

Clinical Study of Qingju Paizhi Tea Combined with Insulin Degludec and Liraglutide Injection in Overweight Type 2 Diabetic Patients with Dampness-Heat Excess Pattern

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How to cite this paper: Zhang, T. (2026) Clinical Study of Qingju Paizhi Tea Combined with Insulin Degludec and Liraglutide Injection in Overweight Type 2 Diabetic Patients with Dampness-Heat Excess Pattern. *Journal of Biosciences and Medicines*, 14, 160-169.

<https://doi.org/10.4236/jbm.2026.1410011>

Received: September 6, 2026

Accepted: October 17, 2026

Published: October 20, 2026

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Abstract

Objective: To explore the effects of Qingju Paizhi Tea combined with Insulin Degludec and Liraglutide Injection on body weight, blood glucose and low-density lipoprotein-cholesterol levels in overweight type 2 diabetic patients with dampness-heat excess pattern, so as to provide practical evidence for optimizing clinical intervention strategies for such patients. **Methods:** Sixty patients clinically diagnosed with overweight type 2 diabetes mellitus of dampness-heat excess syndrome were enrolled and randomly divided into the control group and the observation group in a double-blind manner, with 30 cases in each group. The control group received Insulin Degludec and Liraglutide Injection via once-daily injection. The observation group was administered one dose of Qingju Paizhi Tea per day in combination with Insulin Degludec and Liraglutide. The intervention course lasted 6 months for both groups. Before and after the intervention, indicators including height, body weight, fasting and postprandial blood glucose levels, LDL-C level and intervention satisfaction were collected from patients in the two groups respectively. **Results:** Before intervention, there were no statistically significant differences in body weight, BMI, blood glucose and LDL-C levels between the two groups (all $P > 0.05$). After 6-month intervention, all indicators decreased significantly in the observation group, and patients in the observation group reported higher satisfaction with intervention outcomes, with statistically significant differences (all $P < 0.05$). **Conclusion:** Qingju Paizhi Tea combined with Insulin Degludec and Liraglutide Injection exerts significant effects on body weight, blood glucose and low-density lipoprotein-cholesterol levels in overweight type 2 diabetic patients with dampness-heat excess pattern, and possesses high popularization and application value.

Keywords

Qingju Paizhi Tea, Insulin Degludec and Liraglutide Injection, Weight Loss, Diabetes Mellitus

1. Introduction

Type 2 diabetes mellitus is a clinically prevalent chronic metabolic disease. Influenced by unhealthy lifestyles and dietary habits, the incidence of overweight complicated with type 2 diabetes mellitus continues to increase. Obesity can aggravate glucose-lipid metabolic disorders in the body, elevate the risk of cardiovascular complications, seriously impair patients' health and increase the social medical burden. Exploring effective comprehensive intervention regimens to improve metabolic status and prognosis of overweight patients with type 2 diabetes mellitus is of great clinical value [1] [2]. Insulin Degludec and Liraglutide Injection is a novel long-acting preparation for type 2 diabetes mellitus. It can effectively lower blood glucose, regulate lipid levels and reduce body weight, featuring convenient administration and satisfactory patient compliance, and is widely used in clinical practice. However, western medicine alone can only control indicators symptomatically and cannot fundamentally ameliorate metabolic disorders induced by dampness-heat constitution, so monotherapy has certain limitations [3].

In traditional Chinese medicine, overweight type 2 diabetes mellitus is classified into the category of "Xiaoke". Dampness-heat excess is its major pattern, and spleen-stomach dysfunction as well as internal retention of dampness-heat serve as the core pathogenesis triggering glucose-lipid metabolic disorders [4]. Syndrome-differentiated therapy of traditional Chinese medicine can regulate body metabolism holistically. Qingju Paizhi Tea can clear heat-dampness, invigorate the spleen to resolve turbidity, reduce lipids and unblock collaterals. It conforms to the core pathogenesis of the disease and possesses favorable advantages for adjuvant treatment [5]. At present, most clinical research focuses on monotherapy with Insulin Degludec and Liraglutide Injection, while controlled studies on the intervention of Qingju Paizhi Tea combined with this drug for overweight type 2 diabetic patients with dampness-heat excess pattern are still insufficient. Therefore, this randomized double-blind controlled trial was carried out to analyze the effects of integrated Chinese-Western therapeutic regimen on patients' body weight, blood glucose, low-density lipoprotein-cholesterol and treatment satisfaction, so as to provide a reliable evidence-based basis for clinical intervention in this disease.

2. Methods

2.1. Study Subjects

A total of 60 diabetic outpatients and inpatients from the Department of Endocrinology of Ma'anshan Hospital of Traditional Chinese Medicine between January

2024 and July 2024 were selected. All participants volunteered and signed informed consent forms.

2.1.1. Inclusion Criteria (Subjects Meeting All the Following Five Items Can Be Included)

① Meeting the western-medicine diagnostic criteria for type 2 diabetes mellitus specified in the Guideline for the Prevention and Treatment of Type 2 Diabetes Mellitus in China (2020 Edition)*, and conforming to the overweight standard (body mass index ≥ 25 kg/m²). The diagnosis of type 2 diabetes mellitus adopts venous plasma glucose and glycated hemoglobin A1c (HbA1c) as indicators. For patients with classic diabetes symptoms (polydipsia with excessive drinking, polyuria, polyphagia, unexplained weight loss), diagnosis is confirmed if any one of the following is met: random venous blood glucose ≥ 11.1 mmol/L, fasting plasma glucose (FPG) ≥ 7.0 mmol/L, 2-hour blood glucose in the oral glucose tolerance test (OGTT) ≥ 11.1 mmol/L, or HbA1c $\geq 6.5\%$. For individuals without classic diabetes symptoms, re-examination on a separate day is required for final confirmation. ② Diagnosed as dampness-heat excess syndrome according to traditional Chinese medicine syndrome differentiation. The diagnosis is made comprehensively based on primary symptoms, secondary symptoms and tongue-pulse manifestations. Primary symptoms include obese body shape, polyphagia with rapid hunger onset, abdominal fullness and distension, and burning epigastric pain. Secondary symptoms include dry mouth with bitter taste, dysphoria and dizziness, constipation or diarrhea, and dark yellow urine. Tongue and pulse findings present as red tongue with yellow or greasy coating, enlarged and plump tongue, and wiry or slippery pulse. The syndrome is confirmed when 2 primary symptoms and 1 secondary symptom are present, combined with corresponding tongue and pulse manifestations. All syndrome assessments are independently conducted by two licensed traditional Chinese medicine physicians with at least 5 years of clinical experience, and any disagreements are resolved through consensus discussion. ③ Aged from 18 to 65 years old with no restriction on gender; ④ Voluntary participation, signed informed consent form and good compliance; ⑤ Complete clinical data.

2.1.2. Exclusion Criteria (Subjects with Any of the Following Items Shall Be Excluded)

① Positive skin test for Insulin Degludec and Liraglutide Injection; ② Prior use of any of the following drugs or therapies before randomization: GLP-1 analogues, growth hormone, corticosteroids, parenteral administration or intra-articular administration; ③ History of severe hypoglycemic episodes; type 1 diabetes mellitus, monogenic diabetes mellitus, diabetes mellitus caused by pancreatic injury or secondary diabetes mellitus; severe acute or chronic gastrointestinal diseases; history of severe cardiovascular diseases, acute or chronic pancreatitis; history of medullary thyroid carcinoma; acute metabolic complications (ketoacidosis, lactic acidosis or hyperosmolar coma), proliferative retinopathy or maculopathy; ④ Pregnant or lactating women.

2.1.3. Discontinuation and Elimination Criteria

① Patients who cannot adhere to the trial protocol and voluntarily request withdrawal; ② Patients taking drugs that interfere with the efficacy observation of this study during the trial; ③ Patients who drop out of the trial or are lost to follow-up during the study for various reasons.

2.1.4. Randomization and Blinding

A 1:1 group allocation sequence was generated using a computer-generated random number table. Allocation concealment was implemented using sequentially numbered, sealed, opaque envelopes. Each envelope contained group assignment information and was opened only after a participant completed baseline examinations and was formally enrolled.

Blinding was applied to the allocation of Qingju Paizhi Tea. Both groups received the same Insulin Degludec and Liraglutide Injection regimen. The placebo of Qingju Paizhi Tea was identical to the active preparation in appearance, flavor and packaging. Participants, outcome assessors and data analysts were all masked to the herbal tea allocation. All study preparations were dispensed by an independent pharmacist not involved in patient recruitment, intervention or outcome evaluation. Clinicians administering injections did not participate in outcome assessment to maintain blinding.

2.2. Intervention Methods

2.2.1. Lifestyle Intervention

Unified diabetes health education manuals and standardized dietary and exercise guidance were formulated for all participants. Regular follow-up visits were conducted every 4 weeks to supervise the implementation of lifestyle intervention, and dietary and exercise records were checked on site.

Medication adherence was assessed at each follow-up by pill count combined with patient self-report. Adherence to Qingju Paizhi Tea was evaluated by checking remaining tea bags and patient drinking diaries. Adherence rate $\geq 80\%$ was defined as good adherence.

2.2.2. Group-Based Intervention

Control group: The control group received lifestyle intervention plus once-daily subcutaneous injection of Insulin Degludec and Liraglutide Injection for 6 months. A fixed-dose regimen was applied in this study, with the daily dose maintained consistently throughout the intervention and no individualized dose titration performed. Blood glucose control targets were in accordance with the *Guideline for the Prevention and Treatment of Type 2 Diabetes Mellitus in China (2020 Edition)*. No additional concomitant glucose-lowering medications were allowed during the study. Dose adjustment or treatment suspension would be implemented only in the event of severe hypoglycemia or intolerable adverse reactions.

Observation group: The observation group received oral Qingju Paizhi Tea plus once-daily subcutaneous injection of Insulin Degludec and Liraglutide Injection for 6 months. The fixed-dose regimen, blood glucose control targets, concomitant

medication restrictions and treatment adjustment criteria were consistent with those of the control group. Qingju Paizhi Tea (ingredients: raw hawthorn 15 g, cassia seed 10 g, wolfberry 5 g, chrysanthemum 6 g, poria 10 g, lotus leaf 3 g, dried tangerine peel 3 g; usage: one dose per day, prepared as herbal tea for drinking) was provided by the Traditional Chinese Medicine Pharmacy of Ma'anshan Hospital of Traditional Chinese Medicine.

2.3. Index Detection

① Patients' height and body weight were recorded routinely, and body mass index (BMI) was calculated. ② Biochemical indicators: Venous blood samples were collected in the Clinical Laboratory of Ma'anshan Hospital of Traditional Chinese Medicine before and after intervention to detect fasting and postprandial blood glucose levels as well as LDL-C. ③ Patients' satisfaction with intervention outcomes was investigated after 6-month intervention.

2.4. Data Analysis

Data analysis was conducted using SPSS 26.0 statistical software. Normally distributed measurement data were presented as mean $\pm$ standard deviation. Inter-group comparisons were performed using independent samples t-test, and intragroup comparisons of pre- and post-intervention data were performed using paired t-test. Non-normally distributed measurement data were expressed as median (interquartile range) and analyzed with rank sum test. A two-sided significance level of $\alpha = 0.05$ was adopted for all statistical tests.

3. Results

3.1. Comparison of Body Weight and BMI between the Two Groups during Intervention

Before intervention, there were no statistically significant differences in body weight and BMI between the two groups ($P > 0.05$). After 6-month intervention, the body weight and BMI in the observation group were significantly lower than those in the control group, and the differences were statistically significant ($P < 0.05$). See **Table 1** and **Table 2**.

Table 1. Comparison of body weight between the two groups during intervention ($\bar{x} \pm s$, kg).

Time-point	Control group (n = 30)	Observation group (n = 30)	P
At admission	82.03 $\pm$ 13.06	80.23 $\pm$ 13.42	0.6006
6 months	77.22 $\pm$ 12.93	69.05 $\pm$ 12.46	0.0156

Table 2. Comparison of BMI between the two groups during intervention ($\bar{x} \pm s$, kg/m²).

Time-point	Control group (n = 30)	Observation group (n = 30)	P
At admission	28.85 $\pm$ 3.34	28.70 $\pm$ 3.72	0.8700
6 months	27.13 $\pm$ 3.21	24.67 $\pm$ 3.62	0.0072

3.2. Comparison of Blood Glucose Levels between the Two Groups during Intervention

Before intervention, there was no statistically significant difference in blood glucose levels between the two groups ($P > 0.05$). After 6-month intervention, the blood glucose level in the observation group was significantly lower than that in the control group, and the difference was statistically significant ($P < 0.05$). See **Table 3** and **Table 4**.

Table 3. Comparison of fasting blood-glucose levels between the two groups during intervention ($\bar{x} \pm s$, mmol/L).

Time-point	Control group (n = 30)	Observation group (n = 30)	P
At admission	10.54 $\pm$ 3.83	10.03 $\pm$ 3.26	0.5808
6 months	7.99 $\pm$ 2.64	6.57 $\pm$ 2.56	0.0387

Table 4. Comparison of postprandial 2-h blood-glucose levels between the two groups during intervention ($\bar{x} \pm s$, mmol/L).

Time-point	Control group (n = 30)	Observation group (n = 30)	P
At admission	18.27 $\pm$ 4.23	18.39 $\pm$ 4.23	0.9129
6 months	14.69 $\pm$ 3.33	12.50 $\pm$ 4.05	0.0258

3.3. Comparison of Low-Density Lipoprotein Levels between the Two Groups during Intervention

Before intervention, there was no statistically significant difference in low-density lipoprotein levels between the two groups ($P > 0.05$). After 6-month intervention, the low-density lipoprotein level in the observation group was significantly lower than that in the control group, and the difference was statistically significant ($P < 0.05$). See **Table 5**.

Table 5. Comparison of low-density lipoprotein levels between the two groups during intervention ($\bar{x} \pm s$, mmol/L).

Time-point	Control group (n = 30)	Observation group (n = 30)	P
At admission	2.80 $\pm$ 1.02	2.73 $\pm$ 0.86	0.7748
6 months	2.29 $\pm$ 0.75	1.76 $\pm$ 0.76	0.0086

3.4. Survey on Patients' Satisfaction with Intervention Outcomes in the Two Groups

After 6-month intervention, the satisfaction status of patients in the two groups was investigated. The satisfaction rate of patients in the observation group was significantly higher than that in the control group, and the difference was statistically significant ($P < 0.05$). See **Table 6**.

Table 6. Comparison of patients' satisfaction with intervention outcomes between the two groups (N).

Dimension	Dissatisfied	Satisfied	P
Control group (n = 30)	18	12	0.0384
Observation group (n = 30)	10	20	---

4. Discussion

The results of this study showed that after 6-month intervention, the observation group receiving Qingju Paizhi Tea on the basis of Insulin Degludec and Liraglutide achieved better improvements in body weight, BMI, fasting blood glucose, 2-h postprandial blood glucose and LDL-C than the control group treated with western medicine alone. Meanwhile, patients in the observation group reported higher treatment satisfaction. It suggests that combined Chinese-western medicine intervention exerts synergistic therapeutic effects on overweight type 2 diabetes mellitus with dampness-heat excess syndrome.

Insulin degludec and Liraglutide combines the stable glycemic control of basal insulin with the appetite-suppressing and gastric-emptying-delaying effects of a GLP-1 receptor agonist, thereby achieving multiple benefits including blood-glucose lowering, weight reduction and lipid regulation, and is a preferred drug for overweight type 2 diabetes mellitus [6] [7]. In this study, after intervention, body weight and glucose-lipid indicators in the control group improved relative to baseline, which confirmed the clinical efficacy of this drug; however, with western medicine alone, the extent of reduction in body weight and blood lipids was limited in some patients. On this basis, the observation group was additionally given Qingju Paizhi Tea, which played an adjuvant regulatory role targeting the pathological state of dampness-heat excess in this population, promoted the excretion of metabolic waste, complemented the western medicine, and further reduced body weight. In terms of glycemic control, Insulin Degludec and Liraglutide can address both fasting and postprandial blood glucose; nevertheless, in some patients with dampness-heat constitution, disordered glucose metabolism tends to recur due to abnormal spleen-stomach transportation and transformation [8]. After the combined intervention, more significant decreases in fasting and 2-h postprandial blood glucose were observed in the observation group. It is speculated that Qingju Paizhi Tea improves the spleen-stomach transportation and transformation function, reduces the interference of damp-heat turbid pathogens on glucose metabolism, and thereby assists in enhancing the hypoglycemic effect.

LDL-C is an important risk factor for cardiovascular complications in diabetes mellitus, and reducing LDL-C can lower the risk of macrovascular events [9]. In this study, the reduction of LDL-C in the observation group was superior to that in the control group, suggesting that combined intervention can strengthen the lipid-regulating effect. Modern pharmacological studies have demonstrated that ingredients such as hawthorn and cassia seed in the formula can assist in regulat-

ing lipid metabolism. When superimposed with the lipid-modulating effect of GLP-1 receptor agonist, they contribute to improving patients' lipid profiles [10] [11]. Higher satisfaction was observed in the observation group, which may be attributed to the more prominent improvements in body weight and metabolic indicators brought by the combined regimen. The regimen better meets the dual demands of weight loss and disease control for patients with overweight type 2 diabetes mellitus, and improves patients' subjective treatment experience.

There are certain limitations in this study. It is a single-center study with a limited sample size, and the follow-up period is only 6 months; long-term endpoint events were not observed. Only patients with the single traditional Chinese medicine syndrome of dampness-heat excess were included, which restricts the extrapolation of the conclusions. Further multi-center studies with larger sample sizes and extended follow-up duration can be carried out to further verify the long-term efficacy and safety of this combined regimen.

5. Conclusions

This study enrolled overweight patients with type 2 diabetes mellitus of dampness-heat excess syndrome as research subjects. Through a randomized double-blind controlled study, it confirmed that the integrated Chinese-western medicine intervention regimen of Qingju Paizhi Tea combined with Insulin Degludec and Liraglutide can effectively reduce patients' body weight, blood glucose and low-density lipoprotein levels, ameliorate glucose and lipid metabolism disorders, and improve satisfaction with clinical intervention. This regimen integrates the advantages of precise indicator regulation by western medicine and constitution conditioning based on traditional Chinese medicine syndrome differentiation, making up for the deficiency that single western medicine treatment only addresses symptoms but not the root cause. It can effectively improve the pathogenesis of dampness-heat excess in patients, break the vicious cycle of metabolic disorders, and meet the clinical intervention needs of patients with this disease.

In conclusion, the intervention mode of Qingju Paizhi Tea combined with Insulin Degludec and Liraglutide has definite therapeutic efficacy and high patient acceptability. It is an effective approach to optimize clinical intervention for overweight type 2 diabetes mellitus of dampness-heat excess syndrome, and possesses favorable clinical promotion value. Further work can be carried out to refine individualized syndrome-differentiated intervention protocols, improve the integrated Chinese-western medicine intervention system, deeply explore the action mechanism of the herbal formula, further enhance the clinical application effect of this regimen, and provide practical references for the integrated Chinese-western diagnosis and treatment of similar metabolic diseases.

Funding

Project support fund number: 2024CCCX204. YL-2023-17. MZH-2023-04.

Ethics Statement

This study was a randomized interventional clinical trial entitled Clinical Study of Qingju Paizhi Tea Combined with Insulin Degludec/Liraglutide Injection in the Treatment of Overweight Type 2 Diabetes with Dampness-Heat Excess Pattern. The study protocol was reviewed and approved by the Medical Ethics Committee of Ma'anshan Hospital of Traditional Chinese Medicine (approval date: May 17, 2024; approval number: (2024) Lun Shen Yan No. 11). Adult participants were recruited on a voluntary basis. Prior to enrollment, all participants were fully informed of the study procedures, purposes and potential risks, and signed written informed consent for the measurement and reporting of their authentic clinical data, as well as for the use of anonymized data in research and publication. No invasive procedures were involved in this study, and all intervention measures consisted of routine clinical treatment combined with Chinese medicinal herbal tea. All personally identifiable information has been removed from all study records. Participants were identified only by designations such as "Participant 1" (P1) and "Participant 2" (P2) to protect their privacy and confidentiality. All procedures were performed in accordance with the ethical standards of the Declaration of Helsinki and relevant clinical research regulations.

Conflicts of Interest

The authors declare that there is no conflict of interest regarding the present study.

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