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Clinical Evaluation of the Efficacy of Calcitriol Combined with Low-Calcium Dialysate in the Treatment of Secondary Hyperparathyroidism

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Abstract: *Objective*: To investigate the clinical effect of combined application of calcitriol and low-calcium dialysate in the treatment of secondary hyperparathyroidism (SHPT). *Methods*: Eighty-nine patients with SHPT who visited the hospital from February 2023 to February 2025 were included in the study. They were divided into an observation group (n=45) and a control group (n=44) using a random number table method. The observation group received calcitriol combined with low-calcium dialysate treatment, while the control group received calcitriol combined with conventional dialysate treatment. The differences in intact parathyroid hormone (iPTH), calcium and phosphorus metabolism indicators, renal function indicators, and adverse reaction rates were compared and evaluated before and after treatment between the two groups. *Results*: Compared with before treatment, the levels of iPTH, serum phosphorus, and calcium-phosphorus product were significantly reduced in both groups after treatment, and the observation group had lower levels than the control group ($P < 0.05$). Additionally, the blood calcium levels in both groups increased compared to before treatment, and the observation group had higher levels than the control group ($P < 0.05$). After intervention, there was no statistically significant difference in renal function indicators between the two groups ($P > 0.05$). The incidence of adverse reactions in the observation group was lower than that in the control group ($P < 0.05$). *Conclusion*: The combination of calcitriol and low-calcium dialysate for the treatment of SHPT can effectively reduce the levels of iPTH, serum phosphorus, and calcium-phosphorus product, increase blood calcium levels, and has a low incidence of adverse reactions. It has no significant effect on renal function and is a safe and effective treatment method.

Keywords: Calcitriol; Hemodialysis; Low-calcium dialysate; Secondary hyperparathyroidism; Clinical efficacy

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1. Introduction

Secondary hyperparathyroidism (SHPT) is a common complication among patients with chronic kidney disease, particularly prevalent in those with end-stage renal disease [1]. According to surveys, SHPT caused by chronic

kidney disease is most widespread in China among global patients, accounting for 85.14% [2]. The occurrence of SHPT is primarily related to calcium and phosphorus metabolism disorders caused by decreased renal function, deficiency of active vitamin D metabolites, and abnormal secretion of parathyroid hormone. Long-term uncontrolled SHPT can lead to a series of severe complications such as skeletal lesions, cardiovascular diseases, and soft tissue calcification, significantly affecting patients' quality of life. Currently, treatment options for SHPT include drugs, surgery, and interventional therapies. Among these, drug therapy is the fundamental and preferred approach, and active vitamin D and its analogs play a critical role in drug therapy.

As a typical representative of active vitamins, calcitriol is widely used in clinical practice. This drug can directly act on the vitamin D receptor of parathyroid cells, inhibiting the synthesis and secretion of PTH while promoting intestinal calcium absorption and regulating calcium and phosphorus metabolism [3]. However, when calcitriol is used alone for SHPT treatment, some patients may experience adverse reactions such as hypercalcemia and hyperphosphatemia, which can restrict its clinical efficacy. In recent years, the application of low-calcium dialysate has gradually gained attention. Reducing the calcium concentration in the dialysate and decreasing calcium load can lower the risk of hypercalcemia. The low blood calcium state can stimulate the calcium-sensing receptor on the surface of parathyroid cells, inhibiting PTH secretion and achieving the goal of treating SHPT [4]. This study aims to explore the clinical efficacy of calcitriol combined with low-calcium dialysate in the treatment of SHPT. The relevant results are described below.

2. Materials and methods

2.1. General information

Eighty-nine patients with SHPT who visited the hospital from February 2023 to February 2025 are included in the study. They are divided into an observation group (n=45) and a control group (n=44) using a random number table method. General information for both groups is shown in **Table 1**.

Table 1. Comparison of general information [($\bar{x}$±s), n(%)]

Item		Observation group (n=45)	Control group (n=44)	t/χ^2	P-value
Age (years)		57.27 ± 6.44	57.56 ± 6.19	0.217	0.829
Gender	Male	24	26	0.300	0.584
	Female	21	18		
Dialysis duration (months)		30.15 ± 5.87	30.54 ± 5.43	0.325	0.746
Disease type	Primary chronic glomerulonephritis	10	11	0.518	0.915
	Hypertensive nephropathy	9	10		
	Diabetic nephropathy	14	14		
	Polycystic kidney disease	12	9		

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

(1) Diagnosis of SHPT

(2) Receiving maintenance hemodialysis treatment for at least 3 months

(3) Aged between 18 and 75 years old
(4) Signed informed consent

2.2.2. Exclusion criteria

(1) Used drugs affecting calcium and phosphorus metabolism or parathyroid hormone secretion in the past month.
(2) Long-term use of glucocorticoids, immunosuppressants, etc.
(3) Presence of primary hyperparathyroidism
(4) History of parathyroid surgery or planned parathyroid surgery in the past 3 months

2.3. Methods

The control group received calcitriol combined with conventional dialysate treatment. Patients in the control group took calcitriol orally once a day (National Medicine Approval Number: H20030491, Specification: 0.25μg × 10 capsules), with a dose of 0.25μg each time. During the entire treatment process, blood calcium levels need to be regularly monitored. If the calcium ion level remains below 2.75mmol/L, the dose is adjusted by 0.5μg each time. Based on medication, patients underwent conventional dialysis using a dialysate with a calcium ion concentration of 1.75mmol/L for 4 hours, 2–3 times a week. The course of treatment for the control group was 6 months.

The observation group received calcitriol combined with low-calcium dialysate treatment. The medication for calcitriol in the observation group is the same as that in the control group. Based on this medication, the observation group required dialysis using a dialysate with a calcium ion concentration of 1.25mmol/L for 2–3 times a week, each lasting 4 hours. The entire course of treatment lasted for 6 months.

2.4. Observation indicators

Peripheral venous blood is collected from patients in both groups before and after treatment. After centrifugation at 3500r/min, the supernatant is extracted, and the level of intact parathyroid hormone (iPTH) is detected using radioimmunoassay. Calcium and phosphorus metabolism indicators (blood calcium, blood phosphorus) and renal function indicators [blood creatinine (Scr), blood urea nitrogen (BUN)] are measured using an automatic biochemical analyzer, and the calcium-phosphorus product is calculated. The adverse reactions that occurred during the treatment of the two groups are recorded.

2.5. Statistical analysis

Data analysis is performed using SPSS 24.0 software. Measurement data are expressed as ($\bar{X} \pm s$), and count data are expressed as n(%). The t-test and χ^2 test are used for comparison between groups, and the significance level was set at $P < 0.05$.

3. Results

3.1. iPTH and Calcium and Phosphorus metabolism indicators

The results before and after treatment are compared, the levels of iPTH, blood phosphorus, and calcium-phosphorus product were significantly reduced in both groups after treatment, and the observation group was lower than the control group ($P < 0.05$). In addition, the blood calcium levels in both groups increased compared to before treatment, and the observation group was higher than the control group ($P < 0.05$), as shown in **Table 2**.

Table 2. Comparison of iPTH and Calcium and Phosphorus metabolism indicators before and after treatment ($\bar{x}$ ±s)

Group	*n*	iPTH(ng/L)		Calcium (mg/dL)	
		Pre- intervention	Post- intervention	Pre- intervention	Post- intervention
Observation group	45	447.56 ± 43.49	231.56 ± 46.57*	8.75 ± 1.18*	8.86 ± 0.64*
Control group	44	451.39 ± 40.87	259.88 ± 47.12*	8.94 ± 1.21*	8.44 ± 0.89*
t		0.428	2.852	0.750	2.551
P		0.670	0.005	0.455	0.013
Group	***n***	**Phosphorus (mg/dL)**		**Ca×P Product (mg²/dL²)**	
		Pre- intervention	**Post- intervention**	**Pre- intervention**	**Post- intervention**
Observation group	45	7.62 ± 1.55	6.25 ± 1.47*	66.68 ± 1.26	55.38 ± 1.39*
Control group	44	7.51 ± 1.49	6.94 ± 1.52*	67.14 ± 1.33	58.57 ± 1.46*
t		0.341	2.177	1.675	10.559
P		0.734	0.032	0.098	< 0.001

Note: Compared with before intervention, *$P < 0.05$

3.2. Renal function indicators

After intervention, there was no statistically significant difference in renal function indicators between the two groups ($P > 0.05$), as shown in **Table 3**.

Table 3. Comparison of renal function indicators ($\bar{x}$ ±s)

Group	*n*	BUN(mmol/L)		Scr(μmol/L)	
		Pre-intervention	1 Month	2 Months	6 Months
Observation group	45	26.71 ± 2.81	27.13 ± 2.28*	839.54 ± 13.54*	829.25 ± 12.45*
Control group	44	26.89 ± 2.94	27.01 ± 2.31*	838.78 ± 14.85*	830.54 ± 14.21*
t		0.295	0.267	0.252	0.456
P		0.769	0.806	0.801	0.650

3.3. Incidence of adverse reactions

The incidence of adverse reactions in the observation group was lower than that in the control group ($P < 0.05$), as shown in **Table 4**.

Table 4. Comparison of the incidence of adverse reactions [n(%)]

Group	*n*	Vomiting	Headache	Muscle pain	Total adverse events
Observation group	45	1 (2.22)	1 (2.22)	1 (2.22)	3 (6.67)
Control group	44	3 (6.82)	3 (6.82)	4 (9.09)	10 (22.73)
χ^2					4.601
P-value					0.032

4. Discussion

Hemodialysis, as a critical life-sustaining treatment for patients with chronic kidney disease, can prolong survival. However, as dialysis time accumulates, various complications gradually emerge, among which secondary hyperparathyroidism is particularly prevalent. Patients often experience symptoms such as skin itching and joint pain, which not only severely affect the efficacy of dialysis treatment but may also pose life-threatening risks, necessitating effective clinical intervention measures [6]. Calcitriol, as the active metabolite of vitamin D metabolized by the liver and kidneys, can effectively inhibit parathyroid hormone secretion and correct disturbances in calcium-phosphorus metabolism and parathyroid hormone secretion [7]. Currently, calcitriol pulse therapy is widely used, but high-dose administration can easily induce hypercalcemia and increase the risk of cardiovascular system calcification. Multiple studies have confirmedthat the combination of low-calcium dialysis and active vitamin D for the treatment of secondary hyperparathyroidism can achieve good efficacy while reducing adverse reactions, making it a clinically recommended treatment option [8, 9] .

The results of this study showed that compared to before treatment, both the conventional group and the observation group had significant reductions in iPTH levels, blood phosphorus levels, and calcium-phosphorus product after treatment, with the observation group showing a more pronounced decrease ($P < 0.05$). Blood calcium levels in both groups increased compared to before treatment, and the observation group had higher levels than the conventional group ($P < 0.05$). These findings suggest that the combination of calcitriol and low-calcium dialysate has significant advantages in reducing iPTH levels, regulating blood calcium and phosphorus metabolism, and controlling the calcium-phosphorus product in patients with SHPT.

These results are consistent with the findings of Xu *et al.* [10]. Analyzing its mechanism of action: Active vitamin D can promote intestinal calcium absorption, inhibit iPTH secretion, and increase blood calcium concentration by increasing the number of parathyroid receptors. However, long-term use can easily lead to hypercalcemia and bone lesions. In the combined therapy used in this study, low-calcium dialysate lowers blood calcium concentration. However, when calcitriol is used alone in the treatment of SHPT, some patients may experience side effects such as hypercalcemia and hyperphosphatemia, which can limit its clinical effectiveness. Low-calcium dialysate, as another treatment modality for SHPT, primarily works by reducing the concentration of calcium ions in the dialysate, creating a calcium ion concentration gradient between the blood and the dialysate. This promotes the transfer of calcium ions from the blood to the dialysate, achieving a negative calcium balance in the body and effectively avoiding the risk of excessively high blood calcium caused by monotherapy.

After the intervention, there was no statistically significant difference in renal function indicators between the two groups ($P > 0.05$). This indicates that the combination of calcitriol and low-calcium dialysate therapy has no significant adverse effects on patients' renal function in the short term. Patients undergoing maintenance hemodialysis already have severely impaired renal function, and the primary goal of treatment is to control complications and improve quality of life, rather than restore renal function. The results of this study show that this combined treatment regimen effectively treats SHPT without causing further damage to residual renal function, demonstrating a certain level of safety.

Furthermore, this study revealed that the incidence of adverse reactions in the observation group was lower than that in the conventional group ($P < 0.05$). This finding suggests that the combination of low-calcium dialysate and calcitriol can effectively reduce adverse reactions in hemodialysis patients with SHPT. The reason for this is that this treatment strategy not only significantly optimizes the balance of calcium and phosphorus metabolism in patients but also avoids a series of discomfort symptoms caused by hypercalcemia, such as decreased appetite and

headache, by controlling blood calcium concentration.

5. Conclusion

In summary, the combination of calcitriol and low-calcium dialysate for the treatment of SHPT can effectively reduce iPTH, blood phosphorus, and calcium-phosphorus product levels, increase blood calcium levels, and has a lower incidence of adverse reactions without significantly affecting renal function. It is a safe and effective treatment method.

Disclosure statement

The authors declare no conflict of interest.

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