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Urology Research

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Efficacy of Yishen Tongluo Formula Combined with Sulodexide in the Treatment of Diabetic Nephropathy with Renal Failure

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Abstract: *Objective:* To analyze the effect of Yishen Tongluo Formula combined with sulodexide in treating patients with diabetic nephropathy and renal failure. *Methods:* A hundred patients with diabetic nephropathy accompanied by renal failure who were admitted to the hospital for treatment from March 2021 to March 2024 were randomly divided into the control group and the observation group, and were treated with sulodexide therapy and Yishen Tongluo Formula + sulodexide therapy, respectively. The treatment efficacy of the two groups was evaluated. *Results:* After treatment, fasting blood glucose and other levels were lower in the observation group, $P < 0.05$; renal function indexes in the observation group improved, where levels of 24-hour urinary protein, blood urea nitrogen, and blood creatinine were significantly lower than those of the pre-treatment and control group; the effect of microinflammatory state relief was significant, as demonstrated by the significant decrease of interleukin-6 and other indexes, $P < 0.05$. *Conclusion:* In the treatment of diabetic nephropathy patients with renal failure, we should pay attention to the protection of renal function, applying sulodexide to improve patients' blood glucose indexes, and at the same time, utilizing Yishen Tongluo Formula to alleviate patients' microinflammatory state and enhance the recovery of renal function.

Keywords: Yishen Tongluo Formula; Sulodexide; Diabetic nephropathy; Renal failure; Application

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1. Introduction

Prolonged high blood sugar levels in patients can lead to chronic kidney damage and eventually progress to kidney failure. In China, approximately 20% to 25% of diabetic nephropathy patients develop renal failure. This condition is characterized by symptoms such as edema and kidney impairment, significantly reducing patients' quality of life, threatening their safety, and posing challenges to effective treatment^[1]. Sulodexide, a glycosaminoglycan

comprising low-molecular-weight heparin and dermatan sulfate, is a commonly used drug for diabetic nephropathy. It has demonstrated efficacy in controlling oxidative stress, reducing inflammation, improving vascular function, and lowering blood lipid levels. These mechanisms help alleviate kidney damage. However, the therapeutic outcomes of sulodexide alone fall short of optimal expectations, necessitating improved treatment approaches. In traditional Chinese medicine (TCM), diabetic nephropathy with renal failure is categorized under “drowning poison” and “Guan Ge,” and is attributed to external factors such as the six excesses and overexertion. This condition is considered a deficiency at the root with excessive manifestations ^[2]. Yishen Tongluo Formula offers a TCM-based intervention by tonifying the kidneys, consolidating the root, enhancing energy, promoting blood circulation, improving glucose metabolism, and protecting kidney function. Furthermore, it mitigates oxidative stress, offering complementary benefits when combined with sulodexide. This study explores the synergistic effects of Yishen Tongluo Formula and sulodexide in treating diabetic nephropathy with renal failure, providing valuable insights into optimizing therapeutic strategies for this challenging condition.

2. General information and methods

2.1. General information

The research subjects selected for this study were 100 patients with diabetic nephropathy with complications of renal failure treated between March 2021 and March 2024. They were randomly divided into the observation group and the control group. In the observation group, there were 31 cases of men and 19 cases of women, with an average age of 61.23 ± 1.52 years, and the average duration of diabetic nephropathy was 5.63 ± 0.53 years. In the control group, there were 32 and 18 cases of men and women, respectively, with a mean age of 61.28 ± 1.46 years and a mean duration of diabetic nephropathy of 5.59 ± 0.51 years. Evaluating the data of both groups, the data were comparable, $P > 0.05$.

Inclusion criteria: Patients suffering from diabetic nephropathy combined with renal failure were selected.

Exclusion criteria: Patients who have received hemodialysis therapy; patients with type I diabetes mellitus.

2.2. Methodology

2.2.1. Control group methods

Based on the guidelines of the Diabetic Nephropathy Act, the conventional treatment methods were implemented. The patients were instructed to adjust their own dietary structure to a low salt and protein diet, regulating blood lipid levels and correcting acid-base and water-electrolyte imbalance problems. At the same time, patients were instructed to take oral sulodexide (Alpha Weissmann Pharmaceuticals [Italy], approval number: H20080618, specification: 250LSU), one tablet once, twice a day.

2.2.2. Observation group methods

On the basis of the control group's treatment protocol, the Yishen Tongluo Formula was utilized, and the main components of the formula were *Astragalus*, ripened rhubarb, Cornelian cherry, peony root, diabase, *Angelica sinensis*, danshen, dangshen, earthworm, leech with licorice, etc., and the dosages were 20 g, 15 g, 15 g, 15 g, 15 g, 15 g, 12 g, 9 g, 3 g, and 6 g, respectively. They were decocted with water, to obtain 300 ml of the medicine, and 150 ml was taken twice a day.

2.3. Observation indicators

Patients' fasting blood glucose and 2-hour postprandial blood glucose were collected to assess their glucose metabolic status using a blood glucose meter, and their glycated hemoglobin level was measured using enzyme-linked immunosorbent assay (ELISA).

When testing the patients' renal function indexes, their blood creatinine and other levels were measured using a fully automatic biochemical detector, and their urine was collected within 24 hours to assess 24-hour urine protein.

To detect patients' microinflammatory state, ELISA assays were utilized to measure patient serum interleukin-6 and other levels.

2.4. Statistical analysis

SPSS23.0 was used for data analysis. Count data were tested by χ^2 test, while measurement data were tested using *t*-test (mean \pm standard deviation [SD]). If $P < 0.05$, the difference between the data was significant.

3. Results

3.1. Glucose metabolism status

As shown in **Table 1**, after treatment, the observation group had lower levels of fasting blood glucose, 2-hour postprandial blood glucose, and glycated hemoglobin ($P < 0.05$).

Table 1. Glucose metabolism status of the two groups before and after treatment (mean \pm SD)

Groups	<i>n</i>	Fasting blood glucose (mmol/L)		2-hour postprandial blood glucose (mmol/L)		Glycated hemoglobin (%)	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Observation group	50	10.62 \pm 2.03	5.01 \pm 1.35	12.16 \pm 1.42	6.32 \pm 0.78	9.53 \pm 0.57	7.48 \pm 0.78
Control group	50	10.57 \pm 2.05	8.13 \pm 1.57	12.23 \pm 1.39	9.85 \pm 0.97	9.49 \pm 0.59	8.76 \pm 0.31
<i>t</i>	-	0.227	10.034	0.098	9.534	0.189	8.362
<i>P</i>	-	0.796	0.001	0.921	0.001	0.851	0.009

3.2. Renal function indicators

Based on **Table 2**, after treatment, the kidney function indexes of the observation group improved significantly and were better than the control group, $P < 0.05$.

Table 2. Renal function indexes of the two groups before and after treatment (mean \pm SD)

Groups	<i>n</i>	24-hour urine protein (g/24h)		Blood urea nitrogen (mmol/L)		Blood creatinine (μ mol/L)	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Observation group	50	3.86 \pm 0.56	1.19 \pm 0.14	10.13 \pm 1.32	4.76 \pm 1.57	99.32 \pm 12.14	71.85 \pm 8.62
Control group	50	3.91 \pm 0.52	1.98 \pm 0.29	10.17 \pm 1.28	6.23 \pm 1.59	99.29 \pm 12.16	86.12 \pm 7.16
<i>t</i>	-	1.678	10.241	0.823	8.534	0.752	9.258
<i>P</i>	-	0.124	0.001	0.278	0.007	0.367	0.003

3.3. Microinflammatory state

As shown in **Table 3**, after treatment, the microinflammatory state of the observation group improved significantly, $P < 0.05$.

Table 3. Microinflammatory status of the two groups before and after treatment (mean \pm SD)

Groups	<i>n</i>	Interleukin-6 (ng/L)		Amyloid (mg/L)		Ultrasensitive C-reactive protein (mg/L)	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Observation group	50	7.42 \pm 1.79	3.81 \pm 0.98*	24.18 \pm 4.72	10.25 \pm 2.31*	7.96 \pm 1.34	4.16 \pm 0.87*
Control group	50	7.39 \pm 1.82	5.16 \pm 1.08*	24.23 \pm 4.68	16.24 \pm 2.47*	7.91 \pm 1.39	5.34 \pm 1.14*
<i>t</i>	-	0.139	10.624	0.048	11.864	0.308	7.524
<i>P</i>	-	0.891	0.001	0.962	0.001	0.758	0.017

Note: Compared with the same group before treatment, * indicates $P < 0.05$.

4. Discussion

The etiology of diabetic nephropathy remains unclear, but numerous studies have highlighted its strong correlation with insulin resistance and oxidative stress. Increased insulin resistance elevates glomerular pressure, placing the glomeruli in a state of hyperfiltration. This condition increases urinary protein excretion, decreases tubular reabsorption, and raises urinary protein levels. Prolonged hyperglycemia can weaken the glomerular filtration membrane's charge barrier, reducing protein stability on renal cell surfaces. Additionally, glycosylation product accumulation can stimulate albumin in circulation, increase glycosylation levels of albumin, and heighten albumin filtration, further elevating proteinuria. As diabetic nephropathy progresses, renal function deteriorates, potentially leading to renal failure and a diminished quality of life for patients^[3]. Currently, there is no definitive cure for diabetic nephropathy combined with renal failure. Clinical management focuses on addressing glucose and lipid metabolism disorders, controlling proteinuria, and preserving residual renal function.

Sulodexide, a therapeutic agent, has shown promise in diabetic nephropathy management. Initially employed in antithrombotic therapy, modern pharmacological research has revealed its capacity to enhance microcirculation and mitigate inflammatory responses. Sulodexide's antioxidative properties are particularly valuable in diabetic nephropathy treatment, where oxidative stress plays a critical role in disease progression. Diabetic patients typically exhibit reduced antioxidant enzyme activity and increased free radicals, which damage renal tissues, promote glomerulosclerosis, and exacerbate renal dysfunction. Sulodexide suppresses oxidative stress by reducing malondialdehyde levels and enhancing superoxide dismutase activity. Furthermore, it inhibits the expression of cell adhesion factors, helping to control inflammation and oxidative damage. A study has demonstrated that integrating sulodexide with conventional treatments significantly reduced urinary protein levels in diabetic nephropathy patients, underscoring its potential as an adjunctive therapy.

In TCM, diabetic nephropathy is not identified as a distinct disease but is instead categorized under conditions such as thirst disease, edema, and renal elimination as discussed by successive generations of TCM practitioners. Diabetic nephropathy aligns with TCM's classification of thirst disease nephropathy, characterized by a combination of deficiency in essence and excess in pathogenic factors, with the most significant organ damage occurring in the kidneys. Over time, thirst disease depletes yin and qi, leading to qi stagnation and

poor blood circulation. Moreover, the disrupted metabolism of fats and proteins in diabetic patients produces internal pathogenic factors that further obstruct meridians and blood flow ^[4]. Modern pharmacological research highlights the effectiveness of the Yishen Tongluo Formula in addressing these pathologies. Ingredients such as *Astragalus* enhance anti-inflammatory responses, protect renal tubules, and inhibit renal interstitial fibrosis. Other components, including Radix Rehmanniae Praeparata and Cornu Cervi Pantotrichum, improve immunity, reduce platelet aggregation, and optimize blood circulation, while Radix Rhizoma Dioscoreae regulates lipid metabolism and mitigates oxidative damage. Ingredients like *Angelica sinensis* accelerate toxin clearance and support renal tissue repair.

This study revealed improved glycemic control in the observation group post-treatment, likely attributable to the Yishen Tongluo Formula. *Astragalus* tonifies qi and promotes yang, aiding in water excretion to reduce swelling. Radix Rehmanniae Praeparata nourishes yin and fortifies the kidneys ^[5], while Cornu Cervi Pantotrichum strengthens liver and kidney function. The bark of the Earth (Dixuepi) clears heat, removes dampness, and nourishes yin in the lungs and kidneys, and Radix Codonopsis Pilosulae boosts vital energy by strengthening the middle jiao. Mudanpi activates blood circulation and resolves stasis, supporting meridian health. Combined with sulodexide, which controls oxidative stress and protects the glomerular filtration barrier, this formula enhances overall glycemic regulation and addresses the multifaceted pathology of diabetic nephropathy effectively.

According to modern medical perspectives, patients with diabetes mellitus often experience increased blood viscosity and lipid deposition ^[6]. These deposits, carried through the bloodstream, can accumulate in the kidneys, exacerbating damage to renal tubules and other tissues, and progressively impairing renal function. In this study, the kidney function indices in the observation group significantly improved after treatment. This improvement may be attributed to the primary component, *Astragalus*. Its polysaccharides support the bidirectional regulation of blood glucose, reducing blood sugar levels and correcting renal hyperperfusion. These effects decrease plasma osmolality and slow the thickening of the glomerular basement membrane. Additionally, Rehmanniae Praeparata contains active compounds such as oligosaccharides, which enhance serum insulin levels, improve gut flora, reduce urinary protein excretion, and aid in the recovery of renal function indicators ^[7,8].

The development of diabetic nephropathy combined with renal failure is closely linked to a microinflammatory state. Elevated interleukin-6 levels promote neutrophil infiltration in the tubular interstitium, increasing the thickness of the glomerular basement membrane and altering glomerular hemodynamics. As renal failure progresses, inflammatory damage intensifies, raising amyloid and ultrasensitive C-reactive protein levels ^[9,10]. This study showed that the microinflammatory state in the observation group improved significantly post-treatment. The improvement may result from the Yishen Tongluo Formula enhancing leukocyte phagocytosis and reducing inflammatory factor levels. The inclusion of sulodexide further contributes by facilitating proteoglycan complex repair and mitigating inflammatory symptoms, thereby improving overall renal function and reducing disease progression.

5. Conclusion

In conclusion, when treating patients with diabetic nephropathy and renal failure, the application of Yishen Tongluo Formula and sulodexide can be used to build a combination of traditional Chinese and Western medicine treatment mechanisms. It can control patients' blood glucose, enhance the protection of patients' renal function, improve patients' microinflammatory state, and promote the improvement of patients' quality of life.

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Disclosure statement

The authors declare no conflict of interest.

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Analysis of the Efficacy of Finerenone Combined with Irbesartan in the Treatment of Diabetic Nephropathy

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Abstract: *Objective:* To analyze the clinical effect of using finerenone combined with irbesartan in the treatment of diabetic nephropathy. *Methods:* Eighty-five patients with diabetic nephropathy who received inpatient treatment in our hospital from July 2023 to June 2024 were selected and divided into the control group (42 cases) and the observation group (43 cases) according to the differences in drug treatment programs. The control group received oral treatment with finerenone tablets, and the observation group received treatment with finerenone combined with irbesartan. The differences in the blood glucose level, renal function indicators, serological level, and adverse reactions of the two groups were compared and analyzed. *Results:* After treatment, the levels of fasting blood glucose, 2-hour postprandial blood glucose, glycated hemoglobin, blood creatinine, urea nitrogen, blood uric acid, TGF- β 1, SFRP-4, GSK-3 β , and ICAM-1 in the observation group were significantly lower than those in the control group ($P < 0.05$). In the control group, there was one case each of vertigo, palpitation, rash, vomiting, and angioneurotic edema during treatment, with a total incidence rate of 11.90%; the observation group had one case each of vertigo and vomiting, with a total incidence rate of 4.65% ($P > 0.05$). *Conclusion:* In the clinical treatment of patients with diabetic nephropathy, finerenone combined with irbesartan therapy can significantly improve patients' blood glucose level and serological levels, and alleviate patients' renal function, showing positive clinical application value.

Keywords: Diabetic nephropathy; Irbesartan tablets; Finerenone tablets; Renal function; Blood glucose level; Serum level

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1. Introduction

Diabetic nephropathy (DN) is one of the common microvascular complications in diabetes mellitus, with an incidence rate of about 40% in diabetes mellitus patients, and has become a major cause of end-stage renal disease (ESRD) ^[1]. With the increasing prevalence of diabetes mellitus worldwide, the incidence of DN has

also increased significantly, posing a serious threat to the quality of life and health of patients. The pathologic features of DN mainly include the thickening of the glomerular basement membrane, proliferation of thylakoid cells, and glomerulosclerosis, which may lead to proteinuria and gradual deterioration of renal function ^[2]. Existing therapeutic strategies for DN include glycemic control, blood pressure management, and proteinuria reduction. Antihypertensive drugs, especially angiotensin receptor blockers (ARBs) such as irbesartan, have shown significant efficacy in reducing urinary protein levels and delaying the deterioration of renal function ^[3]. Irbesartan dilates blood vessels and lowers blood pressure by inhibiting the action of angiotensin II, while having a protective effect on the kidneys. However, the use of ARB analogs alone has limited effect in some patients, thus new treatment options are necessary to further improve patient prognosis ^[4]. Finerenone is a novel non-steroidal mineralocorticoid receptor antagonist (MRA), which has been widely used in chronic kidney disease (CKD) and diabetes-related nephropathy in recent years. It acts by blocking the activation of mineralocorticoid receptors and reducing inflammatory response and fibrotic process ^[5]. Clinical studies have shown that finerenone can significantly reduce the level of urinary protein and delay the decline of renal function, and its mechanism of action has better selectivity and fewer side effects than traditional MRA drugs such as spironolactone. In order to investigate the effectiveness of finerenone combined with irbesartan regimen in the treatment of diabetic nephropathy, the present study was conducted as a small-sample clinical trial.

2. General information and methods

2.1. General information

Eighty-five patients with diabetic nephropathy who received inpatient treatment in our hospital from July 2023 to June 2024 were selected and divided into a control group (42 cases) and an observation group (43 cases) according to the differences in drug treatment regimens. In the control group, there were 23 males and 19 females, with an average age of 60.4 ± 7.3 years, a disease duration of 3 to 14 years, and a body mass index (BMI) of 21.45 ± 0.62 kg/m². In the observation group, there were 22 males and 21 females, with an average age of 61.1 ± 6.8 years, a disease duration of 3 to 16 years, and a BMI of 21.51 ± 0.71 kg/m². A comparison of the general data of the two groups of patients found no significant difference ($P > 0.05$). This study has been approved by the Ethics Committee of the hospital for implementation.

Inclusion criteria: (1) Diagnosed with diabetic nephropathy according to the Diagnostic Criteria of Chinese Guidelines for the Prevention and Control of Diabetic Kidney Disease (2021 Edition) ^[6]; (2) Aged between 18 and 75 years old; (3) Glomerular filtration rate (eGFR) of 30–90 mL/min/1.73m², with moderate renal hypoplasia but not severe renal insufficiency; (4) Patients and their legal guardians were able to understand the content of the study and voluntarily signed an informed consent form.

Exclusion criteria: (1) Presence of severe hepatic insufficiency; (2) Patients receiving medications that affect renal function, such as ACEI (angiotensin-converting enzyme inhibitor) or ARB; (3) Pregnant or lactating women; (4) Patients with a previous history of coronary artery disease, heart failure, or myocardial infarction; (5) Patients with a history of allergic reaction to the investigational drugs (finerenone, irbesartan).

2.2. Methodology

After admission, all patients were given correct lifestyle guidance and standardized metabolic therapy. Patients in the control group were given finerenone tablets (BayerAG, specification of 20 mg/tablet, product batch numbers

202103028, 202307027) for oral treatment. The starting dose was half tablet/time, once a day, and the dose was increased to one tablet/time, once a day after four weeks of continuous use. The dose of finerenone tablets in the observation group was the same as that of the control group, and the oral treatment of irbesartan (Yangzijiang Pharmaceutical Group Jiangsu Zilong Pharmaceutical Co., Ltd., specifications of 75 mg/tablet, product batch numbers 202104017, 202305019) was increased from the fifth week. Both groups were treated for three months.

2.3. Observation indicators

- (1) The changes in blood glucose levels of the two groups were observed and compared after three months of medication, including fasting blood glucose (FBG), 2-hour postprandial blood glucose (2hPG) levels, and glycated hemoglobin (HbA1c) levels.
- (2) The changes in renal function of the two groups of patients were observed and compared, including blood creatinine (SCr), blood urea nitrogen (BUN), and blood uric acid (UA).
- (3) Fasting venous blood of 5 mL was centrifuged for 10 minutes to separate the serum. Enzyme-linked immunosorbent assay was used to detect serum glycogen synthase kinase-3 β (GSK-3 β), secreted frizzled-related protein-4 (SFRP-4), transforming growth factor- β 1 (TGF- β 1), and intercellular adhesion molecule-1 (ICAM-1) levels.
- (4) The occurrence of adverse reactions was observed and recorded such as vertigo, palpitation, rash, vomiting, and angioneurotic edema during the administration of the drug in both groups. Total incidence rate = total incidence cases/total cases \times 100%.

2.4. Statistical methods

SPSS24.0 statistical software was applied to analyze and process the relevant data. Measurement data were expressed as mean \pm standard deviation (SD) and compared with *t*-test; count data were expressed as [*n* (%)] and compared with χ^2 test. $P < 0.05$ was used to indicate that the difference was statistically significant.

3. Results

3.1. Comparison of blood glucose levels between the two groups after treatment

After treatment, the levels of FBG, 2hPG, and HbA1c of patients in the observation group were significantly lower than those of the control group, and the difference was statistically significant ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of blood glucose levels between the two groups after treatment (mean \pm SD)

Groups	<i>n</i>	FBG (mmol/L)	2hPG (mmol/L)	HbA1c (%)
Control group	42	6.57 \pm 1.04	9.08 \pm 1.32	7.34 \pm 0.49
Observation group	43	5.21 \pm 1.01	7.97 \pm 1.24	6.12 \pm 0.43
<i>t</i>	-	6.116	3.997	12.209
<i>P</i>	-	0.000	0.001	0.000

3.2. Comparison of renal function between the two groups after treatment

After treatment, the levels of SCr, BUN, and UA of patients in the observation group were significantly lower than those of the control group, and the difference was statistically significant ($P < 0.05$), as presented in **Table 2**.

Table 2. Comparison of renal function between the two groups after treatment (mean \pm SD)

Groups	<i>n</i>	SCr ($\mu\text{mol/L}$)	BUN ($\mu\text{mol/L}$)	UA (mmol/L)
Control group	42	86.34 \pm 15.29	7.51 \pm 1.35	318.35 \pm 16.49
Observation group	43	73.79 \pm 11.16	6.29 \pm 1.14	305.17 \pm 17.37
<i>t</i>	-	4.330	4.506	3.586
<i>P</i>	-	0.000	0.000	0.001

3.3. Comparison of serological levels between the two groups after treatment

After treatment, the levels of TGF- β 1, SFRP-4, GSK-3 β , and ICAM-1 of patients in the observation group were significantly lower than those of the control group, and the difference was statistically significant ($P < 0.05$), as shown in **Table 3**.

Table 3. Comparison of serological levels between the two groups after treatment (mean \pm SD)

Groups	<i>n</i>	TGF- β ($\mu\text{g/L}$)	SFRP-4 (pg/mL)	GSK-3 β ($\mu\text{g/L}$)	ICAM-1 (ng/mL)
Control group	42	280.79 \pm 18.78	125.62 \pm 32.44	35.93 \pm 10.25	382.29 \pm 49.13
Observation group	43	191.72 \pm 11.06	90.71 \pm 12.08	29.31 \pm 8.22	265.45 \pm 37.18
<i>t</i>	-	26.719	6.604	3.289	12.382
<i>P</i>	-	0.000	0.000	0.002	0.000

3.4. Comparison of the occurrence of adverse reactions between the two groups

One case each of vertigo, palpitation, rash, vomiting, and angioneurotic edema occurred during treatment in the control group, with a total incidence rate of 11.90%, while one case each of vertigo and vomiting occurred in the observation group, with an incidence rate of 4.65%. The chi-square test was $P > 0.05$, as illustrated in **Table 4**.

Table 4. Comparison of adverse reactions between the two groups [*n* (%)]

Groups	<i>n</i>	Vertigo	Palpitation	Rash	Vomiting	Angioneurotic edema	Occurrence rate
Control group	42	1	1	1	1	1	5 (11.90)
Observation group	43	1	0	0	1	0	2 (4.65)
χ^2	-	-	-	-	-	-	1.321
<i>P</i>	-	-	-	-	-	-	0.250

4. Discussion

Diabetic nephropathy is one of the common and serious complications in patients with diabetes mellitus, and it is the primary cause of ESRD. Once patients develop ESRD, they often need to undergo long-term dialysis treatment or renal transplantation, which not only greatly increases the medical burden, but also significantly reduces patients' quality of life. The pathogenesis of DN is complex and diverse, involving multiple metabolic signals and abnormal regulation of molecular signaling pathways. With the in-depth study of DN, it is now believed that

blood glucose levels, serum metabolites, intrarenal inflammatory response, and fibrosis all play a role in the onset and progression of DN ^[7]. Hyperglycemia is one of the main characteristics of diabetic patients, and a persistent hyperglycemic state stimulates inflammatory responses and fibrosis in the kidney by increasing the production of advanced glycation end products (AGEs), leading to glomerulosclerosis and tubulointerstitial lesions ^[8]. At the same time, hyperglycemia activates several intracellular signaling pathways such as protein kinase C (PKC) and transforming growth factor beta (TGF- β), which exacerbate the process of kidney injury. Under hyperglycemia, the production of angiotensin II increases, leading to intraglomerular hyperperfusion and a high-pressure environment, accelerating the decline of glomerular filtration rate and the damage of renal structure, which not only increases the burden on the kidneys by narrowing the blood vessels, but also promotes the release of inflammatory factors, exacerbating the process of renal fibrosis and sclerosis.

In addition to glycemic and hemodynamic factors, oxidative stress is also an important mechanism in the pathogenesis of DN. Hyperglycemia damages the microvascular structure and cells of the kidney by increasing the production of reactive oxygen species (ROS), leading to the gradual decline of renal function. Meanwhile, in the diabetic state, the expression of inflammatory factors in the kidney is increased, such as monocyte chemoattractant protein-1 (MCP-1) and tumor necrosis factor-alpha (TNF- α), which further aggravate the damage of glomerular and tubulointerstitial. Diabetic patients are often associated with hyperlipidemia, and fat deposition in renal tubular epithelial cells can trigger renal lipotoxicity, leading to tubulointerstitial injury and fibrosis. The complex interaction of multiple factors leads to the pathogenesis of DN, which is difficult to reverse, and therefore a multi-targeted comprehensive treatment strategy is necessary. The use of finerenone or irbesartan alone in the treatment of diabetic nephropathy has limitations despite its efficacy ^[9]. Finerenone, as a non-steroidal MRA, is effective in reducing renal inflammation and fibrosis, thereby lowering urinary protein levels and delaying the decline of renal function. However, finerenone alone may have a limited effect on blood pressure regulation in DN patients with hypertension, limiting its clinical application to some extent. Irbesartan, as an ARB, can effectively delay the decline of renal function by vasodilating blood vessels, lowering blood pressure, and reducing glomerular hyperperfusion. However, the use of irbesartan alone cannot effectively inhibit fibrosis and inflammation in the kidney, making its efficacy less significant in some patients.

In this study, by comparing the clinical efficacy of the control group, who received oral finerenone tablets alone, and the observation group, who received a combination of finerenone and irbesartan, it was found that the patients in the observation group had a significant advantage in several clinical indicators. Glucose metabolic indexes such as FBG, 2hPG, HbA1c, and renal function indexes such as SCr, BUN, and UA of patients in the observation group were significantly lower than those of the control group, suggesting that the combined treatment had a stronger effect on glycemic control and renal function protection. The levels of inflammation- and fibrosis-related factors such as TGF- β 1, SFRP-4, GSK-3 β , and ICAM-1 in the observation group were also significantly lower than those in the control group, indicating that the combined treatment showed more obvious effects in reducing inflammatory responses and delaying renal fibrosis. The reason for this result lies in the complementary mechanism of action of finerenone and irbesartan, i.e., finerenone mainly works by inhibiting inflammation and fibrosis, while irbesartan works by lowering blood pressure and improving renal hemodynamics, and the two act synergistically to ameliorate the pathological process of diabetic nephropathy in a more comprehensive way ^[10].

5. Conclusion

In conclusion, the application of irbesartan combined with finerenone tablets in the treatment of diabetic nephropathy can obtain significant clinical effects. It can not only greatly improve patients' blood glucose levels and renal function status, but also further reduce patients' inflammatory reactions, which is worthy of popularization and application in the clinical field.

Disclosure statement

The authors declare no conflict of interest.

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Clinical Efficacy of Tamsulosin Combined with Huang'e Capsules in Improving Type III Prostatitis

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Abstract: *Objective:* To explore the clinical efficacy and safety of tamsulosin combined with Huang'e capsules in treating type III prostatitis. *Methods:* A total of 74 patients from the Department of Urology at Jiaying University Affiliated Jiashan Hospital were selected and randomly divided into treatment group and control group by double-blind method, with 37 cases in each group. The treatment group was given tamsulosin combined with Huang'e capsules, and the control group was given tamsulosin alone. The NIH-CPSI, IIEF-5, and EPS-WBC scores and the incidence of adverse reactions in the two groups were compared before treatment as well as 15 and 30 days after treatment. *Results:* The treatment group showed statistically significant differences compared to the control group in terms of pain or discomfort, urinary symptoms, quality of life, NIH-CPSI, and EPS-WBC after treatment ($P < 0.05$). There was no statistically significant difference in IIEF-5 scores between the two groups ($P > 0.05$). No major adverse reactions occurred in either group during the treatment. *Conclusion:* Tamsulosin combined with Huang'e capsules can effectively improve the clinical symptoms of patients with type III prostatitis, enhance the quality of life, and has good safety.

Keywords: Type III prostatitis; Tamsulosin; Huang'e capsule; NIH-CPSI; EPS-WBC; IIEF-5

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1. Introduction

Chronic prostatitis is one of the most common disorders in the urinary system, with type III prostatitis being particularly prevalent ^[1]. In recent years, the incidence of the disease has shown a gradual upward trend. Clinically, it presents with symptoms such as pain (in the perineum, testicles, pubic area, etc.), urinary storage and voiding symptoms, and sexual dysfunction, significantly affecting the quality of life and physical and mental health of men. Epidemiologically, prostatitis patients account for 8% to 25% of urology outpatient visits, with the reported prevalence in China ranging from 6.0% to 32.9% ^[2]. Huang'e capsules, developed by Professor Jinming Jia and his team in China, contain 12 traditional Chinese medicinal ingredients: astragalus, peach kernel, curcuma, motherwort, selfheal, rhubarb, earthworm, coix seed, cinnamon, pueraria, platycodon, and epimedium.

Current studies show that Huang'e capsules can alleviate symptoms such as difficulty urinating, frequent urination, urgency, and lower abdominal discomfort by reducing the tension of the urethral sphincter, improving microcirculation, and exerting anti-inflammatory effects^[3,4]. This study aims to investigate the efficacy and safety of tamsulosin combined with Huang'e capsules in patients with type III prostatitis.

2. General information and methods

2.1. General information

A total of 74 patients diagnosed with type III prostatitis between May 2022 and December 2023 were selected and randomly divided into a treatment group and a control group, with 37 patients in each group. The subjects' age ranged from 30 to 65 years old, and the course of the disease ranged from 1 to 60 months. None of the patients had underlying diseases.

2.2. Inclusion and exclusion criteria

Inclusion criteria: (1) Meet the diagnostic criteria for type III prostatitis according to the "2019 Edition of Chinese Urological Disease Diagnosis and Treatment Guidelines"; (2) Have not received other drug treatments or methods in the 15 days prior to treatment; (3) Have agreed to participate in the study through informed consent. Exclusion criteria: (1) Cases that have received other related treatments; (2) Cases with interfering diseases such as other prostate disorders, cystitis, urethritis, etc.; (3) Cases with severe underlying diseases; (4) Cases with mental disorders; (5) Cases where complete information cannot be collected due to personal reasons such as withdrawal in the middle of the study. This study has been reviewed and approved by the ethics committee of our hospital, and all subjects have been informed and signed informed consent forms.

2.3. Methods

The treatment group took Huang'e capsules (manufacturer: Zhejiang Kang En Bei Pharmaceutical Co., Ltd., specification: 0.4 g/capsule), 1.6 g per dose, three times a day; and tamsulosin capsules (manufacturer: Zhejiang Qianyuan Hailisheng Pharmaceutical Co., Ltd., specification: 0.2 mg/capsule), 0.2 mg per dose, once at night.

The control group took tamsulosin capsules (manufacturer: Zhejiang Qianyuan Hailisheng Pharmaceutical Co., Ltd., specification: 0.2 mg/capsule), 0.2 mg per dose, once at night.

Assessments were conducted 15 and 30 days after starting treatment.

2.4. Evaluation metrics

- (1) National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI): This scale consists of three parts: pain symptoms, urinary symptoms, and the impact of symptoms on quality of life. The total score ranges from 1 to 14 for mild, 15 to 29 for moderate, and 30 to 43 for severe. A higher score indicates more severe clinical symptoms.
- (2) International Index of Erectile Function (IIEF-5): A score of less than 7 indicates severe erectile dysfunction, 8–11 indicates moderate erectile dysfunction, and 12–21 indicates mild erectile dysfunction.
- (3) White Blood Cell Count in Prostatic Fluid (EPS-WBC): Prostatic fluid was obtained through prostate massage and sent to the hospital's laboratory for leukocyte counting under high magnification.

2.5. Statistical methods

Data analysis was performed using SPSS26.0 software. Categorical data are expressed as percentages (%) and

analyzed using the chi-square test. Quantitative data are expressed as mean \pm standard deviation (SD) and analyzed using the *t*-test. A *P*-value less than 0.05 was considered statistically significant.

3. Results

3.1. Comparison of basic information

The comparison results showed no statistically significant differences in age, disease duration, body mass index (BMI), and underlying diseases between the two groups of patients, indicating that the subjects were comparable (Table 1).

Table 1. Comparison of basic patient information (mean \pm SD)

Basic information	Age	Disease duration (months)	BMI
Treatment group	48.32 \pm 9.45	15.38 \pm 10.82	23.89 \pm 2.38
Control group	48.32 \pm 9.01	14.16 \pm 9.76	23.42 \pm 2.38

Note: Compared with the control group, *P* > 0.05

3.2. Comparison of NIH-CPSI scores

Before treatment, there were no statistically significant differences in pain or discomfort, urinary symptoms, quality of life, and total scores between the two groups (*P* > 0.05). After treatment, the scores for pain or discomfort, urinary symptoms, and quality of life in the treatment group were significantly reduced; the difference between the treatment group and the control group was statistically significant (*P* < 0.05). The results are shown in Table 2.

Table 2. Comparison of NIH-CPSI scores before and after treatment in both groups (mean \pm SD)

Group	Treatment group			Control group		
	Pre-treatment	15 days after treatment	30 days after treatment	Pre-treatment	15 days after treatment	30 days after treatment
Pain or discomfort	8.72 \pm 3.54	6.54 \pm 2.06	4.17 \pm 2.38 ^a	9.02 \pm 2.54	7.87 \pm 2.56	7.12 \pm 2.78 ^a
Urinary symptoms	7.63 \pm 1.94	4.16 \pm 1.18	2.01 \pm 1.04 ^b	7.48 \pm 1.78	6.08 \pm 1.79	5.57 \pm 1.06 ^b
Quality of life	9.05 \pm 0.92	5.72 \pm 1.54	3.23 \pm 1.67 ^c	9.76 \pm 1.08	7.33 \pm 2.35	6.78 \pm 1.97 ^c
Total score	24.75 \pm 3.01	16.78 \pm 1.98	12.51 \pm 1.06 ^d	25.45 \pm 3.64	19.06 \pm 1.98	18.98 \pm 1.98 ^d

Note: For between-group comparisons, *P* < 0.05; compared with the control group, ^a*P*, ^b*P*, ^c*P*, and ^d*P* are all less than 0.05.

3.3. Comparison of IIEF-5 scores

Based on Table 3, there was no significant difference in erectile dysfunction between the two groups before and after treatment, and the difference was not statistically significant (*P* > 0.05).

Table 3. Comparison of IIEF-5 scores before and after treatment in both groups (mean \pm SD)

Group	Treatment group		Control group	
	Pre-treatment	30 days after treatment	Pre-treatment	30 days after treatment
IIEF-5 score	13.45 \pm 1.57	13.98 \pm 1.64 ^a	12.33 \pm 1.78	12.01 \pm 1.61 ^a

Note: Compared with the control group, *P* > 0.05

3.4. Comparison of EPS-WBC

There was no significant difference in white blood cell count in prostatic fluid between the two groups before treatment, and the difference was not statistically significant ($P > 0.05$). After treatment, the white blood cell count in prostatic fluid of the treatment group decreased significantly; compared with the control group, the difference was statistically significant ($P < 0.05$), as presented in **Table 4**.

Table 4. Comparison of EPS-WBC changes before and after treatment in both groups (mean \pm SD)

Group	Treatment group		Control group	
	Pre-treatment	30 days after treatment	Pre-treatment	30 days after treatment
EPS-WBC	24.49 \pm 3.78	6.37 \pm 2.05	23.57 \pm 3.08	18.78 \pm 3.12

Note: Comparison between groups, $P < 0.05$; compared with the control group, $P < 0.05$

3.5. Comparison of adverse reaction incidence

During the treatment process, only one case of nausea was reported in the treatment group, and no other adverse reactions occurred (**Table 5**). The P -value between the two groups was greater than 0.05, indicating no statistical significance.

Table 5. Incidence of adverse reactions in both groups ($n = 37$, %)

Group	Nausea	Dizziness	Allergic reaction	Other	Total incidence
Treatment group	1/37	0/37	0/37	0/37	2.70
Control group	0/37	0/37	0/37	0/37	0

Note: Compared with the control group, the total incidence of adverse reactions was $P > 0.05$

4. Discussion

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is the most common, symptomatically complex, and difficult-to-treat type of prostatitis, with an unclear etiology. Current clinical treatment typically involves α -receptor blockers, plant-based formulations, nonsteroidal anti-inflammatory analgesics, and M-receptor blockers to alleviate symptoms. Cognitive-behavioral education^[5], acupuncture^[1], and other methods have also demonstrated clinical effectiveness. Huang'e capsule, formulated with a combination of 12 traditional Chinese medicinal herbs based on the principles of Chinese medicine, primarily works by tonifying qi and invigorating blood to improve urinary symptoms. It has been shown to antagonize $\alpha 1$ -receptor adrenal receptors^[6], regulating prostate smooth muscle tone and urethral pressure, thus reducing urinary resistance. It can also decrease the activity of 5 α -reductase in the prostate interstitial cells^[7], lowering dihydrotestosterone levels and shrinking prostate volume. Additionally, Huang'e capsule has been reported to improve microcirculation^[8] and exhibit anti-inflammatory effects^[9], providing a strong theoretical basis for its use in treating type III prostatitis.

Tamsulosin sustained-release capsules are a selective $\alpha 1$ -adrenergic receptor blocker that relaxes prostate smooth muscle to alleviate urinary symptoms, and they are commonly used in patients with prostatitis and urinary disorders. The "Jun-Chen-Zuo-Shi" method, originating from the *Shennong Bencao Jing*, outlines the roles of the ingredients in the formulation: the Jun (emperor) drug is the primary tonic; the Chen (minister) drug supports the

main tonic; and the Zuo-Shi (assistant) drug treats the disease. In Huang'e capsule, the Jun drugs are astragalus and peach kernel. Modern pharmacology shows that astragalus contains polysaccharides, saponins, flavonoids, folic acid, and riboflavin^[10], with properties such as antibacterial, anti-inflammatory, immune regulation, antioxidant, and diuretic effects^[10-12]. Peach kernel is traditionally used in Chinese medicine to promote blood circulation and remove blood stasis^[13]. This study selected 74 patients with type III prostatitis, and the results demonstrated significant differences in urinary pain or discomfort, urinary symptoms, quality of life scores, total NIH-CPSI scores, and EPS-WBC between the treatment group and the control group. These findings confirm the clinical efficacy of Huang'e capsule in treating type III prostatitis. Previous studies by Yang *et al.*^[14], Geng *et al.*^[15], and others have also reported similar outcomes.

Although Huang'e capsule has theoretical support and research evidence for improving urinary symptoms and quality of life in type III prostatitis patients, there have been no clinical reports on its effect on erectile dysfunction in these patients. During the study, we also assessed patients with lower urinary tract symptoms and concurrent erectile dysfunction, and found significant improvement in urinary symptoms, but minimal improvement in erectile dysfunction. Factors such as the patient's condition, emotions, lifestyle, and sexual psychology can affect erectile dysfunction^[16] and may have interfered with the research data. The adverse reactions were monitored, with one case of nausea reported in the treatment group, but no major adverse effects were observed.

5. Conclusion

In conclusion, the combination of tamsulosin sustained-release capsules and Huang'e capsule is effective and safe for treating type III prostatitis. However, the study's limitation lies in the small sample size. Future research should expand the sample size and include multi-center collaboration to obtain more reliable clinical data.

Disclosure statement

The authors declare no conflict of interest.

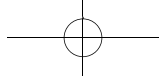
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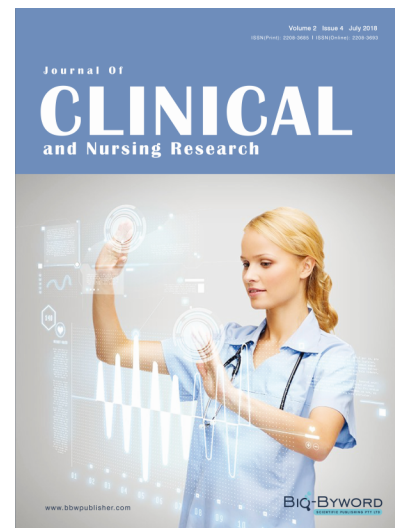
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