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Effect of *Huangqi Sijunzi* Decoction combined with rosiglitazone on type 2 diabetes mellitus

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Abstract: Objective To investigate the therapeutic effects, Chinese medicine syndrome score, glycolipid metabolism and islet function of *Huangqi Sijunzi* Decoction combined with rosiglitazone on type 2 diabetes mellitus (T2DM) patients. **Methods** A prospective study was conducted on 120 T2DM patients who visited the Second Hospital of Shijiazhuang from 1 January 2022 to 31 March 2023. The patients were randomly divided into a research group and a control group using a random number table method, with 60 patients in each group. The control group received oral administration of rosiglitazone tablets, while the research group received additional administration of *Huangqi Sijunzi* Decoction. The changes of various indicators between the two groups were compared. **Results** The research group demonstrated a clinically superior total effective rate compared to the control group after 3 months of treatment (96.67% *vs* 83.33%, χ^2 =5.926, *P*=0.015). After treatment, the Chinese medicine syndrome scores of both groups decreased, and those of the research group were even lower (*P*<0.05). After treatment, the levels of fasting blood glucose (FBG), 2-hour postprandial blood glucose (2hPG), glycated hemoglobin (HbA1c), triglyceride (TG), low-density lipoprotein cholesterol (LDL-C), and total cholesterol (TC), fasting insulin (FINS), and homeostatic model assessment of insulin resistance (HOMA-IR) in both groups were lower than before treatment, while the levels of high-density lipoprotein cholesterol (HDL-C), 2-hour postprandial C-peptide (2hC-P), and HOMA-β were higher than before treatment (*P*< 0.05). After treatment, the levels of all indicators of glucose metabolism and all indicators of lipid metabolism, FINS, HOMA-IR in the research group were lower than those in the control group, while HDL-C, 2hC-P, and homeostasis model assessment-β (HOMA-β) were higher than those in the control group (*P*<0.05). There was no statistically significant difference in the total incidence of adverse reactions between the research group and control group (13.33% *vs* 10.00%, χ^2 =0.323, *P*=0.570). **Conclusion** The combination of *Huangqi Sijunzi* Decoction and rosiglitazone can significantly improve clinical symptoms and glycolipid metabolism indicators in T2DM patients, and the safety is high. **Keywords:** Type 2 diabetes; *Huangqi Sijunzi* Decoction; Rosiglitazone; Chinese medicine symptoms

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Type 2 diabetes mellitus (T2DM) is a complex metabolic disease resulting from the interaction between genetic background and environmental factors. Its core pathophysiological changes include insulin resistance and relative insulin deficiency caused by progressive impairment of pancreatic β-cell function [1]. The gut microbiota is involved in regulating host energy metabolism. Once its homeostasis is disrupted, it may trigger a persistent state of low-grade intestinal inflammation, which in turn interferes with glucose homeostasis through multiple pathways, playing a key role in the development and progression of T2DM [2]. In the clinical pharmacotherapy of T2DM, rosiglitazone (RSG) is a widely used drug for improving insulin sensitivity. Its mechanism of action is to selectively activate peroxisome proliferator-activated receptor γ, helping to achieve blood glucose control [3]. However, it has certain limitations in clinical application, such as potential increased risks of adverse reactions like hypoglycemic events and edema caused by fluid retention [4]. *Huangqi Sijunzi* Decoction is a classic formula in Chinese medicine for the treatment of spleen-stomach qi deficiency syndrome. Clinical reports have indicated that the combination of *Huangqi Sijunzi* Decoction with drugs such as saxagliptin and acarbose shows synergistic effects in improving islet function, insulin resistance, and Chinese medicine syndrome in T2DM patients [5-6]. However, systematic research verification on the clinical efficacy and characteristics of the combined application of *Huangqi Sijunzi* Decoction and RSG is still lacking. Based on this, this study evaluates the improving effects of the combined regimen of *Huangqi Sijunzi* Decoction and RSG on Chinese medicine clinical syndromes and overall therapeutic efficacy.

1 Materials and Methods

1.1 General Information

A total of 120 T2DM patients who were treated in the Second Hospital of Shijiazhuang from January 1, 2022 to March 31, 2023 were prospectively enrolled. They were divided into a study group and a control group using a random number table method, with 60 cases in each group. In the study group, there were 37 males and 23 females, with an age of (54.39±7.01) years and a disease duration of (3.95±0.58) years. In the control group, there were 31 males and 29 females, with an age of (53.62±5.94) years and a disease duration of (4.09±0.71) years. There were no statistically significant

differences in baseline clinical data between the two groups (P>0.05), indicating comparability. Written informed consent was obtained from all participants before the start of the study.

Inclusion criteria:

(1) Conformed to the diagnostic criteria for T2DM in reference [7] in Western medicine; in terms of Chinese medicine syndrome differentiation, patients must be of the qi-yin deficiency type, with clinical manifestations including but not limited to fatigue and lassitude, spontaneous sweating or night sweating, shortness of breath and disinclination to talk, thirst with a preference for drinking, five-palm heat, palpitations and insomnia, yellowish urine, dry stool, red tongue with less fluid, etc. [8-9];

(2) Newly diagnosed T2DM cases;

(3) Normal cognitive and communication abilities, able to cooperate with the completion of this study.

Exclusion criteria:

(1) Diagnosed with type 1 diabetes mellitus, or T2DM complicated with complications such as lower extremity ulceration or gangrene;

(2) Suffering from definite intestinal inflammation, peptic ulcer or other active gastrointestinal diseases;

(3) Complicated with immune system diseases or in the acute infection stage;

(4) Having severe liver insufficiency or renal failure;

(5) Having a history of major gastrointestinal surgery;

(6) Having contraindications or allergies to any drugs used in this study protocol;

(7) Having received treatments such as antibiotics or probiotics that may significantly affect the composition of intestinal microbiota within 4 weeks before enrollment;

(8) Having used any anti-diabetic drugs within 3 months before enrollment;

(9) Having high difficulty in enrollment judged by researchers, such as frequent changes in living or working places, which may easily lead to patient dropout and loss to follow-up.

Dropout criteria:

(1) Failure to complete the full course of treatment;

(2) Poor compliance and inability to complete the treatment as required.

This study was approved by the Ethics Committee of the Second Hospital of Shijiazhuang (Approval No. SEY-KYLL-2021043).

1.2 Treatment Methods

Both groups received strict dietary control, appropriate aerobic exercise, weight maintenance or reduction, and were strictly prohibited from smoking and alcohol consumption. The control group was given 1 tablet of RSG orally daily (Huakang Pharmaceutical Co., Ltd., Shanghai; National Medicine Approval Number: H20051288; Specification: 4 mg) in addition to the basic interventions. The study group was treated with the combination of RSG and *Huangqi Sijunzi* Decoction on the basis of the control group's regimen. The specific formula was as follows: chief herb, *Astragalus membranaceus* (20 g); puty herb, *Dendrobium officinale* (15 g); assistant herbs: *Poria cocos* (9 g), *Atractylodes macrocephala* (10 g), *Rehmannia glutinosa* (10 g), *Ligustrum lucidum* (10 g), *Pseudostellaria heterophylla* (6 g); envoy herb: *Coptis chinensis* (5 g).

Preparation and course of treatment: The above herbs were combined in the specified proportions, 1 dose per day, decocted with water to a concentrated solution, and the resulting liquid was taken warm in two divided doses (morning and evening). The treatment course for both groups was 3 months.

1.3 Efficacy Observation

After treatment, the clinical symptoms of patients were evaluated, including main symptoms and secondary symptoms, with each symptom scored on a 0–3 scale (higher scores indicating more severe symptoms). The total score was 30 points [10].

Main symptoms (0–3 points)

- Polydipsia [0 points: no thirst, normal water intake; 1 point: mild dry mouth, slightly increased water intake (daily intake increase < 500 mL); 2 points: obvious thirst, frequent drinking (daily intake increase 500–1,000 mL); 3 points: extreme thirst, uncontrolled drinking (daily intake increase > 1,000 mL)]
- Fatigue and weakness (0 points: energetic, able to move freely; 1 point: mild fatigue, relieved by rest; 2 points: persistent fatigue, affecting daily activities; 3 points: extreme weakness, difficulty getting out of bed)
- Polyphagia (0 points: normal appetite, no hunger; 1 point: slightly increased food intake, occasional hunger between meals; 2 points: easy hunger, overeating, feeling hungry shortly after meals; 3 points: uncontrollable binge eating)

Shortness of Breath and Reticence (0 points: stable breathing, fluent speech; 1 point: mild shortness of breath, pauses needed for long sentences; 2 points: intermittent speech, shortness of breath after short phrases; 3 points: dyspnea, only able to speak single words)

Secondary symptoms (0–3 points)

- Fever [0 points: normal body temperature (36.5–37.2 °C); 1 point: low-grade fever (37.3–38.0 °C); 2 points: moderate fever (38.1–39.0 °C); 3 points: high fever (> 39.0 °C) or persistent fever]
- Hyperhidrosis (0 points: no abnormal sweating; 1 point: slight sweating after activity; 2 points: sweating at rest; 3 points: profuse sweating, soaking clothes and bedding)

Bitter taste in mouth (0 points: no bitter taste; 1 point: transient bitter taste in the morning;2 points: persistent bitter taste affecting appetite; 3 points: bitter taste accompanied by halitosis and greasy tongue coating)

- Dizziness (0 points: clear-headed; 1 point: occasional dizziness, self-relieving; 2 points: persistent dizziness affecting concentration; 3 points: lightheadedness with unsteadiness when standing)
- Hot flashes [0 points: no hot flashes; 1 point: 1–2 episodes/day, lasting < 10 minutes; 2 points: 3–5 episodes/day, lasting 10–30 minutes; 3 points: frequent episodes (> 5 times/day) accompanied by facial flushing and sweating]

• Dry stool (0 points: normal bowel movements, 1–2 times/day, well-formed stools; 1 point: occasional dry stools, once every 2–3 days; 2 points: difficulty defecating, requiring straining; 3 points: pellet-like hard stools or constipation with abdominal distension)

Each item is scored on a scale of 0 to 3 points, with a total score of 30 points, where a higher score indicates more severe symptoms [10]. Efficacy was determined with reference to the C*linical guiding principles for new traditional Chinese medicine drugs* [11], and the symptom improvement degree of each patient was calculated using the syndrome score reduction rate formula: (total score before treatment - total score after treatment) / total score before treatment × 100%. Markedly effective was defined as significant improvement in the patient's clinical symptoms and signs, accompanied by a ≥40% reduction in fasting blood glucose (FBG) and 2-hour plasma glucose (2hPG) levels compared with pre-treatment levels, and a syndrome score reduction rate of ≥70%; effective referred to improvement in the patient's clinical signs and symptoms, with a ≥20% reduction in FBG and 2hPG levels compared with pre-treatment levels and a Chinese medicine syndrome score reduction rate of ≥30% but <70%; ineffective meant no improvement in blood glucose control, where FBG and 2hPG levels failed to meet the above effective criteria, or any decrease did not reach the effective threshold. The total effective rate was calculated as (number of markedly effective cases + number of effective cases) / total number of cases × 100%.

1.4 Observation Indicators

(1) Glycolipid-related biochemical indicators: fasting venous blood samples were collected from patients in the early morning. Before and after treatment, the levels of 2hPG, FBG, glycated hemoglobin (HbA1c), high-density lipoprotein cholesterol (HDL-C), triglyceride (TG), low-density lipoprotein cholesterol (LDL-C), and total cholesterol (TC) were detected. (2) Assessment of islet secretion function: The levels of fasting C-peptide (FCP), fasting insulin (FINS), and 2-hour postprandial C-peptide (2hCP) were measured using the chemiluminescence method. (3) Insulin sensitivity and β-cell function: Relevant indices were calculated via homeostasis model assessment. The insulin resistance index (HOMA-IR) was calculated as FBG × FINS / 22.5, and the β-cell function index (HOMA-β) was calculated as 20 × FINS / (FBG - 3.5). (4) Treatment safety: hypoglycemic events, gastrointestinal discomfort (such as nausea, abdominal distension, diarrhea), and lower extremity edema were recorded and compared throughout the treatment process.

1.5 Statistical Methods

Data were analyzed using SPSS 25.0. Count data were expressed as case (%) and compared using the χ^2 test. Measurement data conforming to a normal distribution were expressed as $\bar{x} \pm s$; independent samples *t* test was used for inter-group comparison, and paired *t* test was used for intra-group comparison. A *P* value < 0.05 was considered statistically significant.

2 Results

2.1 Comparison of Clinical Efficacy

After 3 months of treatment, 40 cases were markedly effective, 18 cases were effective, and 2 cases were ineffective in the study group; in the control group, 26 cases were markedly effective, 24 cases were effective, and 10 cases were ineffective. The total effective rate of the study group was significantly higher than that of the control group (96.67% *vs* 83.33%, χ^2=5.926, *P*=0.015).

2.2 Comparison of Chinese Medicine Syndrome Scores

There was no statistically significant difference in Chinese medicine syndrome scores between the two groups before treatment (*P*>0.05). After treatment, the scores of both groups showed a downward trend, and the score of the study group was significantly lower than that of the control group (P<0.05). See **Table 1**.

2.3 Comparison of Glucose Metabolism Indicators

Compared with pre-treatment levels, the levels of FBG, 2hPG and HbA1c in both groups decreased significantly after treatment, and the reduction amplitude of the above indicators in the study group was greater than that in the control group (*P*<0.05). See **Table 2**.

2.4 Comparison of Lipid Metabolism Indicators

Compared with pre-treatment levels, all blood lipid indicators in both groups were significantly improved (*P*<0.05). In addition, the levels of TG, TC and LDL-C in the study group were lower than those in the control group, while the level of HDL-C was higher than that in the control group (*P*<0.05). See **Table 3**.

2.5 Comparison of Islet Function Indicators

After treatment, FINS in both groups decreased significantly, and 2hCP increased significantly (*P*<0.05); FINS in the study group was lower than that in the control group, and 2hCP was higher than that in the control group (*P*<0.05). There was no statistically significant difference in FCP between the two groups before and after treatment (*P*>0.05). See **Table 4**.

2.6 Comparison of HOMA-IR and HOMA-β between the two groups

After treatment, HOMA-IR decreased and HOMA-β increased in both groups (*P*<0.05); the improvement ranges of the two indicators in the study group were greater than those in the control group (*P*<0.05). See **Table 5**.

2.7 Comparison of the incidence of adverse reactions between the two groups

In the study group, the number of cases with hypoglycemia, gastrointestinal reactions, and lower extremity edema was 4, 2, and 2 respectively; while in the control group, the corresponding numbers were 3, 2, and 1. There was no statistically significant difference in the total incidence of adverse reactions between the study group and the control group (13.33% *vs* 10.00%, χ^2=0.323, *P*=0.570).

Tab.1 Comparison of Chinese medicine syndrome scores between two groups （$\bar{x}$ ±s）

Group	*n*	Chinese medicine syndrome score (points)	
		Before treatment	After treatment
Control group	60	24.12±3.35	15.87±2.04[a]
Study group	60	23.95±3.22	10.83± 1.45[a]
t value		0.283	15.598
P value		0.777	<0.001

Note: Compared with the same group before treatment, [a]*P* < 0.05.

Tab.2 Comparison of glucose metabolism indicators between two groups （$\bar{x}$±s）

Group	*n*	FBG（mmol/L）		2hPG（mmol/L）		HbA1c（%）	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	60	9.98±2.46[a]	7.12±0.82[a]	13.34±2.41	10.26±1.42[a]	10.08±1.68	8.76±0.82[a]
Study group	60	9.45±2.52[a]	6.43±0.76[a]	13.22±2.35	9.13±1.15[a]	9.94±1.41	6.18±0.71[a]
t value		1.166	4.780	0.276	4.790	0.494	18.425
P value		0.246	<0.001	0.783	<0.001	0.622	<0.001

Note: Compared with the same group before treatment, [a]*P* < 0.05.

Tab.3 Comparison of lipid metabolism indicators between two groups （$\bar{x}$ ±s）

Group	*n*	TG（mmol/L）		TC（mmol/L）		LDL-C（mmol/L）		HDL-C（mmol/L）	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	60	2.94±0.65	1.78±0.22[a]	5.31±0.61	4.53±0.49[a]	3.01±0.34	2.48±0.29[a]	1.09±0.19	1.32±0.24[a]
Study group	60	3.08±0.69	1.62±0.18[a]	5.27±0.58	4.08±0.45[a]	3.12±0.37	2.19±0.26[a]	1.13±0.21	1.47±0.26[a]
t value		1.144	4.360	0.368	5.239	1.696	5.767	1.094	3.284
P value		0.255	<0.001	0.713	<0.001	0.093	<0.001	0.276	0.001

Note: Compared with the same group before treatment, [a]*P* < 0.05.

Tab.4 Comparison of islet function indicators between two groups（$\bar{x}$ ±s）

Group	*n*	FINS（mmol/L）		FC-P（mmol/L）		2hC-P（mmol/L）	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	60	17.92±2.58	12.48±1.52[a]	2.41±0.61	2.39±0.55[a]	4.52±0.81	5.37±1.76[a]
Study group	60	18.35±2.46	10.05±1.35[a]	2.44±0.62	2.42±0.58[a]	4.38±0.75	6.35±1.87[a]
t value		0.934	9.259	0.267	0.291	0.982	2.956
P value		0.352	<0.001	0.790	0.772	0.328	0.004

Note: Compared with the same group before treatment, [a]*P* < 0.05.

Tab.5 Comparison of HOMA-IR and HOMA-β between two groups （$\bar{x}$ ±s）

Group	*n*	HOMA-IR		HOMA-β	
		Before treatment	After treatment	Before treatment	After treatment
Control group	60	7.31±0.88	5.52±1.31[a]	35.24±4.71	48.12±8.85[a]
Study group	60	7.19±0.94	2.68±0.61[a]	34.65±4.92	69.83±9.47[a]
t value		0.722	15.223	0.671	12.974
P value		0.472	<0.001	0.504	<0.001

Note: Compared with the same group before treatment, [a]*P* < 0.05.

3 Discussion

T2DM is a complex metabolic disease involving multiple etiological factors, with its global incidence showing a continuous upward trend. Its pathological core lies in relative insufficiency of insulin secretion or reduced insulin action efficacy, leading to chronic elevation of blood glucose levels. Although the disease cannot be completely cured at present, standardized medication and lifestyle interventions can effectively control blood glucose and delay the progression of complications, which has become a key goal of clinical management [12].

Recent studies have found that in addition to regulating systemic glucose homeostasis, RSG also exerts potential effects on local intestinal metabolism. It can regulate lipid metabolism and immune genes in the intestine, and by

enhancing lipid utilization and altering immune signals, it provides a new target for intervening in intestinal metabolic disorders in diabetes mellitus [13]. Previous studies have pointed out that in the early stage of the disease, RSG can alleviate chronic inflammation and insulin resistance by regulating the transcription of insulin-related genes [14]. However, its specific efficacy coexists with cardiovascular risks, which requires clinical vigilance [15]. Based on the above evidence, this study selected RSG as the basic treatment, aiming to effectively control blood glucose and improve insulin resistance.

From the perspective of Chinese medicine theory, T2DM can be categorized into "Xiaoke" and similar syndromes. Its pathogenesis evolution often starts from spleen deficiency in the middle jiao, followed by the generation of dryness-heat. The syndrome of stomach heat and spleen deficiency is common in the early and middle stages, and prolonged disease course damages qi and yin, so qi-yin deficiency has become a common clinical syndrome type. Targeting the core pathogenesis, the main therapeutic principles should be invigorating the spleen and clearing heat, replenishing qi and nourishing yin [16]. *Huangqi Sijunzi* Decoction was selected, in which the monarch drug *Astragalus* membranaceus (Huangqi) is effective in replenishing qi and consolidating the exterior, *Dendrobium nobile* (Shihu) nourishes yin and clears heat, *Atractylodes macrocephala* (Baizhu) invigorates the spleen and dries dampness, *Rehmannia glutinosa* (Shengdihuang) cools blood and nourishes yin, *Ligustrum lucidum* (Nüzhenzi) nourishes the liver and kidney, *Poria cocos* (Fuling) invigorates the spleen and excretes dampness, *Pseudostellaria heterophylla* (Taizishen) replenishes both qi and yin, and *Coptis chinensis* (Huanglian) clears heat and purges fire. The combined use of these herbs achieves the effects of replenishing qi and invigorating the spleen, nourishing yin and clearing heat. Previous studies have shown that the combination of this decoction with saxagliptin can effectively improve glucose and lipid metabolism and insulin resistance [17]. Relevant studies have also initially confirmed the efficacy and safety of its combination with RSG [18].

The results of this study further support the above viewpoints. After 3 months of treatment, the total effective rate of the intervention study group was significantly better than that of the conventional treatment group, and the improvement of Chinese medicine syndrome scores was more obvious. In terms of laboratory indicators, the study group showed advantages in reducing FBG, 2hPG, HbA1c, blood lipids (TG, TC, LDL-C), FINS, and HOMA-IR index, while better increasing the levels of HDL-C, postprandial C-peptide, and HOMA-β. These results suggest that the combined application of *Huangqi Sijunzi* Decoction and RSG can synergistically improve glucose and lipid metabolism disorders and islet function in patients through multiple targets, which is consistent with the research results of Wang Yawen *et al.* [19]. In addition, the incidence of adverse reactions in the two groups was comparable, indicating that the combined medication regimen has good safety, reliable clinical safety, and does not increase additional safety risks.

In conclusion, the treatment regimen of *Huangqi Sijunzi* Decoction combined with RSG can significantly improve the clinical symptoms and glucose and lipid metabolism indicators of T2DM patients, with good safety.

Conflict of Interest The authors declare no competing interest

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·论 著·

黄芪四君子汤联合罗格列酮治疗2型糖尿病的疗效

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摘要：目的 分析黄芪四君子汤联合罗格列酮对2型糖尿病（T2DM）患者疗效、中医证候积分、糖脂代谢、胰岛功能的影响。**方法** 前瞻性选取在2022年1月1日至2023年3月31日于石家庄市第二医院就诊的120例T2DM患者，采用随机数字表法分为研究组与对照组，各60例。对照组口服罗格列酮片，研究组在此基础上加服黄芪四君子汤。比较两组各项指标变化。**结果** 治疗3个月后，研究组的总有效率高于对照组（96.67% *vs* 83.33%，χ^2=5.926，*P*=0.015）。治疗后两组中医证候积分均降低，研究组更低（*P*<0.05）。治疗后，两组空腹血糖（FBG）及餐后2 h血糖（2hPG）、糖化血红蛋白（HbA1c）、三酰甘油（TG）、低密度脂蛋白胆固醇（LDL-C）、总胆固醇（TC）、空腹胰岛素（FINS）、胰岛素抵抗指数（HOMA-IR）水平低于治疗前，β细胞功能指数（HOMA-β）、高密度脂蛋白胆固醇（HDL-C）、餐后2 h C肽（2hC-P）水平高于治疗前（*P*<0.05）。治疗后，研究组糖脂代谢指标、FINS和HOMA-IR的降幅更大，而HOMA-β、HDL-C和2hC-P的升高更明显（*P*<0.05）。研究组和对照组总不良反应发生率差异无统计学意义（13.33% *vs* 10.00%，χ^2=0.323，*P*=0.570）。**结论** 黄芪四君子汤联合罗格列酮能显著改善T2DM患者的临床症状及糖脂代谢指标，且安全性良好。

关键词： 2型糖尿病；黄芪四君子汤；罗格列酮；中医证候；血脂
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Effect of *Huangqi Sijunzi* Decoction combined with rosiglitazone on type 2 diabetes mellitus

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Abstract: Objective To investigate the therapeutic effects, Chinese medicine syndrome scores, and indicators of glycolipid metabolism and islet function of *Huangqi Sijunzi* Decoction combined with rosiglitazone on patients with type 2 diabetes mellitus (T2DM). **Methods** A prospective study was conducted on 120 T2DM patients who visited the Second Hospital of Shijiazhuang from 1 January 2022 to 31 March 2023. The patients were randomly divided into a research group and a control group using a random number table method, with 60 patients in each group. The control group received oral administration of rosiglitazone tablets, while the research group received additional administration of *Huangqi Sijunzi* Decoction. The changes of various indicators between the two groups were compared. **Results** The research group demonstrated a clinically superior total effective rate compared to the control group after 3 months of treatment (96.67% *vs* 83.33%, χ^2=5.926, *P*=0.015). After treatment, the Chinese medicine syndrome scores of both groups decreased, and those of the research group were even lower (*P*<0.05). After treatment, the levels of fasting blood glucose (FBG), 2-hour postprandial blood glucose (2hPG), glycated hemoglobin (HbA1c), triglyceride (TG), low-density lipoprotein cholesterol (LDL-C), and total cholesterol (TC), fasting insulin (FINS), and homeostatic model

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assessment of insulin resistance (HOMA-IR) in both groups were lower than before treatment, while the levels of high-density lipoprotein cholesterol (HDL-C), 2-hour postprandial C-peptide (2hC-P), and HOMA-β were higher than before treatment (P<0.05). After treatment, the levels of all indicators of glucose metabolism and all indicators of lipid metabolism, FINS, HOMA-IR in the research group were lower than those in the control group, while HDL-C, 2hC-P, and homeostasis model assessment-β (HOMA-β) were higher than those in the control group (P<0.05). There was no statistically significant difference in the total incidence of adverse reactions between the research group and control group (13.33% *vs* 10.00%, χ^2=0.323, P=0.570). **Conclusion**　The combination of *Huangqi Sijunzi* Decoction and rosiglitazone can significantly improve clinical symptoms and glycolipid metabolism indicators in T2DM patients, and the safety is high.

Keywords: Type 2 diabetes; *Huangqi Sijunzi* Decoction; Rosiglitazone; Chinese medicine symptoms; Blood lipid

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2 型糖尿病(type 2 diabetes mellitus, T2DM)作为一种复杂的代谢性疾病,其发病是遗传背景与环境因素共同作用的结果。该病的核心病理生理学改变为胰岛素抵抗,以及胰岛β细胞功能进行性减退所导致的胰岛素分泌相对不足[1]。肠道菌群参与宿主的能量代谢调节,其稳态一旦失衡,可能引发持续的肠道低度炎症状态,进而通过多种途径干扰葡萄糖稳态,在T2DM的发生与进展中扮演着关键角色[2]。在T2DM的临床药物治疗中,罗格列酮(rosiglitazone, RSG)是一种被广泛用于改善胰岛素敏感性的药物,其作用机制为选择性激活过氧化物酶体增殖物激活受体γ,帮助实现血糖控制[3]。但在临床应用中也存在一定的局限性,例如可能增加低血糖事件、体液潴留引发水肿等不良反应风险[4]。黄芪四君子汤是中医治疗脾胃气虚证的经典方剂。临床报道指出,黄芪四君子汤与沙格列汀、阿卡波糖等药物联用在改善T2DM患者胰岛功能、胰岛素抵抗及中医证候方面显示出协同效应[5-6]。然而,目前关于黄芪四君子汤与RSG联合应用的临床疗效与作用特点,尚缺乏系统性的研究验证。基于此,本研究评估黄芪四君子汤与RSG联合方案对中医临床证候与整体疗效的改善作用。

1　资料与方法

1.1　*一般资料*　前瞻性选取2022年1月1日至2023年3月31日于石家庄市第二医院就诊的120例T2DM患者,按照随机数字表法分为研究组与对照组,各60例。研究组男37例,女23例,年龄(54.39±7.01)岁,患病时间(3.95±0.58)年;对照组男31例,女29例,年龄(53.62±5.94)岁,病程(4.09±0.71)年。两组基线临床资料比较差异均无统计学意义(P>0.05),具有可比性。研究开始前均已获取所有参与者的书面知情同意。纳入标准:(1) 西医符合文献[7]中T2DM诊断标准;中医辨证方面,需属气阴两虚证型,临床表现包括但不限于倦怠乏力、自汗或盗汗、气短懒言、口渴喜饮、五心烦热、心悸失眠、小便黄赤、大便偏干、舌质红而少津等[8-9];(2) 为初次确诊的T2DM病例;(3) 认知与沟通能力正常,能够配合完成本研究。排除标准:(1) 确诊为1型糖尿病,或T2DM合并下肢破溃、坏疽等并发症;(2) 患有明确的肠道炎症、消化性溃疡或其他活动性胃肠道疾病;(3) 合并免疫系统疾病或处于急性感染期;(4) 存在严重的肝功能不全或肾功能衰竭;(5) 既往有胃肠道重大手术史;(6) 对本研究方案中所使用的任何药物有禁忌证或过敏史;(7) 入组前4周内曾接受过抗生素、益生菌等可能显著影响肠道菌群构成的药物治疗;(8) 入组前3个月内使用过任何抗糖尿病药物治疗;(9) 据研究人员判断,患者入组难度可能较大,如生活或工作地点频繁变动等情况,易导致患者脱落失访。脱落标准:(1) 未能完成完整疗程者;(2) 依从性差,不能按要求完成治疗者。本研究经石家庄市第二医院伦理委员会批准通过(SEY-KYLL-2021043)。

1.2　*治疗方法*　两组均进行严格饮食控制,适当有氧运动,维持或减轻体质量,严禁烟酒等。对照组在基础干预的同时,每日口服1片RSG片(上海华康制药有限公司国药准字H20051288,规格:4 mg)。研究组在对照组基础联合黄芪四君子汤,具体方案如下:君药黄芪(20 g),臣药石斛(15 g),佐以茯苓(9 g)、白术(10 g)、生地黄(10 g)、女贞子(10 g)、太子参(6 g),使药黄连(5 g)。制法与疗程:上述药材按既定比例配伍,每日1剂,以水浓煎,所得药液于早、晚分次温服。两组疗程为3个月。

1.3　*疗效观察*　治疗后,对患者临床症状进行评估,包括主证口渴多饮[0分,无口渴感,饮水如常;1分,轻度口干,饮水稍增(日饮水量增加<500 mL);2分,明显口渴,频繁饮水(日饮水量增加500~1 000 mL);

3分，极度口渴，饮水无度（日饮水量增加>1 000 mL）］、疲乏无力（0分，精力充沛，活动自如；1分，轻度疲劳，休息可缓解；2分，持续乏力，影响日常活动；3分，极度虚弱，卧床难起）、消谷善饥（0分，食欲正常，无饥饿感；1分，食量稍增，餐间偶有饥饿；2分，易饥多食，食后不久即饿；3分，暴饮暴食，无法控制进食量）和气短少言（0分，呼吸平稳，言语流利；1分，轻度气促，长句需停顿；2分，言语断续，短句即喘；3分，呼吸困难，仅能单字表达）。次证发热［0分，体温正常（36.5~37.2 ℃）；1分，低热（37.3~38.0 ℃）；2分，中热（38.1~39.0 ℃）；3分，高热（>39.0 ℃）或持续不退］、多汗（0分，无异常出汗；1分，活动后稍汗出；2分，静息状态下汗出；3分，大汗淋漓，衣被浸湿）、口苦（0分，无口苦感；1分，晨起短暂口苦；2分，持续口苦影响食欲；3分，口苦伴口臭、舌苔厚腻）、头昏（0分，头脑清醒；1分，偶有头昏，可自行缓解；2分，持续头昏影响专注力；3分，头重脚轻伴站立不稳）、潮热［0分，无潮热感；1分，发作1~2次/d，持续<10 min；2分，发作3~5次/d，持续10~30 min；3分，频繁发作（>5次/d）或伴面红汗出］和便干（0分，排便正常，1~2次/d，成形；1分，偶有便干，2~3 d 1次；2分，排便困难，需用力；3分，羊粪状硬便或便秘伴腹胀）。

每项计分为0~3分，总分30分，分值越高，症状越严重[10]。疗效判定参照《中药新药临床研究指导原则》[11]，根据证候积分下降率=（治疗前总积分−治疗后总积分）/治疗前总积分×100%计算每位患者的症状改善程度。显效：患者临床症状与体征得到显著改善，同时空腹血糖（fasting blood glucose，FBG）及餐后2 h血糖（2-hour plasma glucose，2hPG）水平较治疗前降低≥40%，且证候积分下降率≥70%。有效：患者临床体征与症状有所改善；在此前提下，其FBG及2hPG水平较治疗前降低≥20%，且中医证候积分下降率≥30%且<70%。无效：患者血糖控制未见改善，FBG与2hPG水平未达到上述有效标准，或虽有下降但未满足有效阈值。总有效率的计算方式为：总有效率=（显效例数+有效例数）/总例数×100%。

1.4 观察指标 （1）糖脂相关生化指标：采集患者晨起空腹静脉血，治疗前后检测2hPG、FBG、糖化血红蛋白（glycated hemoglobin，HbA1c）、高密度脂蛋白胆固醇（high-density lipoprotein cholesterol，HDL-C）、三酰甘油（triglyceride，TG）、低密度脂蛋白胆固醇（low-density lipoprotein cholesterol，LDL-C）及总胆固醇（total cholesterol，TC）。（2）胰岛分泌功能评估：采用化学发光法测定空腹C肽（fasting C-peptide，FC-P）、空腹胰岛素（fasting insulin，FINS）及餐后2 h C肽（2-hour postprandial C-peptide，2hC-P）水平。（3）胰岛素敏感性与β细胞功能：通过稳态模型评估计算相关指数，胰岛素抵抗指数（homeostatic model assessment of insulin resistance，HOMA-IR）为FBG×FINS/22.5，β细胞功能指数（homeostasis model assessment-β，HOMA-β）为20×FINS/（FBG−3.5）。（4）治疗安全性：全程记录并比较低血糖事件、胃肠道不适（如恶心、腹胀、腹泻）及下肢水肿等。

1.5 统计学方法 采用SPSS 25.0软件分析数据，计数资料以例（%）表示，采用χ^2检验；计量资料符合正态分布，以$\bar{x}\pm s$表示，组间用独立样本t检验，组内用配对t检验。P<0.05为差异有统计学意义。

2 结 果

2.1 临床疗效比较 治疗3个月后，研究组显效40例，有效18例，无效2例。对照组显效26例，有效24例，无效10例。研究组的总有效率显著高于对照组（96.67% *vs* 83.33%，χ^2=5.926，P=0.015）。

2.2 中医证候积分比较 治疗前两组中医证候积分差异无统计学意义（P>0.05）。治疗后，两组积分均呈现下降趋势，且研究组的积分值显著低于对照组（P<0.05）。见表1。

2.3 糖代谢指标比较 与治疗前相比，两组患者治疗后的FBG、2hPG及HbA1c水平均显著降低，且研究组上述指标的下降幅度大于对照组（P<0.05）。见表2。

2.4 脂代谢指标比较 与治疗前相比，两组所有血脂指标均显著改善（P<0.05），且研究组TG、TC、LDL-C水平低于对照组，HDL-C水平高于对照组（P<0.05）。见表3。

2.5 胰岛功能指标比较 治疗后，两组FINS明显降低，2hC-P明显升高（P<0.05）；研究组FINS低于对照组，2hC-P高于对照组（P<0.05）。两组FC-P治疗前后比较差异无统计学意义（P>0.05）。见表4。

表1 两组中医证候积分比较 （$\bar{x}\pm s$）

Tab.1 Comparison of Chinese medicine syndrome scores between two groups （$\bar{x}\pm s$）

组别	例数	中医证候积分（分）	
		治疗前	治疗后
对照组	60	24.12±3.35	15.87±2.04[a]
研究组	60	23.95±3.22	10.83±1.45[a]
t值		0.283	15.598
P值		0.777	<0.001

注：与同组治疗前比较，[a]P<0.05。

2.6　两组HOMA-IR和HOMA-β比较　治疗后，两组HOMA-IR降低，HOMA-β升高（P<0.05）；研究组两项指标的改善幅度均大于对照组（P<0.05）。见表5。

2.7　比较两组不良反应发生率　研究组中，低血糖、胃肠道反应、下肢水肿的发生例数分别为4、2、2例；对照组的发生例数则依次为3、2、1例。研究组和对照组总不良反应发生率差异无统计学意义（13.33% *vs* 10.00%，χ^2=0.323，P=0.570）。

表2　两组糖代谢指标比较　（$\bar{x}\pm s$）

Tab.2　Comparison of glucose metabolism indicators between two groups　（$\bar{x}\pm s$）

组别	例数	FBG（mmol/L）		2hPG（mmol/L）		HbA1c（%）	
		治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
对照组	60	9.98±2.46	7.12±0.82[a]	13.34±2.41	10.26±1.42[a]	10.08±1.68	8.76±0.82[a]
研究组	60	9.45±2.52	6.43±0.76[a]	13.22±2.35	9.13±1.15[a]	9.94±1.41	6.18±0.71[a]
t值		1.166	4.780	0.276	4.790	0.494	18.425
P值		0.246	<0.001	0.783	<0.001	0.622	<0.001

注：与同组治疗前比较，[a]P<0.05。

表3　两组脂代谢指标比较　（$\bar{x}\pm s$）

Tab.3　Comparison of lipid metabolism indicators between two groups　（$\bar{x}\pm s$）

组别	例数	TG（mmol/L）		TC（mmol/L）		LDL-C（mmol/L）		HDL-C（mmol/L）	
		治疗前	治疗后	治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
对照组	60	2.94±0.65	1.78±0.22[a]	5.31±0.61	4.53±0.49[a]	3.01±0.34	2.48±0.29[a]	1.09±0.19	1.32±0.24[a]
研究组	60	3.08±0.69	1.62±0.18[a]	5.27±0.58	4.08±0.45[a]	3.12±0.37	2.19±0.26[a]	1.13±0.21	1.47±0.26[a]
t值		1.144	4.360	0.368	5.239	1.696	5.767	1.094	3.284
P值		0.255	<0.001	0.713	<0.001	0.093	<0.001	0.276	0.001

注：与同组治疗前比较，[a]P<0.05。

表4　两组胰岛功能指标比较　（$\bar{x}\pm s$）

Tab.4　Comparison of islet function indicators between two groups　（$\bar{x}\pm s$）

组别	例数	FINS（mmol/L）		FC-P（mmol/L）		2hC-P（mmol/L）	
		治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
对照组	60	17.92±2.58	12.48±1.52[a]	2.41±0.61	2.39±0.55	4.52±0.81	5.37±1.76[a]
研究组	60	18.35±2.46	10.05±1.35[a]	2.44±0.62	2.42±0.58	4.38±0.75	6.35±1.87[a]
t值		0.934	9.259	0.267	0.291	0.982	2.956
P值		0.352	<0.001	0.790	0.772	0.328	0.004

注：与同组治疗前比较，[a]P<0.05。

表5　比较两组HOMA-IR和HOMA-β　（$\bar{x}\pm s$）

Tab.5　Comparison of HOMA-IR and HOMA-β between two groups　（$\bar{x}\pm s$）

组别	例数	HOMA-IR		HOMA-β	
		治疗前	治疗后	治疗前	治疗后
对照组	60	7.31±0.88	5.52±1.31[a]	35.24±4.71	48.12±8.85[a]
研究组	60	7.19±0.94	2.68±0.61[a]	34.65±4.92	69.83±9.47[a]
t值		0.722	15.223	0.671	12.974
P值		0.472	<0.001	0.504	<0.001

注：与同组治疗前比较，[a]P<0.05。

3　讨　论

T2DM是一种多因素参与的复杂代谢病，其全球发病率呈持续增长趋势。其病理核心在于胰岛素分泌的相对不足或作用效能下降，导致血糖水平慢性升高。尽管目前该病尚无法根治，但通过规范的药物及生活方式干预，能够有效控制血糖、延缓并发症进程，现已成为临床管理的关键目标[12]。

近年研究发现RSG在调节全身葡萄糖稳态之外，对肠道局部代谢亦存在潜在影响。其能调控肠道内的脂代谢与免疫基因，通过提升脂质利用与改变免疫信号，为干预糖尿病肠道代谢紊乱提供了新靶点[13]。既往研究指出，RSG在疾病早期可通过调控胰岛素相关基因的转录，以缓解慢性炎症与胰岛素抵抗[14]；但其特异性疗效与心血管风险并存，需引起警惕[15]。基于上述证据，本研究选用RSG作为基础治疗，旨在有效控制血糖并改善胰岛素抵抗。

从中医理论辨析，T2DM可归入“消渴”等范畴，其病机演变常始于中焦脾虚，继而化生燥热，早中期多见胃热脾虚之证，病程迁延则伤及气阴，故气阴两虚成为临床常见证型。针对核心病机，当以健脾清

热、益气养阴为主[16]。选用黄芪四君子汤，其中君药黄芪功擅补气固表，石斛滋阴清热，白术健脾燥湿，生地黄凉血养阴，女贞子滋补肝肾，茯苓健脾渗湿，太子参气阴双补，黄连清热泻火。诸药合用，共奏益气健脾、滋阴清热之效。既往研究显示，该方与沙格列汀联用可有效改善糖脂代谢与胰岛素抵抗[17]；相关研究也初步证实了其与RSG联合应用的疗效与安全性[18]。

本研究结果进一步支持了上述观点。经过3个月治疗，干预研究组的总有效率显著优于常规治疗组，且中医证候积分的改善程度更为明显。在实验室指标方面，研究组在降低FBG及2hPG、HbA1c、血脂（TG、TC、LDL-C）、FINS及HOMA-IR指数上均展现出优势，同时能更好地提升HDL-C、餐后C肽及HOMA-β水平。这些结果提示，黄芪四君子汤与RSG的联合应用，能从多靶点协同改善患者的糖脂代谢紊乱与胰岛功能，该结论与王雅雯等[19]的研究结果相吻合。此外，两组的不良反应发生率相当，表明联合用药方案安全性良好，具有可靠的临床安全性，未增加额外的安全风险。

综上所述，黄芪四君子汤联合RSG治疗方案能显著改善T2DM患者的临床症状及糖脂代谢指标，且安全性良好。

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