

## Retrospective study of Traditional Chinese Medicine treatment of type 2 diabetes mellitus

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### Abstract

**OBJECTIVE:** To provide clinical evidence in support of Dahuang Huanglian Xiexin decoction (DHXD) to treat type 2 diabetes mellitus (T2DM) and to introduce a new treatment option for clinicians.

**METHODS:** Retrospective analysis was used to evaluate DHXD for the treatment of T2DM by analyzing clinical records of 183 cases. Patients with T2DM who met the inclusion criteria between January 1, 2013 and January 1, 2014 were enrolled. The effects of the treatment were evaluated by the changes in fasting blood-glucose (FBG), postprandial blood sugar (PBG), hemoglobin A1c (HbA1c), blood lipid profiles and body mass index (BMI) at 1, 2, 3 and 6 months. The changes in main symptoms were also

evaluated. The dosage of Huanglian (*Rhizoma Coptidis*) and related factors were analyzed.

**RESULTS:** There was a significant improvement in mean HbA1C at 3 and 6 months after DHXD treatment compared with the baseline level ( $P < 0.01$ ). There were also significant improvements in FBG, PBG, blood lipid series and BMI. DHXD also improved the main symptoms of stomach and intestine excessive heat syndrome in patients with obese T2DM. Huanglian (*Rhizoma Coptidis*) was the most frequently used in 678 clinical visits, the dosage of Huanglian (*Rhizoma Coptidis*) was related to age, BMI, DM duration, the level of blood glucose, and use of Western hypoglycemic drugs.

**CONCLUSION:** This study suggests that DHXD could decrease blood glucose and improve T2DM symptoms and reduce body weight. The use of DHXD may indicate a new optional treatment for T2DM.

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**Key words:** Diabetes mellitus, type 2; Blood glucose; Body weight; Dahuang Huanglian Xiexin decoction; Retrospective studies

### INTRODUCTION

Type 2 diabetes mellitus (T2DM) is the predominant form of DM, which accounts for 95% of the global diabetes population.<sup>1,2</sup> The cause of T2DM has not yet been fully elucidated, although both genetic and environmental factors (obesity and sedentary lifestyles) are commonly cited.<sup>3</sup> China has the world's largest diabetes population, with more than 92.4 million people af-

fects.<sup>4</sup> The standard therapy for DM includes diet, exercise, use of oral hypoglycemic drugs, and/or subcutaneous insulin injections.<sup>5</sup> Traditional Chinese Medicine (TCM) has been used to treat T2DM in China for over 2000 years.<sup>6</sup> Treatment by TCM has the advantage of lower toxicity and/or fewer side effects, and herbal medicine could provide multiple therapeutic effects on multiple targets.<sup>6-8</sup> Professor Tong Xiaolin, an expert in TCM for treating T2DM in China, reported in a syndrome analysis study involving 2518 cases of obese T2DM that stomach and intestine excessive heat syndrome is common in obese T2DM.<sup>9</sup> Prof. Tong<sup>10,11</sup> suggested a method using Dahuang Huanglian Xiexin Decoction (DHXD) to clear away the heat and direct the turbidity downward. DHXD has been established as a fundamental formula for stomach and intestine excessive heat syndrome in obese T2DM.<sup>12</sup> By using large scale randomized controlled trials (RCTs),<sup>13</sup> our group has confirmed that Chinese herbal medicine possesses independent anti-hyperglycemic effects. In one study with 122 cases of obese patients with T2DM, Kaiyu Qingre Jiangzhuo formula (KQJF) (modified DHXD) was given to the treatment group and metformin to the control group. The results showed no statistically significant difference between the two groups on lowering the blood glucose ( $P > 0.05$ ), and no obvious adverse events were reported in the treatment group. This was the first evidence of a Chinese herbal medicine lowering blood glucose in clinical conditions.<sup>14</sup> In the

present study, a retrospective analysis was used to evaluate DHXD for the treatment of T2DM and for introducing a new treatment option for clinicians.

## METHODS

### General information

The clinical records from Professor Tong Xiaolin were used as the database. Patients who met the inclusion criteria between January 1, 2013 and January 1, 2014 were enrolled in the study. Progress of the study is shown in Figure 1.

The diagnostic criteria were: (a) diagnosis of T2DM referred to World Health Organization (WHO) T2DM diagnostic criteria (1999);<sup>15</sup> and (b) TCM syndrome differentiation referred to Guideline for TCM Diabetes Prevention and Treatment (2007).<sup>16</sup> The inclusion criteria included: (a) minimum age of 18 years; (b) a confirmed diagnosis of T2DM; and (c) DHXD as the primary prescription. The baseline data were recorded as follow-up data within 6 months of blood glucose or hemoglobin A1c (HbA1c). Patients were excluded if they had type 1 diabetes mellitus or had diabetic ketoacidosis.

### Information collection and standardization

A full medical history was recorded, including general information about diabetes, related diabetic complications, diagnosis, therapeutic treatments and prescribed

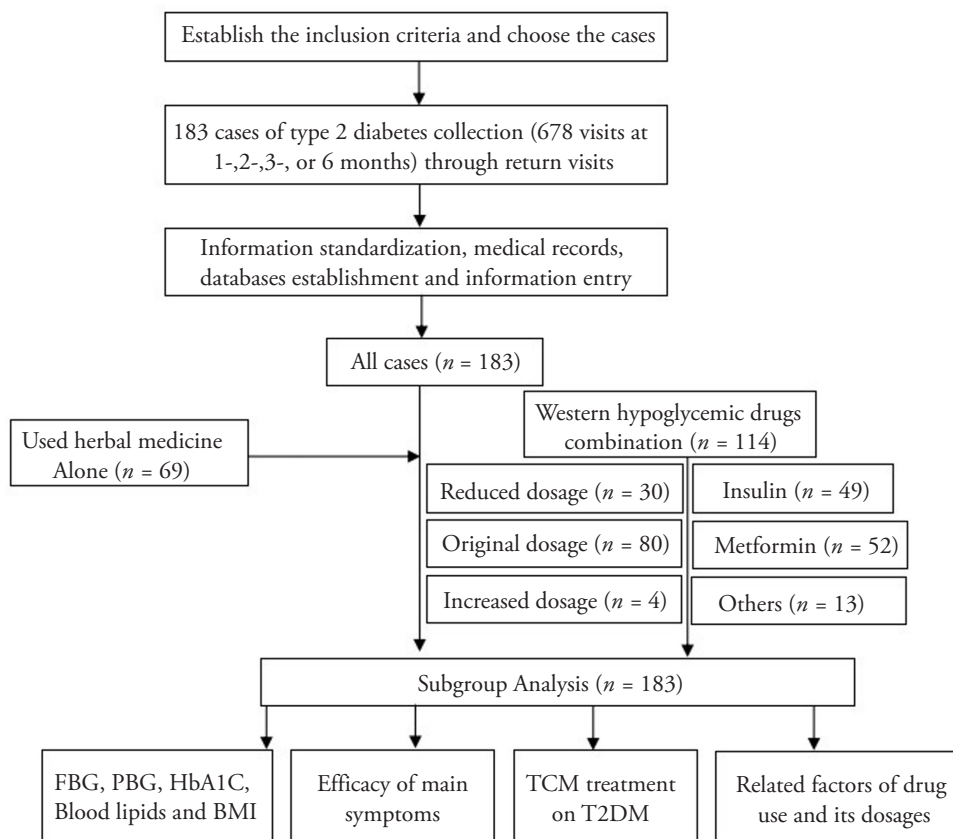


Figure 1 Progress of patients' information collected in the study

FBG: fasting blood-glucose; PBG: postprandial blood sugar; HbA1c: Hemoglobin A1c; BMI: Body mass index; TCM: Traditional Chinese Medicine; T2DM: type 2 diabetes mellitus.

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