## **ARTICLE**

# Analysis of the efficacy and safety of traditional Chinese medicine fasting therapy in relieving type 2 diabetes: a case report

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(Received 15 May 2022; revised 19 May 2022; accepted 30 June 2022; first published online 30 September 2022)

## **Abstract**

Traditional Chinese medicine fasting therapy is a new, safe and effective clinical therapy. Because it can reduce weight and insulin resistance and alleviate diabetes symptoms, it can be used to treat type 2 diabetes with obesity, metabolic syndrome and other diseases. To promote people's understanding of traditional Chinese medicine fasting therapy, this case report reports the treatment process of a patient with type 2 diabetes who underwent traditional Chinese medicine fasting therapy, and discusses the efficacy and some adverse reactions.

Keywords: case report, fasting, insulin resistance, adverse reaction

## 1. Introduction

Type 2 diabetes is a serious and common chronic disease, which can be caused by complex genetic-environmental interactions and other risk factors such as obesity and sedentary lifestyle [1, 2]. Fasting therapy can effectively treat or alleviate chronic diseases such as type 2 diabetes, metabolic syndrome, obesity and hyperlipidemia by changing diet, restricting caloric intake and other methods to change life style, so it is widely used in Europe [3]. The series of diabetes remission clinical trials (direct) still in progress, focusing on weight loss and diet replacement, have achieved significant remission effects on diabetes [4, 5]. It can be seen that various fasting therapies based on lifestyle change are expected to provide a new direction for the clinical treatment of type 2 diabetes.

In the theory of traditional Chinese medicine, there are also many theories about how lifestyle, especially diet, affects the body and causes diseases. There is a saying in the Yellow

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Emperor's Canon of Internal Medicine: "if the taste is thick, it will leak; if the taste is thin, it will pass." In other words, if the food we eat is too fat or too much, it will reduce the physiological function of the organs, making us fall ill. Therefore, the food we eat should be as light and slight as possible to keep the organs' function normal. The Yellow Emperor's Canon of Internal Medicine also indicates that if you eat too much thick and turbid part of the water and grain essence for a long time, your body is prone to fall ill [6]. These theories are similar to modern nutrition and the pathogenesis of chronic diseases such as diabetes.

Based on this theory, traditional Chinese medicine fasting therapy combines with traditional Chinese medicine theory and clinical practice, modifies the basis of fasting therapy. Through the use of traditional Chinese medicine and L-carnitine supplementation to reduce adverse reactions during fasting period [7], supplemented by diet control and traditional Chinese medicine characteristic treatment, a set of fasting therapy with Chinese and Western characteristics has been formed, which is a traditional Chinese medicine therapy with weight control and caloric restriction as the core. Its safety and effectiveness have been preliminarily clarified in the expert consensus [8].

According to the consensus of experts on traditional Chinese medicine fasting therapy, traditional Chinese medicine fasting therapy generally includes 7 days, including a buffer period of 1 day, a fasting period of 5 days and a recovery period of 1 day. During the fasting period, it's forbidden to eat any food, patient can only take water and traditional Chinese medicine Modified Lingguizhugan Decoction. At the same time, levocarnitine injection is injected intravenously. The specific course of treatment can be adjusted according to clinical practice and the wishes of patients. The application of traditional Chinese medicine Modified Lingguizhugan Decoction and levocarnitine injection can greatly reduce the hunger and fatigue of patients during fasting period, improving their compliance and making it easier to promote clinically. At the present, the indications of traditional Chinese medicine fasting therapy include type 2 diabetes, obesity, metabolic syndrome, fatty liver, etc [9]. Its adverse reactions usually include fatigue, dizziness, hunger discomfort, hypoglycemia, and transient increases in ketones, uric acid, and bilirubin [10]. The incidence of serious adverse reactions is low, but it still needs attention and clinical monitoring [11].

Through traditional Chinese medicine fasting therapy and lifestyle education, diabetes can be alleviated by drugs alone or in combination. Timely selection of traditional Chinese medicine fasting therapy and understanding of the risk of adverse reactions will contribute to the new direction of treatment of type 2 diabetes and the clinical application of traditional Chinese medicine fasting therapy. Therefore, we will introduce and discuss the efficacy and safety in the case report.

# 2. Physical examination

A thirty-five years old woman came to the hospital outpatient clinic on July 15, 2019. Blood routine examination showed that her random blood glucose was 11.38 mmol/L and her Uric acid was 409.2 mol/L. The patient said that she had no disease and family history such as diabetes and metabolic syndrome. So, she was diagnosed with hyperuricemia. The next day, the patient was given oral glucose tolerance test (OGTT), insulin release test, C-peptide Release Test and other auxiliary examinations. The results of oral glucose tolerance test

(OGTT) were 0 h-5.55 mmol/L0.5 h-8.5 mmol/L1 h-11.38 mmol/L2 h-11.57 mmol/L3 h-7.96 mmol/L. The results of the insulin release test were 0 h-15.1 U/mL0.5 h-49.63 U/mL1 h-89.79 U/mL2 h-196.79 U/mL3 h-70.84 U/mL. The results of the C-peptide Release Test were 0 h-880.94 pmol/L0.5 h-1837.49 pmol/L1 h-2915.44 pmol/L2 h-5284.85 pmol/L3 h-3571.91 pmol/L. The OGTT-2h value of the patient was 11.57 mmol / L and the random blood glucose value was 11.39 mmol / L, so she was diagnosed with type 2 diabetes, which was one of the indications of traditional Chinese medicine fasting therapy. Then she was given traditional Chinese medicine fasting therapy. During the treatment period, there were no any serious adverse events and the liver and kidney functions were normal. Ion index such as sodium, potassium and chloride are normal. She was discharged after treatment on July 22, 2019. After discharge, the patient was instructed to limit her diet, control her weight and strengthen exercise. Patient's compliance was good.

She came to the hospital outpatient clinic on July 25, 2021 again. Blood routine examination showed that her random blood glucose was 9.26 mmol/L, and her Uric acid was 409.2 mol/L. So, she was diagnosed with hyperuricemia, which was one of the indications of traditional Chinese medicine fasting therapy. She was given traditional Chinese medicine fasting therapy according to her request. The next day, the patients were given oral glucose tolerance test (OGTT), insulin release test, C-peptide Release Test and other auxiliary examinations. The results of oral glucose tolerance test (OGTT) were 0 h-4.64 mmol/L0.5 h-7.36 mmol/L1 h-9.62 mmol/L2 h-9.00 mmol/L3 h-8.4 mmol/L. The results of the insulin release test were 0 h-9.60 U/mL0.5 h-43.31 U/mL1 h-50.14 U/mL2 h-44.76 U/mL3 h-76.77 U/mL. The results of the C-peptide Release Test were 0 h-705.14 pmol/L0.5 h-1670.34 pmol/L1 h-2486.18 pmol/L2 h-2703.95 pmol/L3 h-3370.57 pmol/L. The OGTT-2h value of the patient was 9.00 mmol / L and the random blood glucose value was 9.26 mmol / L, indicating that the patient had impaired glucose tolerance. She said that she had not taken any hypoglycemic drugs in these two years. However, the C-peptide Release test showed that the peak secretion was delayed, which showed that the patient had still been with insulin resistance. So, she was continue given traditional Chinese medicine fasting therapy. During the treatment period, there were no any serious adverse events and the liver and kidney functions were normal. Ion index such as sodium, potassium and chloride are normal. She was discharged after treatment on July 31, 2021. After discharge, the patient was instructed to limit her diet, control her weight and strengthen exercise.

## 3. Discussion

## 3.1 Therapeutic effect analysis

Thus, as a novel type of traditional Chinese medicine therapy for type 2 diabetes, fasting therapy is highly effective in reducing obesity level in patients with type 2 diabetes [12, 13]. Relevant studies have shown that the mechanism to improve type 2 diabetes may include anti-inflammatory, improving intestinal flora, reducing insulin resistance, increasing insulin sensitivity, and so on [14].

The results of OGTT and insulin release test (IRT) in the first and second examination before hospitalization are shown in the table below. The insulin resistance status of patients was applied and compared by homeostasis model assessment of insulin resistance index (HOMA - IR) [15]. We could find that HOMA - IR of patients decreased after fasting and diet control, and insulin resistance was partly improved. Therefore, traditional Chinese medicine fasting therapy can effectively control the progress of type 2 diabetes.

Table 1 - Comparison of HOMA - IR between two admission examinations

OGTT 0 h (mmol/L) IRT 0 h(μU/mL) HOMA

	OGTT 0 h (mmol/L)	IRT 0 $h(\mu U/mL)$	HOMA-IR
First examination	5.55	15.10	3.72
Second examination	4.64	9.60	1.98

Formula: HOMA-IR = fasting blood glucose\*Fasting insulin / 22.5

## 3.2 Adverse reactions and safety analysis

During the fasting therapy of traditional Chinese medicine, the case did not appear sense of fatigue and hunger, or other adverse reactions, which could cause the intolerance of withdrawal from treatment, and serious adverse reactions didn't occur as well. In clinical monitoring, the electrolyte indexes were normal, such as serum sodium, potassium and calcium. It means that the Chinese medicine fasting therapy has good tolerance and safety, and can be promoted in clinical practice.

In this case report, we also should pay attention to the occurrence of some common adverse reactions. First of all, patients in the process of treatment appeared mild diabetes hypoglycemia, and then was cured timely in the clinical intervention. Diabetes hypoglycemia, which means the blood glucose of diabetic patients is less than or equal to 3.9 mmol / L, is a complication of diabetes treatment. If it occurs repeatedly for a long time, it will lead to poor blood glucose control and even emergencies like hypoglycaemia unawareness [16]. This is a common adverse reaction in fasting therapy, and any fasting therapy for diabetic patients has the risk of hypoglycemia [17, 18]. But each medication used for diabetes also carries the risk of causing diabetes hypoglycemia. At present, there is still no comparative study on the risk of diabetic hypoglycemia caused by fasting therapy. However, because fasting therapy is carried out under clinical monitoring, it can be considered that diabetic hypoglycemia caused by fasting therapy is easier to be detected and controlled, and the possibility of serious health hazards is lower.

Second, there was also a temporary increase in uric acid during fasting, which is also a common adverse reaction in fasting therapy. After the fasting, uric acid will return to the previous level. A possible mechanism is that fasting can induce starvation ketosis, which causes an increase in the body's organic acids, such as -hydroxybutyric acid, free fatty acids, lactic acid, etc. It has a competitive inhibitory effect on the secretion of uric acid by renal tubules, and then reduces the excretion of uric acid, leading to hyperuricemia [10]. It may also relate to the factors of mild dehydration caused by the changes of diet and mental factors during the period of fasting therapy in hospital [19]. Although the patient in this report suffered from the underlying diseases of hyperuricemia, she did not show gout and

other clinical symptoms before treatment, and did not induce symptoms during or after treatment. The mainstream view now is that asymptomatic hyperuricemia has potential risks of many complications like hypertension and chronic kidney disease, but the researches are still in progress [20]. In the treatment of traditional Chinese medicine fasting therapy, if the patient's uric acid is above proof, it should be timely drug intervention. In addition, there is a study showing that hyperuricemia with only crystalline urine and no other symptoms can lead to the progression of chronic kidney disease [21]. Therefore, it is necessary to consider cautiously whether the patients with nephropathy can be treated with the fasting therapy of traditional Chinese medicine.

Finally, a transient increase in bilirubin was observed in the reported case. It is related to the low calorie fasting, and its bilirubin level is related to the fasting time [22]. The possible reason is a reduction of fat intake caused by fasting, and the obstruction of bile excretion due to the lack of stimulation [10]. It is different from the increase of bilirubin caused by liver function and hemolysis and has lower adverse health effects. Meanwhile, it is proved that a degree of increase of bilirubin level has protective effect on metabolic syndrome and coronary heart disease [23, 24].

In a word, under the condition of correct diagnosis, treatment and clinical monitoring, fasting therapy of traditional Chinese medicine is indeed a safe and effective treatment for diabetes.

## 4. CONCLUSION

Through the contents provided in this case report, we can have a deeper understanding of the clinical application of traditional Chinese medicine fasting therapy to alleviate type 2 diabetes with obesity and metabolic syndrome and improve insulin resistance. At the same time, we also have a more systematic understanding of the possible adverse reactions of traditional Chinese medicine fasting therapy, such as hypoglycemia, and transient increases in uric acid and bilirubin. It is helpful to promote the clinical application of traditional Chinese medicine fasting therapy.

## **Acknowledgments**

The authors thank Traditional Chinese Medicine department of the Seventh Affiliated Hospital, Sun Yat-sen University for considerate guidance and assistance.

## Funding

This research was funded by Sun Yat-Sen University and the Seventh Affiliated Hospital, Sun Yat-sen University.

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