

The Efficacy of Jinlida Granules on Type 2 Diabetes Mellitus was Discussed Based on the Theory of “Treating from Spleen”

Dandan Hu¹, Minhui Zheng¹, Xiaohong Li²

¹Department of Internal Medicine, Fujian Provincial Corps Hospital of Chinese People's Armed Police Forces, Fuzhou 250000, Fujian, China

²Department of Pathology, Changle District People's Hospital, Fuzhou 250000, Fujian, China

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Abstract: *Objective:* To explore the clinical efficacy of the spleen-strengthening and body fluid-moving formula, Jinlida Granules, in combination with Metformin for treating type 2 diabetes based on the theory of ‘treating from the spleen.’ *Methods:* A case-control study was conducted, involving 62 patients with type 2 diabetes admitted between August 2022 and December 2024. These patients were randomly divided into a control group (31 patients treated with Metformin) and an observation group (31 patients treated with Jinlida Granules), both for a 12-week course of treatment. The study compared changes in blood glucose levels (FPG, 2hPG, HbA1c), lipid levels (TC, TG, LDL, HDL), and pancreatic function indicators (HOMA-B, HOMA-IR) before and after treatment in both groups, and assessed the overall clinical effectiveness. *Results:* The overall effectiveness rate of the observation group was 90.3%, significantly higher than the 74.2% in the control group ($P < 0.05$). After treatment, the FPG in the observation group decreased by $2.1 \pm 0.8\%$ mmol/L, and HbA1c decreased by $1.5 \pm 0.6\%$. Additionally, the 2hPG in the observation group was significantly better than that in the control group, with a $18.3 \pm 5.2\%$ increase in HOMA-B and a $1.5 \pm 0.6\%$ decrease in HOMA-IR, all of which were better than those in the control group ($P < 0.05$). *Conclusion:* Jinlida Granules combined with Metformin can significantly improve the glucose and lipid metabolism and pancreatic cell function in patients with type 2 diabetes.

Keywords: Treating from the spleen; Jinlida granules; Type 2 diabetes

Online publication:

1. Introduction

In traditional Chinese medicine (TCM), the spleen is often regarded as the pivotal organ for the body's Qi movement. Its ability to transform and transport nutrients and fluids directly affects the body's metabolic balance. The “Huangdi Neijing” (Yellow Emperor's Inner Canon) states, “When food enters the stomach, it circulates with vital energy, which then ascends to the spleen, where the spleen disperses the essence.” If this dynamic regulatory system,

centered on the spleen, malfunctions, it can lead to the pathological condition of “water turning into dampness and grains becoming stagnant” [1]. In modern medicine, the typical symptoms of diabetes, such as polyuria, polydipsia, polyphagia, and weight loss, closely mirror the TCM concept of “spleen deficiency leading to impaired transformation and distribution of body fluids,” which results in diabetes 脾虚. When the spleen fails to function properly, it not only prevents the transformation of nutrients and fluids into Qi and blood but also leads to the accumulation of turbid substances [2]. In this pathological state, the abnormal rise in blood sugar is merely an external manifestation of organ dysfunction, with the core issue being the spleen’s failure to properly transform and distribute body fluids, leading to a comprehensive disorder in the metabolism of qi, blood, and body fluids [3]. From a clinical perspective [4], while the traditional method of “nourishing yin and clearing heat” can alleviate some symptoms of diabetes, it often overlooks the spleen’s crucial role in the distribution of body fluids, leading to a situation where treating the symptoms is difficult without addressing the root cause. For example, some patients who take cold-natured medications for a long time may experience reduced appetite and heaviness in the limbs, indicating damage to the spleen yang. This phenomenon has prompted medical practitioners to reassess the theoretical value of “treating from the perspective of the spleen,” emphasizing that “strengthening the spleen and transforming body fluids” is not just about tonifying the spleen qi but also about restoring the spleen’s physiological functions of transforming and distributing body fluids to the lungs [5]. By activating the spleen’s ability to transport the essence of food and water, it reconstructs the metabolic cycle where the spleen disperses essence, which then returns to the lungs, regulates the water pathways, and transports it to the bladder. This holistic regulatory approach resonates with modern medicine’s goals of improving insulin resistance and repairing pancreatic function. The formula of Jinlida Granules, with its key ingredients like Astragalus and Atractylodes for strengthening the spleen and drying dampness, is complemented by Pueraria root to enhance spleen yang and Coptis to clear heat, embodying the principle of ‘pungent to open, bitter to descend.’ This not only restores the Qi mechanism in the middle energizer but also promotes the normal distribution of body fluids [6,7]. This study, based on the theory of ‘treating from the spleen,’ explores the clinical efficacy of the spleen-strengthening and body fluid-regulating formula Jinlida Granules combined with Metformin in treating type 2 diabetes.

2. General information and methods

2.1. General information

A case-control study design was conducted, involving 62 patients with type 2 diabetes admitted between August 2022 and December 2024. The patients were randomly divided into a control group (31 cases treated with metformin) and an observation group (31 cases treated with Jinlida Granules). The 31 patients in the control group ranged in age from 47 to 70 years, with an average age of 55.1 ± 7.0 years old. Among them, 15 were male (48.4%) and 16 were female (51.6%), with an average BMI of 25.9 ± 3.1 kg/m². The 31 patients in the observation group ranged in age from 45 to 68 years, with an average age of 54.2 ± 6.3 years old. Of these, 17 were male (54.8%) and 14 were female (45.2%), with an average BMI of 26.3 ± 2.8 kg/m².

Inclusion criteria: (1) Conforming to the World Health Organization (WHO) diagnostic criteria for type 2 diabetes mellitus; (2) No insulin treatment within the past 6 months; (3) Fasting blood glucose > 7.0 mmol/L and postprandial 2-hour blood glucose ≥ 11.1 mmol/L; (4) Age 40–70 years old.

Exclusion criteria: (1) Severe organ dysfunction, such as renal failure or decompensated liver cirrhosis; (2) History of immune system diseases, mental disorders, or malignant tumors; (3) Known allergy to metformin or the components of Jinlida Granules; (4) Pregnant or breastfeeding women; (5) Women who have participated in clinical

trials of other antidiabetic drugs within the past 3 months.

2.2. Method

2.2.1. Drug regimen of the control group

Take the oral metformin hydrochloride tablets (0.5 g per tablet) at a starting dose of 500 mg twice daily with meals. Based on the patient's blood glucose levels and gastrointestinal tolerance, the dose should be increased by 500 mg weekly, with a maximum daily dose of 2000 mg. During treatment, monitor liver and kidney function as well as blood glucose levels. Adjust the current dose or make appropriate adjustments based on individual conditions as needed.

2.2.2. Medication regimen of the observation group

In addition to the medication in the control group, Jinlida Granules (ingredients: Astragalus, Atractylodes, Pueraria, Coptis, etc., specification: 9 g/bag) are taken at a dose of 9 g three times daily, 30 minutes before meals, mixed with 200 mL of warm water. The dosage adjustment principle for Metformin is the same as that of the control group. Jinlida Granules should be taken continuously for 12 weeks, during which other Chinese herbal hypoglycemic preparations are prohibited. Liver and kidney function should be rechecked every 4 weeks during treatment. If severe diarrhea or gastrointestinal discomfort occurs, Jinlida Granules should be suspended for 3 days, and the dose should be adjusted to 6 g per dose.

2.3. Evaluation criteria

2.3.1. Evaluation of clinical efficacy

According to the "Guidelines for the Prevention and Treatment of Type 2 Diabetes in China" and the improvement rate of TCM syndrome scores, the criteria are as follows: For significant effect, FPG should be ≤ 7.0 mmol/L, HbA1c should decrease by at least 1.5%, and the TCM syndrome score should decrease by at least 60%; for effective effect, FPG should decrease by at least 10% and HbA1c should decrease by at least 0.5%, and the TCM syndrome score should decrease by at least 30%; for ineffective effect, if the above criteria are not met, the total effective rate is calculated as (number of cases with significant effect + number of cases with effective effect) / total number of cases $\times 100\%$.

2.3.2. Evaluation of blood glucose metabolism

Fasting blood glucose (FPG) and 2-hour postprandial blood glucose (2hPG) were detected by a fully automatic biochemical analyzer, and hemoglobin A1c (HbA1c) was analyzed by high-pressure liquid phase method, and a difference of $\geq 10\%$ before and after treatment was considered as an effective improvement.

2.3.3. Evaluation of blood lipid metabolism

A decrease of total cholesterol (TC), triglyceride (TG) and low-density lipoprotein cholesterol (LDL-C) by more than 10% or an increase of high-density lipoprotein cholesterol (HDL-C) by more than 0.1 mmol/L is considered as effective regulation. The detection is performed by fully automatic biochemical analyzer, and the operation is carried out according to the kit instructions.

2.3.4. Evaluation of islet function

The steady-state model evaluation method was used to calculate the pancreatic β -cell function index (HOMA-B) and insulin resistance index (HOMA-IR). The improvement of pancreatic function was determined by HOMA-B increased by more than 10% and HOMA-IR decreased by more than 0.5 after treatment.

2.4. Statistical methods

The data were imported into SPSS 26.0 software for statistical analysis, and the measurement data were presented in the form of mean \pm standard deviation (SD). The independent sample *t*-test was used for inter-group comparison, and the rate (%) was used to express the count data and the chi-square test was used. $P < 0.05$ was set as the threshold value for statistically significant difference.

3. Results

3.1. Comparison of total efficiency

The total effective rate of the observation group was 90.3%, significantly higher than that of the control group (74.2%) ($P < 0.05$) (Table 1).

Table 1. Comparison of total effective rate between the two groups

Group	Example	Efficacy (example)	Effective (example)	Ineffective cases(example)	Overall effective rate (%)
Observation group	31	15	13	3	90.3%
Control group	31	10	13	8	74.2%
χ^2					8.294
<i>P</i>					0.000

3.2. Blood sugar index

After treatment, the FPG of the observation group decreased (2.1 ± 0.8) mmol/L and HbA1c decreased (1.5 ± 0.6)%, and the 2hPG index of the patients in the observation group was significantly better than that of the control group, and the improvement degree was significantly better than that of the control group ($P < 0.05$) (Table 2).

Table 2. Changes of blood glucose indexes in two groups of patients (mean \pm SD)

Parameters	Group	Before treatment	After treatment
FPG (mmol/L)	Observation group	9.2 ± 1.5	7.1 ± 1.2
	Control group	9.3 ± 1.6	8.0 ± 1.3
HbA1c (%)	Observation group	8.5 ± 1.0	7.0 ± 0.8
	Control group	8.6 ± 1.1	7.6 ± 0.9
2hPG (mmol/L)	Observation group	12.5 ± 1.0	7.6 ± 0.8
	Control group	12.6 ± 1.1	9.1 ± 0.9

3.3. Lipid indicators

The degree of TC, TG, LDL reduction and HDL increase in the observation group was significantly higher than that in the control group ($P < 0.05$) (Table 3).

Table 3. Changes of lipid indexes in two groups of patients (mean \pm SD)

Parameters	Group	Before treatment	After treatment
TC (mmol/L)	Observation group	5.8 \pm 1.2	4.5 \pm 0.9
	Control group	5.7 \pm 1.1	5.0 \pm 1.0
TG (mmol/L)	Observation group	2.5 \pm 0.7	1.8 \pm 0.5
	Control group	2.6 \pm 0.6	2.2 \pm 0.6
LDL (mmol/L)	Observation group	3.4 \pm 0.8	2.6 \pm 0.6
	Control group	3.3 \pm 0.7	3.0 \pm 0.7
HDL (mmol/L)	Observation group	1.0 \pm 0.2	1.3 \pm 0.3
	Control group	1.1 \pm 0.2	1.2 \pm 0.2

3.4. Insulin function index

In the observation group, HOMA-B increased by $18.3 \pm 5.2\%$ and HOMA-IR decreased by $1.5 \pm 0.6\%$, both significantly better than the control group ($P < 0.05$) (Table 4).

Table 4. Changes of pancreatic function indexes (mean \pm SD) in two groups of patients

Parameters	Group	Before treatment	After treatment
HOMA-B (%)	Observation group	60.0 \pm 10.0	78.3 \pm 12.0
	Control group	61.0 \pm 9.5	68.0 \pm 10.5
HOMA-IR	Observation group	4.5 \pm 1.2	3.0 \pm 0.8
	Control group	4.6 \pm 1.1	3.8 \pm 1.0

4. Discussion

Type 2 diabetes is characterized by insulin resistance and the progressive decline of β -cell function. The “high sugar toxicity” it causes often leads to metabolic disorders, including lipid abnormalities, chronic inflammation, and damage to multiple systems [8]. While modern medicine can control blood glucose fluctuations with short-term hypoglycemic drugs, it struggles to reverse the fundamental TCM pathogenesis of spleen dysfunction and fluid distribution disorders. As stated in the “Suwen Qibing Lun”: “This condition arises from overindulgence in rich foods; the person must frequently consume sweet and fatty foods. Fatty foods cause internal heat, while sweet foods lead to fullness in the middle, causing qi to rise and transform into thirst,” highlighting the pathogenic chain of spleen dysfunction caused by excessive consumption of rich and sweet foods [9]. The formula of Jinli Da Granules focuses on “restoring the spleen’s transformation and promoting the smooth flow of the middle energizer.” It uses Astragalus (a warming herb) to tonify Qi and elevate Yang to invigorate the spleen Yang, Atractylodes (a bitter-warm herb) to dry dampness and awaken the spleen to expel internal dampness, Pueraria (a raw herb) to generate body fluids and clear the clear, assisting the spleen to disperse essence, and Coptis (a bitter-cold herb) to clear and purge depressed heat and prevent dampness from transforming into fire. The combination of these four herbs, with their pungent and bitter properties, avoids the drawbacks of Yin-nourishing herbs that can be greasy and obstruct the stomach, as well as the risks of clearing heat herbs that can damage the middle yang, allowing body fluids to ‘ascend and descend’ and restore their normal flow [10].

In this study, the total effective rate of the observation group increased by 16.1% compared to the control group (90.3% vs 74.2%). The HbA1c level decreased by 1.5%, and the HOMA-B score increased by 18.3%. These results

confirm the unique advantages of the spleen-strengthening and fluid transporting method in improving insulin secretion function. The spleen's role in governing muscles and promoting metabolism means it plays a crucial role in regulating glucose uptake and transport. When the spleen is strong, nutrients are efficiently distributed to muscle tissue for oxidation and energy production rather than being retained in the blood as "turbid sugar." This aligns with modern medical theories on enhancing skeletal muscle insulin sensitivity and inhibiting liver glucose output. The active ingredients in Jinlida Granules, such as Puerarin and Astragaloside A, have been shown to activate the AMPK signaling pathway, promoting glycolipid metabolism, which is a molecular biological expression of the "spleen dispersing essence" theory [11]. The LDL level in the observation group decreased by 0.8 mmol/L, and the HDL level increased by 0.3 mmol/L, showing a better lipid-regulating effect compared to the control group. This improvement is due to the pathological characteristics of fat turbidity accumulation in the spleen deficiency and impaired transportation. According to "Medical Classics Must Read," "the change from rich food can lead to severe boils; in wealthy and noble people, this disease is caused by rich food." When the spleen fails to disperse essence, the fat does not return to its normal state, leading to stagnation in the pulse channels, which is known as phlegm and stasis. Jinlida Granules restore the spleen's ascending function, converting lipids into Qi, blood, and body fluids rather than depositing them as pathological products. Its multi-target regulation characteristic compensates for the limitations of Western medicine, which focuses on enzyme inhibitors [12]. The 18.3% improvement in pancreatic β -cell function suggests that the spleen-strengthening and fluid-moving method may delay the apoptosis of β -cells during the natural course of diabetes. This aligns well with the theory that "the spleen is the foundation of postnatal health and the source of qi and blood production."

In a state of spleen deficiency, oxidative stress and endoplasmic reticulum stress continuously attack β -cells. Components such as astragalus polysaccharides and atractylodes ketone can reduce pancreatic inflammation by inhibiting the NF- κ B pathway. This treatment strategy of "strengthening the middle energizer to nourish the innate constitution" provides a new paradigm for the integrated Chinese and Western medicine intervention in type 2 diabetes [13,14]. Current diabetes management is shifting from a "blood glucose-centric" approach to a "metabolic homeostasis holistic regulation." The concept of "spleen-body-fluid-metabolism" axis regulation embodied in Jinlida granules not only offers a modern interpretation of the "treatment from the spleen" theory but also highlights the importance of restoring the ascending and descending Qi mechanism of the middle energizer or breaking the vicious cycle of insulin resistance. Future research should further explore the mechanisms linking "spleen governing transformation and transportation" with the intestinal microbiota and adipokine network systems, promoting the deep integration of traditional Chinese medicine theory with precision medicine.

5. Conclusion

To sum up, the combination of Jinlida granules and Metformin can significantly improve the glucose metabolism and islet cell function of patients with type 2 diabetes, clarify the theoretical basis of "treating from the spleen" for the clinical guidance of type 2 diabetes, and provide new ideas for the treatment of diabetes.

Funding

School Management Project of Fujian University of Traditional Chinese Medicine (Project No.: XB2022193)

Disclosure statement

The author declares no conflict of interest.

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