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Effect of Jianpi Wenshen Granules on the Nutritional Control Status Score in Elderly Patients Undergoing Maintenance Hemodialysis

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Abstract: *Objective:* To explore the effect of Jianpi Wenshen Granules on the Controlling Nutritional Status (CONUT) score in elderly patients undergoing maintenance hemodialysis. *Methods:* Seventy elderly outpatients undergoing maintenance hemodialysis from January 2023 to January 2024 at the Blood Purification Centers of Taizhou Traditional Chinese Medicine Hospital and Taizhou Second People's Hospital were selected as the study subjects. The patients were randomly divided into two groups: the study group and the control group, with 35 patients in each group. Both groups received maintenance hemodialysis, while the control group received only conventional Western medicine treatment, and the study group was additionally treated with Jianpi Wenshen Granules. The changes in biochemical and inflammatory markers before and after treatment were compared between the two groups. The nutritional status of the patients was assessed using the Controlling Nutritional Status (CONUT) score, and detailed statistics were gathered on anemia and albumin levels in both groups. *Results:* After treatment, the CONUT score in the study group significantly decreased compared to the control group, showing a significant correlation ($P < 0.05$). Albumin and hemoglobin levels significantly increased, with a notable difference ($P < 0.05$). There were no significant differences in alanine aminotransferase and aspartate aminotransferase levels between the two groups before and after treatment ($P > 0.05$). *Conclusion:* In elderly patients undergoing maintenance hemodialysis, Jianpi Wenshen Granules improve the CONUT score and enhance nutritional status, demonstrating potential for clinical application and promotion.

Keywords: Jianpi Wenshen Granules; Maintenance hemodialysis; Controlling Nutritional Status score

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1. Introduction

Cardiovascular diseases and infections are the most common causes of death in elderly hemodialysis patients, while factors such as nutritional status and age have become important risk factors affecting their survival rates [1]. Maintenance hemodialysis is a common renal replacement therapy that can effectively prolong the life of patients with chronic kidney disease and improve their quality of life. Therefore, improving

dialysis techniques can help extend patient survival. As a large number of dialysis patients gradually enter old age, research has confirmed that age is an independent risk factor for mortality in dialysis patients. In addition, anemia, malnutrition, calcium-phosphorus metabolism disorders, and microinflammatory states are also associated with the mortality of dialysis patients [2]. The spleen and kidneys are important metabolic organs, crucial for elderly patients undergoing maintenance hemodialysis. However, long-term dialysis may damage the kidneys and spleen, affecting nutrient absorption and metabolic capabilities. Weakness of the spleen and kidneys is detrimental to elderly maintenance hemodialysis patient recovery and nutritional improvement. Based on this, and combined with years of clinical experience, this study suggests that improving the nutritional status of elderly maintenance hemodialysis patients must start with the spleen and kidneys, adopting the principle of "Jianpi Wenshen" (strengthening the spleen and warming the kidneys), applying a syndrome differentiation treatment approach to improve malnutrition, promote recovery, and thus improve the quality of life and survival status of patients [3].

2. Materials and methods

2.1. General information

From January 2023 to January 2024, 70 elderly outpatients undergoing maintenance hemodialysis at the Blood Purification Centers of Taizhou Traditional Chinese Medicine Hospital and Taizhou Second People's Hospital were selected as study subjects.

Inclusion criteria: (1) Age 60–75 years; (2) Diagnosed with end-stage renal disease (ESRD); (3) Received maintenance hemodialysis (MHD) treatment for ≥ 6 months; (4) Clear consciousness and ability to communicate verbally; (5) Able to complete relevant scales and tests independently or with the help of family members; (6) Diagnosed with spleen and kidney yang deficiency syndrome: aversion to cold, cold limbs, fatigue, shortness of breath, lack of speech, poor appetite, weak waist and knees, cold pain in the waist, abdominal distension, loose stools, frequent nocturia. Pale tongue with teeth marks, weak pulse; (7) Voluntarily participated in the study and signed written informed consent.

Exclusion criteria: (1) Clinical inflammatory reactions such as pneumonia, fever, diarrhea, trauma, surgery, or malignant tumors within the past month; (2) Severe heart, lung, brain, or liver failure; (3) Received immunosuppressive or immunoenhancing therapy within the past month; (4) Incomplete data.

2.2. Methods

2.2.1. Control group (35 cases)

This group received purely Western medicine treatments, including a low-salt, low-phosphorus diet rich in high-quality protein, while correcting electrolyte and acid-base imbalances, anemia, and other complications. Basic treatments included blood pressure and blood sugar control.

2.2.2. Study group (35 cases)

In addition to the treatment received by the control group, the study group was also given Jianpi Wenshen Granules. The granules included Astragalus (30 g), Codonopsis (15 g), Atractylodes (15 g), Poria (12 g), Epimedium (12 g), Eucommia (15 g), Cornus (10 g), Cuscuta (10 g), Achyranthes (10 g), Curculigo (10 g), Jujube (12 g), and Ginger (10 g). These granules were prepared by the Chinese pharmacy at Taizhou Traditional Chinese Medicine Hospital, with the granule preparation provided by CR Sanjiu Chinese Herbal Formula Granules. The dosage was one dose per day, mixed with 150 mL of water, taken in two doses (75 mL each in the morning and evening), with a treatment course of 12 weeks.

2.3. Observation indicators

The therapeutic effects on the two groups were compared. The CONUT (Controlling Nutritional Status) score was used to assess the nutritional status of both groups, and the following data were collected.

2.3.1. CONUT score (before enrollment and 12 weeks after treatment)

(1) Lymphocyte count: Reflects immune defense impairment due to malnutrition. Score range: ≥ 1,600 cells/mm³ = 0 points, 1,200–1,599 cells/mm³ = 1 point, 800–1,199 cells/mm³ = 2 points, < 800 cells/mm³ = 3 points;

(2) Total cholesterol (TC) level: Reflects energy reserve status. Score range: ≥ 4.65 mmol/L = 0 points, 3.60–4.64 mmol/L = 1 point, 2.6–3.6 mmol/L = 2 points, < 2.6 mmol/L = 3 points;

(3) Albumin level: Reflects protein storage and utilization. Score range: ≥ 3.50 g/dL = 0 points, 3.00–3.49 g/dL = 2 points, 2.50–2.99 g/dL = 4 points, < 2.50 g/dL = 6 points. The total score is out of 12, and the nutritional status is categorized as 0–1 points = normal; 2–4 points = mild malnutrition; 5–8 points = moderate malnutrition; 9–12 points = severe malnutrition. Lymphocyte count, albumin, and total cholesterol were tested using a biochemical analyzer.

2.3.2. Inflammatory factors

C-reactive protein (CRP) is a non-specific inflammatory marker. CRP was tested using immunoassays (e.g., immunoturbidimetry or ELISA).

2.3.3. Anemia indicators

Hemoglobin is an important indicator of the improvement of renal anemia. When kidney function is impaired, the production of erythropoietin decreases, leading to a reduction in red blood cells and hemoglobin levels, resulting in anemia.

2.3.4. Traditional Chinese medicine syndrome score evaluation

Traditional Chinese Medicine (TCM) syndrome score was evaluated based on the severity of symptoms and categorized as severe, moderate, mild, or none, with scores of 3, 2, 1, and 0, respectively. Symptoms included shortness of breath, weak waist and knees, fatigue, and poor appetite. The score range was 0 to 12, with higher scores indicating more severe TCM syndrome symptoms.

2.3.5. Safety indicators

Safety indicators were assessed by monitoring liver function, including alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels. Elevated levels indicate increased side effects of the medication on elderly maintenance dialysis patients.

2.4. Statistical analysis

SPSS 26.0 was used for data processing. Measurement data were expressed as mean ± standard deviation (SD) and analyzed using *t*-tests. Count data were expressed as *n* and percentages, and the chi-squared (χ^2) test was used. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Comparison of general data

As shown in **Table 1**, there were no statistically significant differences in gender and age between the two groups ($P > 0.05$).

Table 1. Comparison of demographic characteristics between the two groups

Groups	Gender (*n*)		Age (mean ± SD, years)
	Male	Female	
Control group (*n* = 35)	22	13	68.94 ± 4.59
Study group (*n* = 35)	28	7	67.23 ± 5.48
χ^2 / *t*-value	2.520		1.415
P-value	0.114		0.162

3.2. Comparison of pre- and post-treatment CONUT scores and TCM syndrome scores between the two groups

After treatment, compared to the control group, the CONUT score of the study group decreased significantly, and the difference was statistically significant ($P = 0.048$). Additionally, the TCM syndrome score in the study group decreased significantly, with a highly significant difference ($P < 0.001$). See **Table 2**.

Table 2. Comparison of pre- and post-treatment CONUT scores and TCM syndrome scores between the two groups (mean ± SD, points)

Groups	Before treatment		After treatment	
	CONUT scores	TCM syndrome scores	CONUT scores	TCM syndrome scores
Control group (*n* = 35)	4.71 ± 1.18	6.09 ± 1.28	4.15 ± 1.08*	4.91 ± 1.04*
Study group (*n* = 35)	4.77 ± 1.23	6.14 ± 1.35	3.66 ± 0.95*	3.54 ± 0.87*
t-value	0.208	0.159	2.015	5.978
P-value	0.836	0.874	0.048	< 0.001

Note: * indicates a comparison within the same group before and after treatment, $P < 0.05$

3.3. Comparison of pre- and post-treatment inflammatory factors and hemoglobin levels between the two groups

After treatment, compared to the control group, the CRP level in the study group decreased significantly, with a statistically significant difference ($P = 0.004$), and hemoglobin levels in the study group increased significantly, with a highly significant difference ($P < 0.001$). See **Table 3**.

Table 3. Comparison of pre- and post-treatment inflammatory factors and hemoglobin levels between the two groups (mean ± SD)

Groups	C-reactive protein (mg/L)		Hemoglobin (g/L)	
	Before treatment	After treatment	Before treatment	After treatment
Control group (*n* = 35)	11.62 ± 1.18	4.74 ± 1.21*	114.14 ± 15.76	118.48 ± 10.37
Study group (*n* = 35)	11.93 ± 1.16	1.90 ± 0.32*	113.77 ± 14.85	128.18 ± 10.29
t-value	1.792	2.984	0.101	3.928
P-value	0.272	0.004	0.920	< 0.001

Note: * indicates a comparison within the same group before and after treatment, $P < 0.05$

3.4. Comparison of pre- and post-treatment serum albumin levels between the two groups

Table 4 shows that after treatment, compared to the control group, the serum albumin level in the study group increased significantly, with a statistically significant difference ($P = 0.045$).

Table 4. Comparison of pre- and post-treatment serum albumin levels between the two groups (mean ± SD, g/L)

Groups	Albumin (g/L)	
	Before treatment	After treatment
Control group ($n = 35$)	35.85 ± 3.47	37.95 ± 3.83
Study group ($n = 35$)	36.27 ± 2.9	40.02 ± 4.60
t-value	0.543	2.046
P-value	0.589	0.045

3.5. Comparison of safety indicators between the two groups

Table 5 shows that there were no significant differences in ALT and AST levels between the control group and the study group before and after treatment ($P > 0.05$), indicating the safety of the medication.

Table 5. Comparison of safety indicators between the two groups (mean ± SD, U/L)

Groups	ALT		AST	
	Before treatment	After treatment	Before treatment	After treatment
Control group ($n = 35$)	11.83 ± 4.04	10.23 ± 2.51	13.82 ± 4.01	16.13 ± 4.04
Study group ($n = 35$)	12.95 ± 4.21	10.12 ± 2.35	12.94 ± 4.16	14.47 ± 4.28
t-value	1.136	0.189	0.901	1.669
P-value	0.260	0.850	0.371	0.100

4. Discussion

According to TCM theory, the kidneys are considered the foundation of congenital essence in the human body, responsible for storing vital essence and playing a crucial role in growth, development, and reproductive functions. Prolonged kidney disease is primarily due to the dysfunction of internal organs, with spleen and kidney deficiency being the main causes. External factors, such as pathogenic invasion and excessive fatigue, lead to weakened vital energy and blood stasis, causing various symptoms [4].

Malnutrition in dialysis patients is a common and serious problem, directly affecting their quality of life and survival rates. Insufficient dialysis is a major cause of malnutrition in MHD patients, leading to the accumulation of acidosis, toxins, and inflammatory mediators in the body. This results in gastrointestinal dysfunction, reduced intake and absorption of protein and calories, and decreased plasma albumin, further contributing to malnutrition, weakened immunity, and increased risk of infection. Malnutrition, in turn, affects the effectiveness of hemodialysis, creating a vicious cycle that reduces quality of life and increases the risk of death [5]. Malnutrition is particularly pronounced in elderly MHD patients, resulting in higher infection and mortality rates. Adequate dialysis can remove toxins, improve intestinal and electrolyte balance, relieve indigestion, regulate acid-base balance, reduce protein catabolism, improve nutritional status and quality of life, and decrease mortality [6,7].

Current methods for assessing malnutrition include the Modified Quantitative Subjective Global Assessment (MQSGA), the Malnutrition Inflammation Score (MIS), the Subjective Global Assessment (SGA), and the Mini Nutritional Assessment Short Form (MNA-SF). However, these methods are largely influenced by the patient's subjective factors [8]. The CONUT score is an objective parameter calculated based on laboratory data and assesses nutritional status by considering indicators such as lymphocyte count, albumin level, and total cholesterol level [9].

This study showed that the CONUT score and CRP levels in the study group significantly decreased, while albumin and hemoglobin levels significantly increased, indicating improvements in inflammation and nutrition. Moreover, the TCM syndrome scores decreased, highlighting the advantages of TCM intervention. In the formula used, Astragalus combined with Codonopsis invigorates qi and strengthens the spleen; Poria combined with Atractylodes invigorates the spleen and dispels dampness; Epimedium, Eucommia, and Cuscuta nourish the kidneys and strengthen yang; Achyranthes and Cornus nourish the liver and kidneys. Additionally, Achyranthes also tonifies the kidneys, strengthens yang, promotes blood circulation, and removes blood stasis, while Curculigo disperses cold and dampness. The entire formula strengthens qi, tonifies the spleen, warms the kidneys, and supports yang.

Modern pharmacology suggests that Astragalus regulates immunity, improves anemia, dilates blood vessels, and lowers blood pressure [10]; Codonopsis regulates the gastrointestinal system, suppresses inflammation, reduces lipid oxidation, and protects the kidneys [11]; Cornus has anti-inflammatory effects and protects against ischemia-reperfusion injury; Poria acts as a diuretic [12]; Achyranthes has analgesic and anti-inflammatory properties; Atractylodes promotes gastrointestinal secretion and absorption; and Epimedium enhances immunity [13].

The microinflammatory state is triggered by the stimulation of chemical substances, endotoxins, and immune compounds in the body, which activate monocytes and macrophages to release pro-inflammatory factors. This leads to chronic, sustained inflammation, increasing the risk of death [14]. The microinflammatory state in maintenance hemodialysis patients is closely related to malnutrition, and the two conditions influence each other. Malnutrition reduces immunity and promotes the occurrence of microinflammation, while microinflammation disrupts muscle protein metabolism, exacerbating malnutrition [15].

In summary, the CONUT score can be used as a tool to assess nutritional status. Jianpi Wenshen Granules help improve the nutritional control status score, nutritional status, and microinflammatory state in maintenance hemodialysis patients and are worth promoting in clinical practice.

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Disclosure statement

The authors declare no conflict of interest.

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