Mechanism of Action and Therapeutic Effect of Modified Qiwei Baishu Powder in Diabetes

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Abstract: Objective: To study the mechanism of action and therapeutic effect of modified Qiwei Baishu powder in diabetic patients. Methods: From January 2021 to January 2022, 80 diabetic patients were recruited in our study and divided into two groups by the random number table method. Group A was treated with modified Qiwei Baishu powder, whereas group B was treated with western medicine. The therapeutic effect, traditional Chinese medicine (TCM) syndrome score, blood sugar level, and incidence of adverse reaction were compared between the two groups. Result: The therapeutic effect in group A was significantly higher than that in group B ($P < 0.05$); the TCM syndrome scores of group A were significantly lower than those of group B ($P < 0.05$); the fasting blood glucose (FBG), 2 hour-postprandial blood glucose (PBG), and glycosylated hemoglobin (HbA1c) levels of group A were significantly lower than those of group B ($P < 0.05$); the incidence of adverse reaction in group A was significantly lower than that in group B ($P < 0.05$). Conclusion: On the basis of western medicine, the addition of modified Qiwei Baishu powder can maintain stable blood sugar levels in patients and alleviate diabetic symptoms; thus, it is not only effective, but also safe for clinical use in diabetes.

Keywords: Diabetes; Modified Qiwei Baishu powder; Therapeutic effect; Mechanism of action

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1. Introduction
Diabetes belongs to the category of “diabetes” in traditional Chinese medicine (TCM), and it is related to various factors such as fatigue, emotional disorders, and improper diet. The typical symptoms of diabetes are polyuria, polyphagia, and polydipsia [1]. TCM practitioners believe that the loss of yin and fluid is the main pathogenesis of diabetes, which falls under the syndrome of deficiency in origin and excess in superficiality. In western medicine, drugs such as metformin are used for treatment. These drugs limit the overall effect and only delay the progression of the disease [2]. In recent years, TCM has been used in the treatment of diabetes. Modified Qiwei Baishu powder is useful in nourishing the kidney, strengthening the spleen, and replenishing qi, as well as lowering blood sugar and preventing diabetic complications [3]. In this study, 80 diabetic patients admitted from January 2021 to January 2022 were studied to explore the therapeutic effect of modified Qiwei Baishu powder.

2. Materials and methods
2.1. Patient information
A sample of 80 diabetic patients admitted from January 2021 to January 2022 was grouped by the random
number table method. In group A, the male to female ratio was 24:16, and the mean age was 52.17 ± 8.41 (36–72 years old); in group B, the male to female ratio was 25:15, and the mean age was 52.21 ± 8.33 (37–73 years old). There was no significant difference in baseline data between group A and group B ($P > 0.05$).

2.2. Inclusion and exclusion criteria
Inclusion criteria: (i) patients who met the diagnostic criteria for diabetes in *Guidelines for the Prevention and Treatment of Diabetes in China* [4] and whose fasting blood glucose/postprandial blood glucose ≥ 7.0/11.1 mmol/L; (ii) patients with symptoms of polyphagia, polyuria, and polydipsia; (iii) patients who had given informed consent; (iv) patients whose body mass index (BMI) ≥ 28.0 kg/m$^2$.

Exclusion criteria: (i) patients who had taken drugs for weight loss and hyperglycemia before enrollment; (ii) patients with infectious diseases; (iii) patients with malignant tumor; (iv) patients with allergies.

2.3. Treatment methods
The western medicine regimen used for patients in group A was the same as that in group B. The prescription of Qiwei Baishu powder used was as follows: *Rehmannia glutinosa* 20 g; *Poria cocos*, Kudzu root, ginseng, and fried *Atractylodes macrocephala*, each 15 g; *Ligusticum wallichii*, sealwort, and corni fructus, each 12 g; *Schisandra* 10 g; licorice and patchouli leaves, each 9 g. The addition and subtraction formulas used were as follows: (i) for those with dry and hot lungs, add corni fructus, common *Anemarrhena* rhizome, and Chinese wolfberry root-bark for lung-clearing effect; *Rehmannia* and *Trichosanthes* to promote body fluid and nourish yin; (ii) for those with abdominal distension and reduced appetite, add *gallinacea* and *Amomum* to invigorate the spleen and aid transportation. After decoction, the patients were required to take one dose in the morning and evening. Each patient had to undergo three courses of treatment in which a single course extended till 15 days after administration.

The western medicine treatment used in group B included metformin (Liaoning Meida Kang Huabang Pharmaceutical Co., Ltd.), 0.5 g orally after meals, 3 times a day; and acarbose (Zhejiang Hisun Pharmaceutical Co., Ltd.), single oral dose 50–100 g, 3 times a day. The treatment lasted for 45 days.

2.4. Observation indicators
(i) Therapeutic effect
“Markedly effective” was denoted by a reduction in traditional Chinese medicine (TCM) syndrome score by more than 90% and normal blood sugar; “effective” was denoted by a reduction in TCM syndrome score by more than 30% and lowered blood sugar level; “ineffective” was denoted by a reduction in TCM syndrome score by less than 30% and no reduction in blood sugar level.

(ii) TCM syndrome score
A 3-point method was used to evaluate diabetic symptoms, including body ache, polydipsia, fatigue, and pain and numbness.

(iii) Blood glucose
Changes in fasting blood glucose (FBG), postprandial blood glucose (PBG), and glycosylated hemoglobin (HbA1c) were detected.

(iv) Adverse reaction
Incidence of abdominal pain, nausea and vomiting, as well as indigestion among the patients was recorded.

2.5. Statistical analysis
SPSS 21.0 was used for data processing. Count data were recorded in percentage (%) and tested by chi-
square ($\chi^2$) test; measurement data were recorded in mean ± standard deviation and tested by $t$-test. $P < 0.05$ indicates statistical significance.

3. Results

3.1. Therapeutic effect

The therapeutic effect in group A (97.5%) was higher than that in group B (85.0%), $P < 0.05$ (Table 1).

Table 1. Comparison of therapeutic effect between group A and group B

<table>
<thead>
<tr>
<th>Group</th>
<th>Markedly effective</th>
<th>Effective</th>
<th>Ineffective</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A (n = 40)</td>
<td>32 (80.0%)</td>
<td>7 (17.5%)</td>
<td>1 (2.5%)</td>
<td>97.5%</td>
</tr>
<tr>
<td>Group B (n = 40)</td>
<td>26 (65.0%)</td>
<td>8 (20.0%)</td>
<td>6 (15.0%)</td>
<td>85.0%</td>
</tr>
<tr>
<td>$\chi^2$</td>
<td></td>
<td></td>
<td></td>
<td>3.9139</td>
</tr>
<tr>
<td>$P$</td>
<td></td>
<td></td>
<td></td>
<td>0.0479</td>
</tr>
</tbody>
</table>

3.2. TCM syndrome score

Before treatment, the TCM syndrome scores of group A were not different from those of group B, ($P > 0.05$). After treatment, the TCM syndrome scores of group A were significantly lower than those of group B ($P < 0.05$), as shown in Table 2.

Table 2. Comparison of TCM syndrome scores between group A and group B

<table>
<thead>
<tr>
<th>Group</th>
<th>Body ache</th>
<th>Polydipsia</th>
<th>Fatigue</th>
<th>Pain and numbness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before treatment</td>
<td>After treatment</td>
<td>Before treatment</td>
<td>After treatment</td>
</tr>
<tr>
<td>Group A (n = 40)</td>
<td>2.64 ± 0.84</td>
<td>0.75 ± 0.35</td>
<td>2.59 ± 0.79</td>
<td>0.72 ± 0.37</td>
</tr>
<tr>
<td>Group B (n = 40)</td>
<td>2.62 ± 0.86</td>
<td>1.41 ± 0.47</td>
<td>2.61 ± 0.83</td>
<td>1.43 ± 0.49</td>
</tr>
<tr>
<td>$t$</td>
<td>0.1052</td>
<td>7.1232</td>
<td>0.1104</td>
<td>7.3134</td>
</tr>
<tr>
<td>$P$</td>
<td>0.9165</td>
<td>0.0000</td>
<td>0.9124</td>
<td>0.0000</td>
</tr>
</tbody>
</table>

3.3. Blood glucose indicators

As shown in Table 3, there was no significant difference in FBG, PBG, and HbA1c between group A and group B ($P > 0.05$) before treatment; however, the FBG, PBG, and HbA1c of group A were lower than those of group B after treatment ($P < 0.05$).

Table 3. Comparison of blood sugar indicators between group A and group B

<table>
<thead>
<tr>
<th>Group</th>
<th>FBG (mmol/L)</th>
<th>PBG (mmol/L)</th>
<th>HbA1c (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before treatment</td>
<td>After treatment</td>
<td>Before treatment</td>
</tr>
<tr>
<td>Group A (n = 40)</td>
<td>8.08 ± 1.11</td>
<td>5.13 ± 0.61</td>
<td>12.62 ± 1.58</td>
</tr>
<tr>
<td>Group B (n = 40)</td>
<td>8.09 ± 1.09</td>
<td>6.87 ± 0.89</td>
<td>12.65 ± 1.56</td>
</tr>
<tr>
<td>$t$</td>
<td>0.0407</td>
<td>10.1992</td>
<td>0.0855</td>
</tr>
<tr>
<td>$P$</td>
<td>0.9677</td>
<td>0.0000</td>
<td>0.9321</td>
</tr>
</tbody>
</table>
3.4. Incidence of adverse reaction
The incidence of adverse reaction in group A was significantly lower than that in group B ($P < 0.05$), as shown in Table 4.

<table>
<thead>
<tr>
<th>Group</th>
<th>Abdominal pain</th>
<th>Nausea and vomiting</th>
<th>Indigestion</th>
<th>Incidence rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A (n = 40)</td>
<td>1 (2.5%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>2.5%</td>
</tr>
<tr>
<td>Group B (n = 40)</td>
<td>2 (5.0%)</td>
<td>3 (7.5%)</td>
<td>1 (2.5%)</td>
<td>15.0%</td>
</tr>
<tr>
<td>$\chi^2$</td>
<td></td>
<td></td>
<td></td>
<td>3.9139</td>
</tr>
<tr>
<td>$P$</td>
<td></td>
<td></td>
<td></td>
<td>0.0479</td>
</tr>
</tbody>
</table>

4. Discussion
The hallmark of diabetes is insulin resistance, which progressively worsens over time. When pancreatic beta cells can no longer compensate for insulin resistance, symptoms of hyperglycemia will develop, thus increasing glycosylation products in the body and the risk of microvascular disease. Therefore, diabetic patients often have blood stasis syndrome, and attention should be paid to regulating the meridians during treatment $^{[5,6]}$. In TCM, diabetes belongs to the category of “wasting-thirst,” which is related to the patient’s preference for fatty and sweet food, poor dietary habits, etc., resulting in deficiency of both qi and yin; thus, the condition should be treated with the formula of blood circulation and blood stasis, nourishing qi and nourishing yin $^{[7]}$. When treating diabetic patients, TCM practitioners emphasize on treating not only the symptoms, but also the root causes, which include restoring visceral functions on the basis of lowering blood sugar and choosing drugs based on the principle of “invigorating the spleen, promoting body fluid, and nourishing qi.” In the present study, we used Qiwei Baishu powder, a famous prescription in TCM, which is suitable for body fluid internal consumption. In the treatment of patients with spleen and stomach deficiency syndrome, this prescription has the effect of nourishing yin and replenishing qi, and the dialectical addition and subtraction of the basic prescription have the effect of regulating blood lipid and lowering blood sugar $^{[8]}$.

According to our results, the therapeutic effect in group A (97.5%) was significantly higher than that in group B ($P < 0.05$); the TCM syndrome scores of group A were significantly lower than those of group B ($P < 0.05$); moreover, group A had significantly lower FBG, PBG, and HbA1c compared to group B ($P < 0.05$); the incidence of adverse reaction in group A was also significantly lower than that in group B ($P < 0.05$). Our findings suggest that modified Qiwei Baishu powder can effectively control the progression of diabetes.

Ginseng, which is a component in Qiwei Baishu powder, can produce body fluid, quench thirst, nourish vitality, promote the recovery of heart function, and stabilize blood pressure in patients; *Poria cocos* can harmonize the stomach, strengthen the spleen, act as a diuretic, and relieve symptoms such as edema and fullness; fried *Atractylodes macrocephala* can promote drainage, generate blood, replenish qi, dry dampness, as well as restore the biochemical function of qi and blood; Kudzu root can produce fluid, quench thirst, stop diarrhea, and relieve thirst; *Rehmannia glutinosa* can produce fluid, nourish yin, cool blood, clear away heat, and relieve knee and hip weakness; *Schisandra* can produce body fluid, replenish qi, solidify astringency, calm the heart, and nourish the kidney; corni fructus can nourish both the liver and the kidney; sealwort can moisten the lungs, invigorate the spleen, and promote body fluid; patchouli leaves can invigorate the spleen, stop vomiting, eliminate belching, and harmonize the stomach; *Ligusticum wallichii* can promote qi, promote blood circulation, relieve pain, and dispel wind; licorice can regulate various medicines and also relieve cough, eliminate phlegm, and clear away heat $^{[9]}$.
By combining Qiwei Baishu powder with various TCMs, it is possible to promote blood circulation, remove blood stasis, nourish yin, and replenish qi. Based on the analysis of modern pharmacological effects, Qiwei Baishu powder contains rich xylene lactones in the woody fragrance, which can reduce insulin resistance; *Poria cocos*, which can strengthen the body’s immune function and relax the smooth muscle of the digestive tract, rendering a hypoglycemic effect; ginseng, *Schisandra*, etc., which can regulate lipid metabolism, increase myocardial oxygen supply, stimulate myocardial contraction, and lower blood lipid levels; *Ligusticum wallichii*, which can inhibit the synthesis of collagen, stimulate local microcirculation, enhance the body’s immune function, and delay the progression of diabetes. The application of modified Qiwei Baishu powder and subtracted prescriptions have better therapeutic effect \[10\].

In conclusion, the addition of modified Qiwei Baishu powder for diabetic patients can alleviate diabetic symptoms and stabilize blood sugar levels. This TCM prescription is mild in nature and has high safety profile; thus, it has some promotional value.

**Disclosure statement**

The authors declare no conflict of interest.

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