

Clinical Efficacy of Modified Shenqi Dihuang Decoction in the Treatment of Early Diabetic Nephropathy and Its Impact on Symptom Scores in Traditional Chinese Medicine

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Abstract: *Objective:* To evaluate the efficacy and symptom scores of early diabetic nephropathy (DKD) treated with modified Shenqi Dihuang Decoction. *Methods:* 82 patients with early DKD who visited the hospital from February 2023 to February 2025 were randomly divided into two groups by drawing. Group A received modified Shenqi Dihuang Decoction + SGLT2 inhibitor, while Group B received SGLT2 inhibitor only. The efficacy, symptom scores, blood glucose, and renal function were compared between the two groups. *Results:* The efficacy of Group A was higher than that of Group B in the treatment of early DKD ($P < 0.05$). The DKD symptom scores of Group A were lower than those of Group B ($P < 0.05$). The fasting blood glucose (FBG), 2-hour postprandial blood glucose (PBG), and glycated hemoglobin (HbA1c) of Group A were better than those of Group B ($P < 0.05$). The serum creatinine (SCr), blood urea nitrogen (BUN), and urinary albumin excretion rate (UAER) of Group A were also better than those of Group B. *Conclusion:* The combination of modified Shenqi Dihuang Decoction and SGLT2 inhibitor dapagliflozin has excellent efficacy in the treatment of early DKD, which can improve renal function, reduce DKD symptoms, and stabilize blood glucose levels.

Keywords: Diabetic nephropathy; Shenqi Dihuang Decoction; Symptom scores; Efficacy

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1. Introduction

DKD is a comorbidity of diabetes, characterized by proteinuria. As the disease progresses, the glomerular filtration rate decreases, leading to end-stage renal disease and increased risk of mortality. Western medicine often treats early DKD with the principle of delaying disease progression and stabilizing the condition, such as using metformin to lower blood glucose. However, these treatments have limited effects on improving renal function. SGLT2 inhibitors, a modern novel therapeutic approach, block the reabsorption of glucose in the kidneys and regulate blood glucose by accelerating urine metabolism. This approach improves cardio-renal outcomes through

metabolic and hemodynamic effects, which is beneficial for protecting cardio-renal function. In traditional Chinese medicine, early DKD is categorized as “consumption-thirst,” which is dialectically considered as a syndrome of Qi and Yin deficiency, with a few patients also experiencing blood stasis syndrome ^[1]. Treatment should focus on removing blood stasis, promoting blood circulation, nourishing the kidneys and liver, and nourishing Yin and Qi. Shenqi Dihuang Decoction can nourish the liver and kidneys, nourish Yin and Qi. Based on this, this article explores the efficacy of modified Shenqi Dihuang Decoction combined with the SGLT2 inhibitor dapagliflozin using 82 patients with early DKD who visited the hospital from February 2023 to February 2025 as samples.

2. Materials and methods

2.1. Materials

Eighty two patients with early DKD visited the hospital from February 2023 to February 2025 and are randomly divided into groups by drawing. The baseline data of early DKD in Group A are compared with those in Group B ($P > 0.05$), as shown in **Table 1**.

Table 1. Baseline data of early DKD patients

| Group | <i>n</i> | Gender (%) | | Age (years) | | Disease duration (years) | |
|------------|----------|------------------------|------------|---------------|--------------|--------------------------|-------------|
| | | Male | Female | Range | Mean±SD | Range | Mean±SD |
| Group A | 41 | 20 (48.78) | 21 (51.22) | 40–68 | 58.43 ± 2.11 | 5–11 | 7.85 ± 1.26 |
| Group B | 41 | 21 (51.22) | 20 (48.78) | 40–69 | 58.41 ± 2.13 | 5–12 | 7.81 ± 1.28 |
| χ^2/t | - | 0.0488 (χ^2) | | 0.0427 (t) | | 0.1426 (t) | |
| <i>P</i> | - | 0.8252 | | 0.9660 | | 0.8870 | |

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

- (1) Meet the criteria for diabetic kidney disease (DKD) as defined in the “Chinese Clinical Guidelines for the Prevention and Treatment of Diabetic Kidney Disease”, with symptoms of stagnation of meridians due to blood stasis and deficiency of Qi and Yin ^[2].
- (2) Signed informed consent
- (3) Normal nutritional status

2.2.2. Exclusion criteria

- (1) Ketoacidosis
- (2) Urinary tract infection
- (3) Congestive heart failure
- (4) Organ lesions or immune system disorders.

2.3. Treatment methods

Group A received a modified version of Shenqi Dihuang Decoction, with the following composition: 20g of *Poria cocos*; 15g each of *Astragalus*, Cinnamon, *Angelica*, Ginseng, Yam, *Rehmannia*, and *Alismatis*; 13g each of *Coptis*

and *Salviae miltiorrhizae*; 12g of *Rehmannia*; 10g each of Dogwood and Cortex Moutan. Based on syndrome differentiation, 15g of stir-fried *Atractylodes macrocephala* is added for fatigue; 20g of *Coicis Semen* for edema; 10g of Ginseng for Qi and blood deficiency. The herbs are decocted in water to obtain 200 ml of juice, which is taken warm, once in the morning and once in the evening. The herbal treatment lasted for 8 weeks, constituting one course of treatment.

Group B is treated with SGLT2 inhibitor Dapagliflozin tablets, with a single dose of 10mg once a day. The dosage is adjusted based on blood glucose re-examination results. Patients are instructed to follow a low-fat and low-salt diet. The treatment lasted for 8 weeks.

2.4. Observation indicators

- (1) Efficacy: A decrease of more than 70% in the syndrome score for early DKD, stable blood glucose, and normal kidney physiology are considered as markedly effective. A decrease of more than 30% in the syndrome score, lower blood glucose, and improved kidney function indicators are considered effective. A decrease of 30% or less in syndrome score, abnormal blood glucose, and severe kidney damage are considered ineffective.
- (2) Symptom score: Based on the assessment of chest tightness, waist pain, numbness of limbs, dry throat and mouth, fatigue, and other symptoms, scores of 0–3 are assigned for none, mild, moderate, and severe symptoms, respectively.
- (3) Blood glucose: FPG, 2hPBG, and HbA1c are detected using an automatic biochemical analyzer after centrifuging the blood samples and taking the supernatant for testing.
- (4) Kidney function: BUN, SCr, and UAER are detected using a biochemical analyzer after centrifuging the blood samples and taking the supernatant for testing.

2.5. Statistical analysis

Data are processed using SPSS 23.0 software. Count data (%) are tested using the chi-square test, and measurement data ($\bar{x} \pm s$) are tested using the t-test. A comparison difference is considered statistically significant if $P < 0.05$.

3. Results

3.1. Efficacy

The efficacy of early DKD patients in Group A was higher than that in Group B, with $P < 0.05$, as shown in **Table 2**.

Table 2. Comparison of efficacy (n,%)

| Group | Markedly effective | Effective | Ineffective | Effectiveness rate |
|----------------|--------------------|-------------|-------------|--------------------|
| Group A (n=41) | 30 (73.17%) | 10 (24.39%) | 1 (2.44%) | 40 (97.56%) |
| Group B (n=41) | 22 (53.66%) | 12 (29.27%) | 7 (17.07%) | 34 (82.93%) |
| χ^2 | - | - | - | 4.9865 |
| P | - | - | - | 0.0255 |

3.2. Symptom score

After medication, the early DKD symptom score in group A was lower than that in group B, with $P < 0.05$, as shown in **Table 3**.

Table 3. Comparison of symptom scores ($\bar{x} \pm s$)

| Group | Chest/Back pain (points) | | Limb numbness (points) | |
|--------------------|--------------------------|------------------|------------------------|------------------|
| | Before medication | After medication | Before medication | After medication |
| Group A ($n=41$) | 2.39 ± 0.41 | 0.67 ± 0.22 | 2.43 ± 0.39 | 0.69 ± 0.23 |
| Group B ($n=41$) | 2.41 ± 0.43 | 1.42 ± 0.35 | 2.45 ± 0.37 | 1.44 ± 0.32 |
| t | 0.2155 | 11.6167 | 0.2382 | 12.1862 |
| P | 0.8299 | 0.0000 | 0.8123 | 0.0000 |

| Group | Dry throat/ Mouth (points) | | Fatigue (points) | |
|--------------------|----------------------------|------------------|-------------------|------------------|
| | Before medication | After medication | Before medication | After medication |
| Group A ($n=41$) | 2.45 ± 0.39 | 0.64 ± 0.24 | 2.47 ± 0.38 | 0.61 ± 0.22 |
| Group B ($n=41$) | 2.47 ± 0.38 | 1.36 ± 0.33 | 2.48 ± 0.37 | 1.37 ± 0.29 |
| t | 0.2352 | 11.2984 | 0.1207 | 13.3690 |
| P | 0.8147 | 0.0000 | 0.9042 | 0.0000 |

3.3. Blood glucose indices

After medication, the FPG, 2hPBG, and HbA1c indices in group A were lower than those in group B, with $P < 0.05$, as shown in **Table 4**.

Table 4. Comparison of blood glucose ($\bar{x} \pm s$)

| Group | FPG(mmol/L) | | 2hPBG(mmol/L) | | HbA1c(%) | |
|--------------------|-------------------|------------------|-------------------|------------------|-------------------|------------------|
| | Before medication | After medication | Before medication | After medication | Before medication | After medication |
| Group A ($n=41$) | 7.46 ± 0.61 | 6.25 ± 0.26 | 10.72 ± 1.02 | 8.41 ± 0.68 | 8.61 ± 1.12 | 6.39 ± 0.43 |
| Group B ($n=41$) | 7.48 ± 0.63 | 6.71 ± 0.41 | 10.74 ± 1.04 | 9.53 ± 0.82 | 8.59 ± 1.14 | 7.62 ± 0.58 |
| t | 0.1460 | 6.0669 | 0.0879 | 6.7321 | 0.0801 | 10.9082 |
| P | 0.8843 | 0.0000 | 0.9302 | 0.0000 | 0.9363 | 0.0000 |

3.4. Renal function indices

After medication, the BUN, SCr, and UAER indices in group A were better than those in group B, with $P < 0.05$, as shown in **Table 5**.

Table 5. Comparison of renal function indices ($\bar{x} \pm s$)

| Group | BUN(mmol/L) | | SCr(μ mol/L) | | UAER(g/24h) | |
|----------------|-------------------|------------------|-------------------|-------------------|-------------------|------------------|
| | Before medication | After medication | Before medication | After medication | Before medication | After medication |
| Group A (n=41) | 15.18 \pm 1.29 | 9.71 \pm 1.06 | 176.25 \pm 6.28 | 147.44 \pm 3.29 | 1.99 \pm 0.51 | 0.72 \pm 0.21 |
| Group B (n=41) | 15.19 \pm 1.31 | 11.26 \pm 1.15 | 176.31 \pm 6.31 | 156.36 \pm 4.11 | 1.98 \pm 0.55 | 1.31 \pm 0.36 |
| <i>t</i> | 0.0348 | 6.3458 | 0.0432 | 10.8490 | 0.0854 | 9.0645 |
| <i>P</i> | 0.9723 | 0.0000 | 0.9657 | 0.0000 | 0.9322 | 0.0000 |

4. Discussion

Early DKD is a microvascular complication associated with structural changes and impaired renal function due to hyperglycemia. Lipid, blood pressure, and blood glucose levels can all affect the progression of DKD. Most patients with early DKD do not exhibit pathological manifestations such as edema or proteinuria. However, as the disease progresses, it can lead to proteinuria, swelling, anemia, and renal failure. Western medicine often manages early DKD through blood glucose regulation, commonly using metformin. Metformin can enhance the body's sensitivity to insulin, block the output of hepatic glucose, and increase the utilization rate of glucose by peripheral tissues. It can also relieve insulin resistance and protect renal function ^[3]. However, long-term use of metformin carries the risk of lactic acidosis, which may further damage renal function. Therefore, it is crucial to explore effective strategies for managing early DKD. Dapagliflozin, an SGLT2 inhibitor, can regulate blood glucose, protect renal function, and has a good safety profile, making it an effective option for managing early DKD. Combining this with traditional Chinese medicine can achieve a comprehensive treatment effect that addresses both the symptoms and the root cause.

Based on the analysis of DKD symptoms, traditional Chinese medicine scholars categorize early DKD under the scopes of “edema” and “diabetes with wasting and thirsting syndrome”. They believe that the prolonged and unhealed condition of this disease can lead to the depletion of yin fluid, dysfunction of organs, and disturbance of qi and blood circulation. This, in turn, can generate internal dampness-heat and phlegm-stasis, exacerbating the severity of DKD ^[4]. Additionally, Chinese medicine practitioners consider the initial stage of DKD as a syndrome of Qi and Yin deficiency, which can damage Yang and weaken the spleen and kidneys. As the disease progresses to its later stages, it transforms into a syndrome of both Yin and Yang deficiency, leading to kidney failure and internal stagnation of toxic stasis. Therefore, the disease's location is primarily in the kidneys, manifesting as a syndrome of deficiency in origin and excess in superficiality ^[5]. Traditional Chinese medicine scholars advocate dialectical treatment for early DKD, recognizing the dynamic changes in the pathogenesis of such patients. They suggest that Qi and Yin deficiency is the foundation of the disease, while impairment of Yin fluid and poor Qi and blood circulation can obstruct the kidney meridians. To address this, they recommend the use of herbs that promote blood circulation, remove stasis, strengthen the spleen, and nourish Qi. In this context, Shenqi Dihuang Decoction is selected for treatment ^[6].

Based on the data analysis in this paper, the treatment efficacy of patients with early diabetic kidney disease (DKD) in Group A is higher than that of Group B, and their symptom scores are lower than those of Group B, with $P < 0.05$. The reason for this may be the combined use of Shenqi Dihuang Decoction on the basis of SGLT2

inhibitors. The prescription includes various herbs with different functions: Fuling (*Poria cocos*) can eliminate dampness and strengthen the spleen; Huangqi (*Astragalus membranaceus*) can elevate Yang and tonify Qi; Taizishen (*Pseudostellaria heterophylla*) can moisturize the lungs, generate body fluid, strengthen the spleen, and benefit Qi; Shengdihuang (*Rehmannia glutinosa*) can generate body fluid, nourish Yin, cool blood, and clear heat; Shanyao (*Dioscorea oppositifolia*) can astringe essence, consolidate the kidneys, benefit Qi, nourish the stomach, and tonify the spleen; Shanyurou (*Cornus officinalis*) can consolidate and prolapse, nourish the liver, and nourish the kidneys; Mudanpi (*Paeonia suffruticosa*) can eliminate stasis, promote blood circulation, and clear heat; Danshen (*Salvia miltiorrhiza*) combined with Danggui (*Angelica sinensis*) can relieve pain, promote menstruation, eliminate stasis, and promote blood circulation; Zexie (*Alisma orientale*) can promote urination, drain heat, eliminate dampness, and promote diuresis; Huanglian (*Coptis chinensis*) can detoxify and purge fire; Guizhi (*Cinnamomum cassia*) can warm the meridians, promote blood circulation, and induce sweating ^[7]. The combined use of these herbs in Shenqi Dihuang Decoction can correct metabolic disorders and improve renal blood circulation through multiple targets, promoting the regression of DKD ^[8]. Another set of data shows that the FPG, 2hPBG, and HbA1c indicators of Group A are lower than those of Group B, with $P < 0.05$. The reason for this is that FPG and 2hPBG can objectively and dynamically reflect the blood glucose level in the body, while HbA1c can provide feedback on the average blood glucose level over the past 2–3 months. Patients with early DKD may experience blood glucose fluctuations due to abnormal pancreatic beta-cell function, leading to an increase in the above indicators.

In this paper, the combined treatment with Shenqi Dihuang Decoction includes berberine from Huanglian, which can block hepatic gluconeogenesis and accelerate glucose uptake by peripheral tissues; diosgenin and catalpol from Shengdihuang can improve the body's sensitivity to insulin; *Astragalus* polysaccharides from Huangqi can relieve insulin resistance; polysaccharides and mucin from Shanyao can correct glucose metabolism disorders and inhibit glucose absorption by body tissues; Fuling polysaccharides can correct lipid metabolism disorders, inhibit the accumulation of large amounts of fat in patients, and indirectly reduce insulin resistance; alisol from Zexie can inhibit hyperlipidemia and stabilize blood glucose; salvianolic acid and tanshinone from Danshen can block oxidative stress and protect islet cells; paeonol from Mudanpi has anti-inflammatory and antioxidant effects while protecting islet cells; and Taizishen, Shanyu, and Renshen can nourish the spleen, tonify Qi, and nourish the kidneys, optimizing the body's metabolic function and correcting glucose metabolism disorders caused by deficiency of both liver and kidney Yin ^[9]. Additionally, the modified Shenqi Dihuang Decoction can regulate blood glucose and blood lipids through multiple targets, achieving stable hypoglycemic effects and delaying kidney function damage in early DKD.

Finally, another set of data indicates that the BUN, SCr, and UAER indicators of patients with early DKD in Group A are better than those in Group B, with $P < 0.05$. The reason for this is that an increase in BUN and SCr suggests a decrease in glomerular filtration rate, while an increase in UAER indicates impaired kidney function. The combined use of modified Shenqi Dihuang Decoction as an adjuvant treatment for early DKD includes ingredients such as Huanglian, Shanyao, and Huangqi, which can affect lipid metabolism and blood glucose fluctuations, relieving renal metabolic disorders; Mudanpi, Danshen, and Shengdihuang can accelerate the elimination of free radicals in the human body, inhibit oxidative stress reactions, and protect the kidneys; Zexie and Huanglian combined with Fuling can block the release of inflammatory factors in the body, avoiding kidney damage caused by inflammatory factors; Guizhi combined with Danggui can dilute the blood, stimulate vasodilation, restore normal blood perfusion to the kidneys, and further optimize kidney function; and Danshen combined with Shanyu can

inhibit the progression of renal fibrosis, facilitating the regression of early DKD ^[10]. However, patients with early DKD should follow a proper diet during treatment with the modified Shenqi Dihuang Decoction. Adjust daily calorie intake based on activity level and physical condition to avoid obesity and overweight; reasonably control the intake of vitamins, fats, proteins, carbohydrates, and minerals, increasing the intake of grains, fruits, and vegetables while reducing the intake of high-fat and high-sugar foods. Adjust the proportion of carbohydrate intake, increasing the intake of low-sugar foods such as brown rice and oats to avoid rapid blood glucose elevation after eating. Control daily protein intake, choosing high-quality proteins such as milk, eggs, fish, and lean meat. Additionally, patients should be guided to exercise reasonably, regularly review blood lipids, blood glucose, and renal function indicators, and adjust medication regimens based on the improvement of various indicators.

5. Conclusion

In summary, the treatment of early DKD patients with SGLT2 inhibitors combined with modified Shenqi Dihuang Decoction can protect renal function, reduce renal inflammatory damage, lower blood glucose levels, and optimize the management of early DKD, making it worthy of promotion.

Disclosure statement

The author declares no conflict of interest.

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