ethambutol (conventional medication) administered together with *Qi*-boosting and *Yin*-nourishing decoction derived from Traditional Chinese Medicine (TCM).

METHODS: A total of 60 patients with T2DM complicated with pulmonary TB were randomly and equally divided into positive control group and treatment group. The control group was treated with Western conventional regiment (WCR): insulin, isoniazid, rifampicin, pyrazinamide, and ethambutol, whereas the treatment group was given both WCR and *Qi*-boosting and *Yin*-nourishing decoction prepared from TCM.

RESULTS: After the treatment, 20 (66.7%) and 11 (36.7%) cases showed sputum bacteria negative conversion in the WCR plus TCM group and WCM group respectively ($P < 0.05$). A total of 25 (83.3%) and 18 (60%) cases showed improvement in lung

lesion in the WCR plus TCM group and WCM group respectively ($P < 0.05$). Compared with WCR group, fasting plasma glucose and 2-hour postprandial blood glucose levels in the WCR plus TCM group significantly decreased ($P < 0.05$ and $P < 0.01$, respectively).

CONCLUSION: *Qi*-boosting and *Yin*-nourishing decoction combined with the Western medication showed better curative effect in treating T2DM complicated with pulmonary TB compared with the group using the conventional Western Medicine alone.

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Key words: Diabetes mellitus, type 2; Tuberculosis, pulmonary; *Qi* and *Yin* deficiency; Medicine, Chinese traditional

INTRODUCTION

Worldwide incidence of diabetes is increasing,^{1,2} and about 2.3 billion people suffer from diabetes. This number may reach 3.66 billion by 2030. The World Health Organization (WHO) has confirmed that diabetes is a global disaster; 80% of the death toll in low- and middle-income countries is associated with diabetes.³ Despite the decline in the trend of pulmonary tuberculosis (TB), it is still one of the major causes of death.⁴ Many studies have explored the relationship between the two diseases, and a recent paper showed that diabetic patients have threefold risk of suffering from TB than patients without diabetes.⁵ A survey shows that, diabetes patients were two to four times more like-

ly to have pulmonary TB compared with patients without diabetes.^{4, 6-8} Currently, 90% to 95% of type 2 diabetes (T2DM) patients suffer from TB.^{4, 9-18} Some studies show that diabetes complicated with pulmonary TB patients have significantly higher discharge of bacteria^{14, 19} and delay in sputum negative conversion, which lead to the increase in drug-resistant bacteria among patients.⁹ These results suggest that diabetes complicated with pulmonary TB patients pose a high risk of disease transmission to the society. Therefore, studies on this subject are urgently needed.

Diabetic patients are susceptible to TB. Active TB is an infection factor that aggravates diabetes, which may induce acute diabetic complications such as ketoacidosis, the treatment of which is challenging among TB doctors. Traditional Chinese Medicine (TCM) has accumulated various treatments for diabetes and TB, which could provide new therapeutic approaches for personalized and comprehensive therapy. From October 2009 to June 2011, the author used *Qi*-boosting and *Yin*-nourishing decoction combined with Western Medicine in treating 30 cases of first-visit patients with T2DM complicated with pulmonary TB.

MATERIALS AND METHODS

General information

According to the visit order and the criteria of the disease, the patients were marked 1-60, respectively. According to randomization table, 60 numbers were selected, of which patients with odd numbers were in treatment group administered Western conventional regiment (WCR) plus TCM decoction, and patients with even numbers in control group treated with WCR alone. The WCR plus TCM group included 30 cases, with 15 male cases and 15 female cases aged 30 to 60 years (mean age of 46.3 years). Pulmonary TB disease duration was from 3 days to 30 days (mean duration of 10 days). The WRC group also included 30 cases, with 11 male cases and 19 female cases aged 28 to 62 years (mean age of 46.7 years). Pulmonary TB disease duration was from 5 days to 40 days (mean duration of 15 days). The two groups were comparable and showed no significant difference ($P < 0.05$). This study was conducted in accordance to the declaration of Helsinki and with the approval of the Ethics Committee of Xinxiang Medical University. Written informed consent was obtained from all of the participants.

Western diagnostic criteria

Diagnosis of T2DM: the diagnosis and classification method of diabetes proposed by WHO in 1999²⁰ was adopted in the current study. All of the patients exhibited symptoms of diabetes (polydipsia, polydipsia, and unexplainable weight loss) and matched one of the following conditions: (a) fasting blood glucose (FPG) \geq

7 mmol/L; (b) random blood glucose >11.1 mmol/L; and (c) glucose ≥ 11.1 mmol/L 2 h after oral glucose tolerance test (75 g glucose).

Diagnosis of pulmonary TB: Diagnosis criteria of pulmonary TB were based on the "classification criteria for the diagnosis of TB in China" formulated in 1998. All of the patients were diagnosed with more than 2 \times sputum smear-positive acid-fast stain. X-ray analysis confirmed the active TB disease. Initial treatment indicated that the patient has never used anti-TB drugs or has irregularly used TB drugs for no more than 1 month).

TCM diagnostic criteria

According to "Traditional Chinese Medicine of Internal Medicine",²¹ both *Qi* and *Yin* deficiencies are diagnosed as pulmonary TB. Deficiencies of *Qi* and *Yin* syndromes include coughing and weakness, coughing up a thin sputum, dry pharynx and arid mouth, lassitude and fatigue, spontaneous perspiration and night sweating, shortness of breath and speech sluggishness, thirst and excessive drinking, dysphonia with feverish sensation in the chest, palms, and soles, palpitation and insomnia, red urine and constipation, red tongue and lack of body fluids, big fat tongue, thin coated tongue or flower stripping tongue, as well as small and wiry pulse or thready rapid pulse.

Treatment

Control group: subjects received. All of the patients were given insulin-intensive treatment. Regular insulin was injected subcutaneously 30 min before every meal, three times a day. Intermediate-acting insulin was subcutaneous injected at 22:00 hours, and the dosage was adjusted according to the blood sugar level. The chemotherapy used for TB in this study was 3HRZE/6HER (H: isoniazid; R: rifampicin; Z: pyrazinamide; E: ethambutol). Hypotensor, lipid-lowering drugs, neurotrophic drug therapy, and other drugs were selected according to the specific circumstances of patients. Isoniazid tablets were provided by Beijing Yongkang Pharmaceutical Co., Ltd., Beijing, China. Rifampicin capsules were purchased from Beijing Yanjing Pharmaceutical Co., Ltd., Beijing, China. Pyrazinamide was provided by Chengdu Jinhua Pharmaceutical Co., Ltd., Chengdu, China. Ethambutol was provided by Shenyang Hongqi Pharmaceutical Co., Ltd., Shenyang, China.

Treatment group: in addition to 3HRZE/6HER plus insulin, *Qi*-boosting and *Yin*-nourishing decoction was administered to the group. The decoction was prepared with Huangqi (*Radix Astragali Mongolici*) 30 g, Xuan-shen (*Radix Scrophulariae*) 30 g, and Dihuang (*Radix Rehmanniae*) 30 g, each of Cangzhu (*Rhizoma Atractylodis Lanceae*) 10 g, Maidong (*Radix Ophiopogonis Japonici*) 10 g, Danggui (*Radix Angelicae Sinensis*) 10 g, and Baishao (*Radix Paeoniae Alba*) 10 g, and of Zhimu (*Rhizoma Anemarrhenae*) 6 g. Some other herbal medi-

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