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Efficacy of Ferric Citrate as Phosphate Binder Among End-Stage Renal Disease Patients on Maintenance Hemodialysis: A Randomized Controlled Trial

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Abstract

Background: End-stage renal disease (ESRD) patients primarily use phosphate binders to manage hyperphosphatemia. Recently, ferric citrate has shown promise as a safer and more acceptable alternative.

Objective: The study aimed to evaluate the efficacy of ferric citrate in patients with ESRD undergoing maintenance hemodialysis in Bangladesh.

Methods: This open-label randomized controlled trial (RCT) was conducted in the Department of Nephrology at Bangabandhu Sheikh Mujib Medical University (BSMMU) and Dhaka Medical College Hospital (DMCH) from August 2022 to March 2023. A total of 45 patients on maintenance hemodialysis with CKD stage 5D were randomized into three groups: Group A (ferric citrate), Group B (sevelamer carbonate), and Group C (calcium acetate) and were treated for three months. Intact parathyroid hormone (iPTH), inorganic phosphate, and corrected calcium levels were measured at baseline and after three months.

Results: Baseline demographics and comorbidities were similar across groups. After three months, all groups showed significant reductions in serum phosphate: Group A (ferric citrate) [median (range): 4.5 (4.0-7.0) to 4.2 (3.2-6.9) (mg/dl)], Group B (sevelamer carbonate) [median (range): 5.9 (4.37-7.80) to 5.4 (3.2-7.00) (mg/dl)], and Group C (calcium acetate) [median (range): 5.6 (4.2-7.0) to 5.0 (3.8-6.8) (mg/dl)]. iPTH levels also decreased significantly in all groups. Corrected calcium increased significantly only in Group C [median (range): 8.8 (8.2-9.9) to 10.0 (9.4-10.9) (mg/dl)], with no significant changes in Groups A and B.

Conclusion: Ferric citrate is an effective and safe option to use as a first-line treatment for hyperphosphatemia in ESRD patients undergoing maintenance dialysis.

Keywords: End-Stage Renal Disease (ESRD); Maintenance Hemodialysis; Phosphate Binders; Hyperphosphatemia; Ferric Citrate

Introduction

Chronic kidney disease (CKD) ranks among the most widespread noncommunicable diseases globally [1]. In its advanced phases, CKD progressively culminates in end-stage renal disease (ESRD) [2]. Patients with ESRD may encounter hyperphosphatemia as a consequence of the condition [3]. A healthy adult's plasma inorganic phosphate level is usually between 2.5 and 4.5 mg/dl. About 60% of this is absorbed through an active uptake

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mechanism controlled by sodium-phosphate co-transporters, and the other 40% comes in through diffusional and non-saturable inflow mainly happening in the jejunum and ileum [4–6].

Phosphate binders function by binding dietary phosphate to form insoluble complexes, which are eliminated by the gastrointestinal tract, potentially decreasing phosphate absorption by up to 40% [7,8] The glomerulus readily filters phosphate under typical physiological conditions, reabsorbing the majority in the proximal tubules [9]. Hyperphosphatemia happens when the kidneys aren't working properly, which upsets the balance of phosphates that is controlled by parathyroid hormone, active vitamin D, and fibroblast growth factor 23 (FGF-23) [10]. Since hyperphosphatemia is a common effect of ESRD, it is important to keep blood phosphate levels within certain limits to improve patients' quality of life and lower death and illness rates during maintenance hemodialysis [11,12].

A lot of people who are getting renal replacement therapy have high phosphate levels and need to be treated with phosphate binders. The limited effectiveness of existing therapeutic agents, the adverse effects of specific medications, financial limitations, inadequate treatment adherence, and, notably, a substantial pill burden complicate the therapeutic strategy [13]. Dialysis treatments, even when combined with limiting phosphate intake, often fail to treat hyperphosphatemia, so most patients need to take phosphate binders to keep their condition under control [14].

The primary phosphate binders utilized consist of calcium-based binders (calcium carbonate and calcium acetate), non-absorbable polymers (sevelamer carbonate), and heavy metal salts (lanthanum carbonate and aluminum hydroxide) [15,16]. Calcium-based phosphate binders and non-absorbable polymers are commonly utilized for patients with ESRD; however, increased dosages of calcium-based binders are frequently required to adequately manage phosphate levels, leading to an augmented total body calcium load, stimulating dynamic bone activity, and potentially increasing the risk of cardiovascular and soft tissue calcification [17,18].

Non-absorbable polymer binders, such as Sevelamer Carbonate, effectively reduce phosphate levels without inducing hypercalcemia; nonetheless, they are frequently linked to elevated prices, increased pill burden, and gastrointestinal adverse effects, including bloating and constipation [19]. These factors can influence adherence, particularly in resource-constrained environments.

Ferric citrate, due to its advantageous side effect profile and iron-replenishing capabilities, offers a pragmatic and patient-centric alternative. Research indicates that iron-based phosphate binders, like ferric citrate, may effectively regulate hyperphosphatemia in ESRD patients by significantly lowering serum inorganic phosphate levels [13,20], while also mitigating iron deficiency anemia, a common complication among CKD patients [21].

Given the socioeconomic challenges and limited healthcare resources in Bangladesh, ferric citrate could be a promising option for managing hyperphosphatemia in ESRD patients. However, studies regarding the use of ferric citrate among ESRD patients in Bangladesh are scarce. Conducting a study to determine the efficacy of ferric citrate as a phosphate binder will contribute to evidence-based clinical practices tailored to the unique needs and socioeconomic conditions of Bangladeshi patients and improve the standard of care for ESRD patients on maintenance hemodialysis. The current study, on the other hand, looked at how well ferric citrate worked as a phosphate binder in ESRD patients in Bangladesh who were on maintenance hemodialysis.

Materials and Methods

This open-label, randomized controlled trial (RCT) was conducted in the Department of Nephrology of Bangabandhu Sheikh Mujib Medical University (BSMMU) and Dhaka Medical College Hospital (DMCH), Dhaka, Bangladesh, between August 2022 and March 2023. The Institutional Review Board (IRB) of BSMMU provided formal ethical approval for the study (Ref: BSMMU/2022/7428).

Selection of the participants

As per selection criteria, adult (age ≥ 18 years) patients diagnosed with CKD Stage 5D, receiving twice-weekly maintenance hemodialysis, were enrolled in the study. The study excluded CKD patients with corrected calcium levels of less than 8.5 mg/dl or more than 10.5 mg/dl, and inorganic phosphate levels of less than 2.5 mg/dl or more than 10 mg/dl. The study also excluded patients with active malignancy, pregnant or lactating women, and known intolerance to ferric citrate, sevelamer carbonate, or calcium acetate. Following informing the aims and objectives of the study, informed written consent was taken from the participants. Data were collected through face-to-face interviews using a semi-structured data collection tool. The study population underwent detailed history taking, physical examination, and relevant investigations. Assessment of serum inorganic phosphate, corrected calcium, and serum intact parathyroid hormone (iPTH) was done at baseline, before initiating the interventions.

Intervention allocation

This study consisted of three groups: one intervention group (Group A) and two control groups (Group B and Group C). People in the intervention group (Group A) were given two tablets a day for three months that contained 210 mg of ferric citrate, an iron-based phosphate binder. As a control, Group B was given 800 mg of Sevelamer Carbonate three times a

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day and Group C was given 667 mg of Calcium Acetate three times a day for three months. Initially, 52 CKD-5D patients meeting the selection criteria were enrolled and divided into three groups following the simple random sampling. Following the lottery technique, 17 patients were included in Ferric citrate (Group A) and Calcium Acetate (Group C) separately, and 18 were enrolled in Group B. Following the baseline assessment, intervention was initiated. The patients were followed up in a 7-day interval to check the drug compliance. Patients were advised to contact immediately over the phone if any adverse drug reaction occurred. Any adverse events resulting from the medications were managed accordingly. All the patients were counseled regarding a phosphate-restricted diet and adherence to phosphate binder intake. The total number of dropouts from the study was 7 patients. 6 patients discontinued intervention due to various reasons (blood transfusion, hospital admission, death, and consent withdrawal). Lost to follow-up was 1 patient. Finally, a total of 45 patients (15 from each group) completed the study. Follow-up assessments of serum inorganic phosphate, corrected calcium, and iPTH were done after 3 months of interventions (Figure 1).

Statistical analysis

Statistical analysis was performed using the Windows®-based software program Statistical Packages for Social Sciences 25 (SPSS-25) (Chicago, IL, USA). After collection, all the data were checked and cleaned. Quantitative data were expressed as mean, standard deviation, median, and range, and qualitative data as frequency (percentage). The normality distribution of the data was assessed by the Shapiro-Wilk test. To determine statistical significance, one-way ANOVA, the chi-square test, and the Wilcoxon signed-rank test were considered according to applicability. The p-value of < 0.05 was considered statistically significant.

Results

The mean age of the patients of the intervention group (Group A) was 49.3 ± 13.5 years, and the mean age of the patients of Group B and Group C was 53.7 ± 12.3 and 54.3 ± 12.9 years, respectively. Patients of each group were male predominant. Patients of each group were demographically similar. Diabetes mellitus was more prevalent among control groups, 60% & 66.7% in Groups B and C, compared to 46.7% in the intervention group. Hypertension was also more prevalent among the control group, 93.3% for both groups B and C, compared to 86.7% in the intervention group. The proportion of comorbidities showed no statistically significant difference between the intervention and control groups (Table 1).

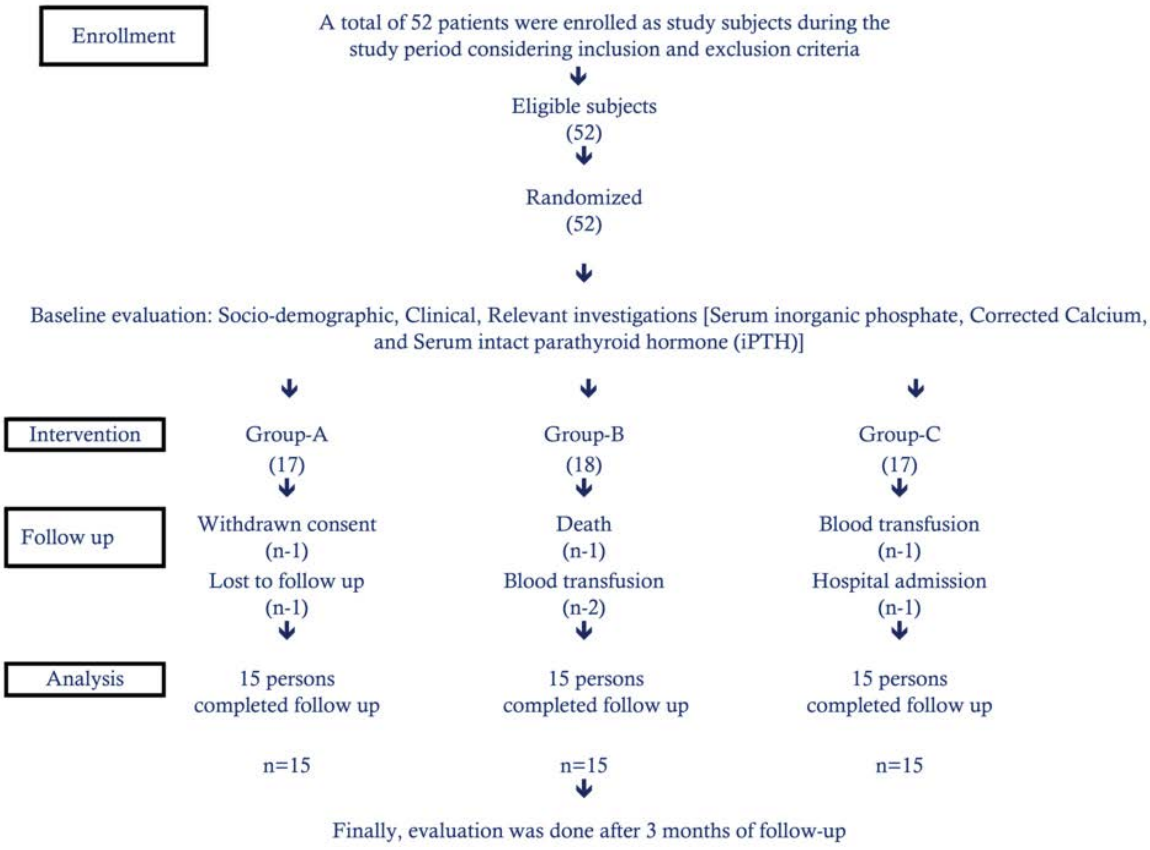

Figure 1: Study flow chart

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Remin Rafi SM, et al., Arch Nephrol Urol 2025
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Table 1: Distribution of the patients according to demographic profile, and comorbidities (n = 45)

Variable		Intervention	Active Control		p-value
		Group A	Group B	Group C	
		(Ferric Citrate) (n=15)	(Sevelamer Carbonate) (n=15)	(Calcium Acetate) (n=15)	
Age (years)		49.3 ± 13.5	53.7 ± 12.3	54.3 ± 12.9	0.517 [a]
Gender	Male	8 (53.3)	8 (53.3)	10 (66.7)	0.695 [b]
	Female	7 (46.7)	7 (46.7)	5 (33.3)	
Comorbidities	Diabetes mellitus	7 (46.7)	9 (60)	10 (66.7)	0.529 [b]
	Hypertension	13 (86.7)	14 (93.3)	14 (93.3)	0.760 [b]

[a] One-way ANOVA, and [b]Chi-square test were used

Data presented as frequency (%), mean ± SD

A significant reduction in the serum phosphate level from baseline was observed in Group A [median (range): 4.5 (4.0-7.0) to 4.2 (3.2-6.9) (mg/dl)], Group B [median (range): 5.9 (4.37-7.80) to 5.4 (3.2-7.00) (mg/dl)], and Group C [median (range): 5.6 (4.2-7.0) to 5.0 (3.8-6.8) (mg/dl)] following treatment with ferric citrate, sevelamer carbonate, and calcium citrate, respectively, for three months (Figure 2).

A significant reduction in the serum iPTH level was observed in Group A [median (range): 490.0 (190.0-717.0) to 333.6 ± 143.36 (ng/L)], Group B [median (range): 312.0 (24.60-700.0) to 230.0 (30.0-461.0) (ng/L)], and Group C [median (range): 400.0 (47.7-1900.0) to 299.0 (78.0-1200.0) (ng/L)] following treatment with ferric citrate, sevelamer carbonate, and calcium citrate, respectively, for three months.

A significant increase in the corrected calcium was observed in Group C [median (range): 8.8 (8.2-9.9) to 10.0 (9.4-10.9) (mg/dl)]; however, no such variation was observed in Group A and Group B (Table 2).

Discolored feces were the most prevalent side effects (73.3%) among the Group A patients treated with ferric citrate, followed by diarrhea (13.3%). Among the Group B patients treated with Sevelamer Carbonate, 20.0% were suffering from dyspepsia, followed by constipation (13.3%) and diarrhea (6.7%). Among the Group C patients treated with calcium acetate, 20.0% were suffering from nausea, followed by diarrhea (13.3%), dyspepsia (13.3%), and constipation (6.7%) (Table 3).

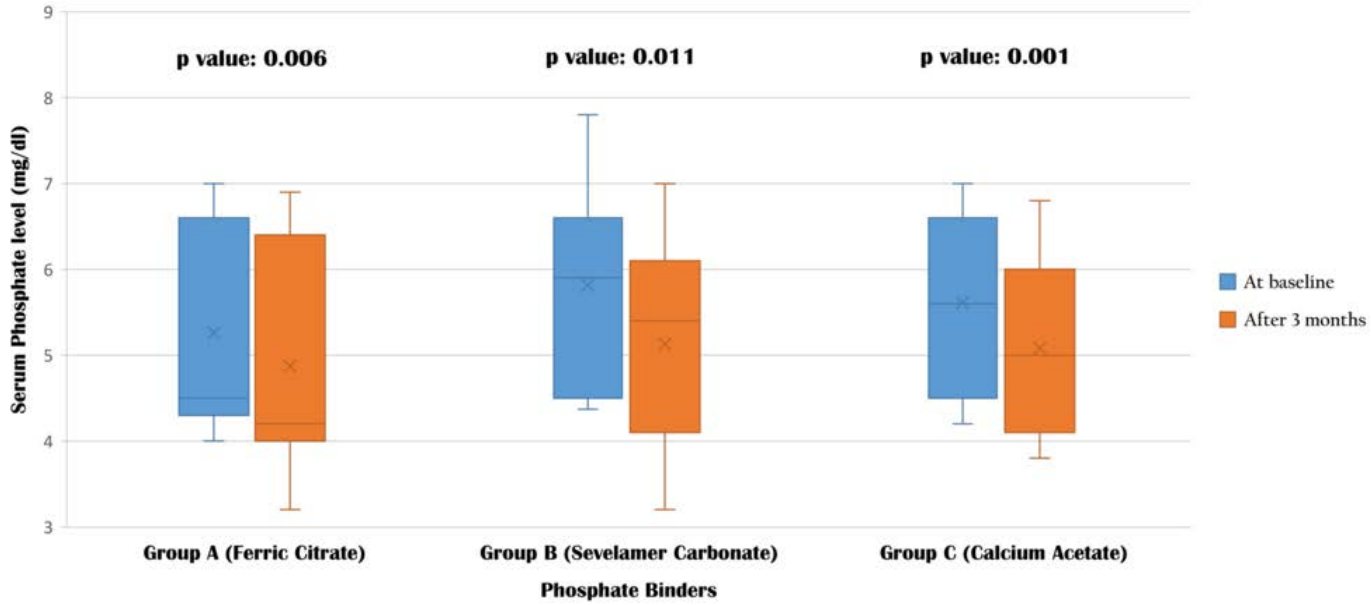

Figure 2: Changes in serum phosphate level with phosphate-binder treatment at baseline and after 3 months (n = 45)

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Table 2: Changes in biochemical parameters with phosphate-binder treatment from baseline to after 3 months (n = 45)

Phosphate Binders			Corrected Calcium (mg/dl)	Serum iPTH (ng/L)
Group A (Ferric Citrate)	At baseline	Mean ±SD	9.01 ± 0.63	452.07 ± 152.82
		Median (range)	8.9 (8.0-10.0)	490.0 (190.0-717.0)
	After 3 months	Mean ±SD	9.22 ± 0.60	333.6 ± 143.36
		Median (range)	9.2 (8.3-10.0)	350.0 (95.0-580.0)
	p-value		0.3	0.001
Group B (Sevelamer Carbonate)	At baseline	Mean ±SD	9.36 ±0.49	312.23 ± 217.34
		Median (range)	9.3 (8.30-10.0)	312.0 (24.60-700.0)
	After 3 months	Mean ±SD	9.4 ±0.55	220.27 ± 126.78
		Median (range)	9.4 (8.70-10.20)	230.0 (30.0-461.0)
	p-value		0.861	0.001
Group C (Calcium Acetate)	At baseline	Mean ±SD	8.92 ± 0.52	521.88 ±562.55
		Median (range)	8.8 (8.2-9.9)	400.0 (47.7-1900.0)
	After 3 months	Mean ±SD	9.93 ± 0.36	391.0 ± 300.53
		Median (range)	10.0 (9.4-10.9)	299.0 (78.0-1200.0)
	p-value		0.001	0.041

SD: Standard Deviation, iPTH: Intact parathyroid hormone

Wilcoxon signed-rank test was used

Data presented as mean ± SD, median (range)

Table 3: Side effects of the phosphate binders (n=45)

Side effect	Intervention	Active Control	
	Group A (Ferric Citrate) (n=15)	Group B (Sevelamer Carbonate) (n=15)	Group C (Calcium Acetate) (n=15)
Constipation	1 (6.7)	2 (13.3)	1 (6.7)
Diarrhea	2 (13.3)	1 (6.7)	2 (13.3)
Discolored feces	11 (73.3)	0	0
Dyspepsia	1 (6.7)	3 (20.0)	2 (13.3)
Nausea	1 (6.7)	1 (6.7)	3 (20.0)
Vomiting	1 (6.7)	0	1 (6.7)

Data presented as frequency (%)

Discussion

Hyperphosphatemia in ESRD markedly elevates morbidity and mortality risks. Addressing hyperphosphatemia is essential for preserving mineral equilibrium, averting cardiovascular disorders, and enhancing overall survival rates. The existing Kidney Disease Improving Global Outcomes (KDIGO) clinical guidelines recommend a tripartite strategy to manage serum phosphorus levels: dietary phosphate restriction, adequate maintenance dialysis, and the use of phosphate-lowering agents to impede intestinal phosphate absorption. About 80% of dietary phosphate is absorbed in the intestinal tract; thus, limiting dietary phosphate intake is essential for treating hyperphosphatemia in persons with CKD. However, this may pose challenges for patients who are already following several nutrient-restricted diets [14,22]. Patients with hyperphosphatemia undergoing dialysis often experience inadequate management of their condition despite dietary phosphate limitations, requiring phosphate binders for effective regulation to maintain mineral equilibrium, prevent cardiovascular diseases, and improve overall survival. This study aimed to assess the efficacy of ferric citrate as a phosphate binder in patients with ESRD receiving maintenance hemodialysis. According to this study, ferric citrate is equally or, to some extent, more effective than other phosphate binders.

In this study, the mean age of the patients was within their early fifties, and male predominance was observed, which was consistent with the findings of Kiss et al. (2013), where the mean age of the patients was between 50 and 60 years with male preponderance (52.8%) [23]. Among the patients of ESRD with hyperphosphatemia, the use of phosphate binders is essential for the management of ESRD patients and mitigates the consequences of it.

In this study, three different forms of phosphate binders were used in three distinct groups of participants. Serum

Remin Rafi SM, et al., Arch Nephrol Urol 2025
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phosphate concentrations were found to decline significantly in the group of patients receiving ferric citrate, sevelamer carbonate, and calcium citrate for three months. The study conducted by Wang et al. (2023) and Chen et al. (2014) reported that ferric citrate and sevelamer carbonate [24,25] potentially reduce the serum phosphate level. Wang et al. (2023) confirmed that ferric citrate is non-inferior to sevelamer carbonate to control hyperphosphatemia in CKD patients undergoing hemodialysis, which is similar to our study findings [24]. Wang et al. (2015) reported that calcium acetate is effective in lowering serum phosphate in chronic dialysis patients [26]. It is possible that the same effect of lowering serum phosphate levels could have been achieved by treating age-sex-matched participants, imposing the same dietary restrictions, and using the same mechanism of action by these three phosphate binders. This mechanism involves forming insoluble complexes with dietary phosphate in the gastrointestinal tract and excreting them in stool by means of the phosphate binder.

The reduction in glomerular filtration rate disrupts calcium and phosphorus equilibrium and decreases renal phosphorus excretion, leading to increased blood phosphorus concentrations [27]. As a result, hyperphosphatemia causes dystrophic calcification, secondary hyperparathyroidism, and other mineral metabolism abnormalities [11,28]. The current analysis revealed that all phosphate binders markedly reduced serum iPTH, alongside a decrease in blood phosphate levels, aligning with the results of Van Buren et al. (2015)[29] . After 3 months of treatment, patients administered calcium acetate exhibited a significant elevation in serum calcium levels, whereas no such increase was observed in persons receiving ferric citrate and sevelamer carbonate. The significant increase in corrected serum calcium levels may elevate the risk of cardiovascular and soft tissue calcification [17,18], indicating that ferric citrate offers a safety advantage by not elevating corrected serum calcium levels, thereby reducing the risk of cardiovascular and soft tissue calcification.

In the present study, it was found that discolored feces, dyspepsia, and nausea were the common adverse events in the Ferric Citrate, Sevelamer Carbonate, and Calcium Acetate groups, respectively. Other adverse events that were noted were diarrhea, vomiting, and constipation. Yoshida et al. (2022) showed diarrhea to be the most commonly reported adverse drug reaction among patients taking ferric citrate, which does not support the present study findings [30]. But, in the current study, patients who were known to have an intolerance to phosphate binders were excluded from the study, which might have influenced the study result. However, these reported side effects were well tolerated. Based on the above-mentioned findings, it can be concluded that ferric citrate is equally effective and cost-efficient with a considerable safety profile when compared to other phosphate binders like sevelamer carbonate and calcium acetate.

Limitations

The study was conducted only in two centers with a relatively small sample size, which limits the generalizability of the study findings. Blinding was not utilized in this study, which may perhaps lead to biases.

Conclusion

Patients with end-stage renal illness were primarily male and in their fifties. Ferric citrate, sevelamer carbonate, and calcium acetate significantly decreased serum phosphate concentrations. All three phosphate binders markedly reduced serum intact parathyroid hormone levels. Ferric citrate shows a significant safety benefit by not elevating corrected serum calcium levels; hence, it reduces the risk of cardiovascular and soft tissue calcification. Adverse effects, such as discolored feces, dyspepsia, and nausea, were documented but were mostly well tolerated. These results show that Ferric Citrate is a safe, effective, and cost-effective alternative that works just as well as Sevelamer Carbonate and Calcium Acetate. This supports its use as a first-line treatment for hyperphosphatemia management in people with ESRD who are on maintenance dialysis.

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Declarations

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Conflict of interest

The authors declared no potential conflicts of interest to this article's research, authorship and publication

Ethical approval

The Institutional Review Board (IRB) of BSMMU provided formal ethical approval for the study (Ref: BSMMU/2022/7428).

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