Association of Biochemical Parameters with Clinical Outcomes among Patients Undergoing Maintenance Hemodialysis

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Abstracts

Background: Patients undergoing maintenance hemodialysis (MHD) face substantial morbidity from biochemical imbalances and symptom burden. However, the association between serial biochemical parameters and specific clinical outcomes remains incompletely characterized.

Objective: To evaluate the association between biochemical parameters and clinical outcomes among patients undergoing MHD over 12 months.

Methods: This prospective observational study included 97 patients on MHD. Biochemical parameters (hemoglobin, serum phosphate, calcium, intact PTH, albumin, CRP, and Kt/V) were measured at baseline, 6 months, and 12 months. Clinical outcomes assessed included pruritus (VAS score), muscle cramps, restless sleep, and dry skin. Univariate and multivariable regression analyses were performed to identify independent predictors of outcomes.

Results: Mean age was 58.2±12.4 years; 56.7% were female. Pruritus was present in 53.6% of patients. On multivariate analysis, lower hemoglobin (adjusted OR 0.68, 95% CI 0.48–0.96, p=0.03), higher phosphate (aOR 1.52, 95% CI 1.02–2.27, p=0.04), higher PTH (aOR 1.96, 95% CI 1.04–3.69, p=0.04), and lower albumin (aOR 0.41, 95% CI 0.18–0.93, p=0.03) independently predicted pruritus. Higher phosphate independently predicted muscle cramps (aOR 1.76, 95% CI 1.10–2.82, p=0.02). Lower albumin was associated with dry skin (β -0.41, p=0.003). Kt/V and CRP showed weaker associations.

Conclusion: Biochemical derangements, particularly hyperphosphatemia, elevated PTH, anemia, and hypoalbuminemia, are significantly associated with adverse clinical outcomes in MHD patients. Routine monitoring and targeted management of these parameters may improve symptom control.

[Dinajpur Medical College Journal, 2026 Jul; 19 (2):275-284]
[Former M Abdur Rahim Medical College Journal]
DOI: https://www.doi.org/10.69861/djmcj.2026.19.2.18

Keywords: Albumin, Hemodialysis, Hyperphosphatemia, Parathyroid hormone, Pruritus, Serum phosphate

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Introduction

Chronic kidney disease (CKD) represents a global health burden with steadily increasing incidence worldwide, particularly affecting adolescents and young adults in low-income countries.[1] As CKD progresses to end-stage renal disease (ESRD), maintenance hemodialysis (MHD) becomes the cornerstone of renal replacement therapy for millions of patients globally. Despite significant advances in dialysis technology and patient care, individuals undergoing MHD continue to experience substantial morbidity from biochemical imbalances and debilitating symptoms that profoundly impair their quality of life.[2] Patients on MHD face a complex interplay of metabolic disturbances, including derangements in mineral metabolism, anemia, inflammation, and malnutrition.[3,4] Among these, disorders of calcium-phosphate homeostasis with secondary hyperparathyroidism represent particularly challenging complications. Elevated serum phosphate levels have been consistently associated with increased cardiovascular mortality in hemodialysis populations, with recent evidence suggesting that the benefit of intensive phosphate management may be most pronounced in patients with prior atherosclerotic cardiovascular disease or diabetic nephropathy.[3] Similarly, elevated parathyroid hormone (PTH) levels contribute not only to bone disease but also to diverse systemic manifestations including pruritus, vascular calcification, and anemia resistance.[4] Uremic pruritus remains one of the most frequent and burdensome symptoms affecting hemodialysis patients, with reported prevalence ranging from 46% to 65%.[5,6] This distressing symptom significantly impairs sleep quality, contributes to depression, and has been independently associated with increased mortality risk.[5] The pathogenesis of uremic pruritus is multifactorial and incompletely understood; however, accumulating evidence implicates hyperphosphatemia, elevated PTH, accumulation of middle-molecular-weight uremic toxins, and systemic inflammation as key contributing factors.[6,7] Notably, improvement in dialysis-related symptoms including pruritus, restless legs syndrome, and muscle cramps has been demonstrated with enhanced removal of medium-molecular-weight substances through hemodiafiltration, suggesting an important role for middle molecules in symptom pathogenesis.[7] Muscle cramps represent another common and distressing complication affecting approximately 50-80% of hemodialysis patients.8 These painful episodes typically occur during or shortly after dialysis sessions and have been associated with intradialytic fluid shifts, electrolyte disturbances, and accumulation of uremic toxins.[8] Restless sleep and insomnia are also highly prevalent in this population, often secondary to pruritus, cramps, or underlying uremic neuropathy.[7,9] Serum albumin, a marker of both nutritional status and inflammation, has emerged as one of the strongest predictors of mortality in hemodialysis patients.[10,11] Hypoalbuminemia in this population reflects the complex syndrome of protein-energy wasting (PEW), characterized by loss of body protein mass and fuel reserves.[10] Inflammation plays a central role in this process, as evidenced by the negative correlation between serum albumin and inflammatory markers such as C-reactive protein (CRP).[11,12] Patients on hemodialysis exhibit significantly elevated CRP and interleukin-6 levels compared to the general population, contributing to both hypoalbuminemia and adverse cardiovascular outcomes.[11,12] The adequacy of dialysis delivery, typically measured by Kt/V (urea clearance index) and urea reduction ratio (URR), has traditionally been the primary focus of quality assessment in hemodialysis care.1[3] However, the relationship between these parameters and patient-reported outcomes such as symptom burden remains

incompletely characterized, with some studies suggesting that conventional adequacy measures may not fully capture the clinical benefits of enhanced middle-molecule clearance.[7,13] Despite the recognized associations between individual biochemical parameters and specific outcomes, comprehensive prospective evaluations examining the simultaneous relationships between multiple biochemical markers (hemoglobin, phosphate, calcium, PTH, albumin, CRP, Kt/V) and diverse clinical outcomes (pruritus, muscle cramps, restless sleep, dry skin) over longitudinal follow-up remain limited. Such integrated analyses are essential for developing evidence-based strategies to optimize symptom control and improve quality of life in this vulnerable population. Therefore, we conducted this prospective observational study to evaluate the association of biochemical parameters with clinical outcomes among patients undergoing maintenance hemodialysis over a 12-month follow-up period. We specifically examined the independent predictive value of key biochemical markers for pruritus, muscle cramps, restless sleep, and dry skin using multivariate regression analyses.

Methods

This prospective observational study was conducted at a tertiary care dialysis center from January 2024 to December 2025. A total of 97 patients undergoing maintenance hemodialysis (MHD) were enrolled consecutively. All participants provided written informed consent. The study protocol was approved by the institutional ethics committee and complied with the Declaration of Helsinki.

Inclusion criteria

Patients aged ≥18 years undergoing conventional MHD for at least three months, with stable vascular access, and a willingness to complete 12-month follow-up were included.

Exclusion criteria

Patients with acute kidney injury, active malignancy, chronic liver disease, HIV infection, pregnancy, or those who underwent parathyroidectomy within six months were excluded. Patients who changed dialysis modality during follow-up were also excluded.

Study procedure

All patients received conventional hemodialysis using high-flux or low-flux dialyzers with standard bicarbonate dialysate. Clinical outcomes were assessed using the Visual Analog Scale (VAS) for pruritus severity, a validated tool for assessing uremic pruritus.[5] Scores ranged from 0 (no pruritus) to 10 (worst imaginable pruritus), categorized as mild (0-3), moderate (4-7), and severe (8-10).[5] Muscle cramps, restless sleep, and dry skin were documented using standardized patient interviews. Biochemical parameters, including hemoglobin, serum phosphate, calcium, intact PTH, albumin, CRP, Kt/V, and URR, were measured at baseline, 6 months, and 12 months following standard laboratory protocols.

Data analysis

Continuous variables were expressed as mean±SD or median (IQR). Categorical variables as frequencies (%). Univariate followed by multivariate logistic and linear regression analyses identified independent predictors of clinical outcomes. Variables with $p<0.10$ in univariate analysis were entered into multivariate models. A two-tailed $p<0.05$ indicated statistical significance. SPSS version 26.0 was used for all analyses.

Result

A total of 97 patients undergoing maintenance hemodialysis completed the 12-month follow-up period. The mean age was 58.2±12.4 years, with a female predominance

(56.7%). Most patients resided in urban areas (91.8%) and belonged to the middle socioeconomic stratum (83.5%). Hypertension was universal (100%), while diabetes mellitus was present in 53.6%. The median dialysis duration was 3 years (interquartile range 2-8 years). Twice-weekly hemodialysis was prescribed for 71.1% of patients, and high-flux dialyzers were used in 50.5%.

Regarding clinical outcomes, pruritus occurred in 53.6% of patients, with moderate severity (VAS 4-7) being most common (16.5%). Mild pruritus (VAS 0-3) was noted in 37.1%, and no patient had severe pruritus (VAS 8-10). Muscle cramps were reported by 63.9% of patients, and restless sleep affected 76.3%. Dry skin was present in 61.9%. Leg cramps during dialysis occurred in 19.6% of patients, and pruritus frequency was daily in 28.9%, weekly in 19.6%, and monthly in 5.2%.

Biochemical parameters showed improvement in hemoglobin from baseline (9.1±1.9 g/dL) to 12 months (10.2±2.0 g/dL), while serum phosphate decreased modestly from 5.0±1.2 mg/dL to 4.9±1.3 mg/dL. Serum albumin remained stable (3.7±0.5 to 3.8±0.6 g/dL), and Kt/V increased from 1.21±0.14 to 1.29±0.15. Intact PTH levels showed wide variability (median baseline 317 pg/mL, 12-month 425 pg/mL). CRP decreased from median 11.8 mg/L to 9.5 mg/L at 12 months.

On multivariate logistic regression, independent predictors of pruritus were lower hemoglobin (adjusted OR 0.68, 95% CI 0.48-0.96, p=0.030), higher serum phosphate (adjusted OR 1.52, 95% CI 1.02-2.27, p=0.040), higher intact PTH (adjusted OR 1.96, 95% CI 1.04-3.69, p=0.040), and lower serum albumin (adjusted OR 0.41, 95% CI 0.18-0.93, p=0.030). Higher serum phosphate independently predicted muscle cramps (adjusted OR 1.76, 95% CI 1.10-2.82, p=0.020). Lower serum albumin was significantly associated with dry skin (β -0.41, 95% CI -0.68 to -0.14, p=0.003). Kt/V and CRP showed weaker or non-significant associations with most outcomes.

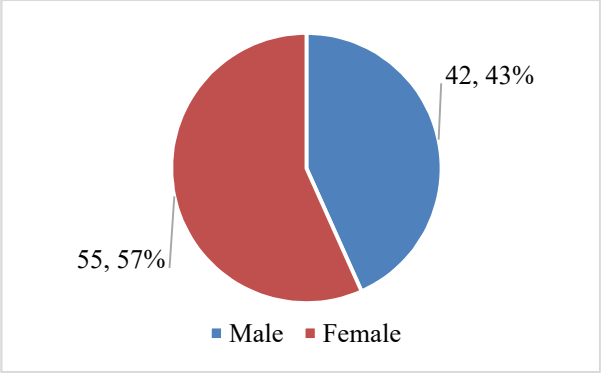

Figure 1. Gender Distribution of Participants (n=97)

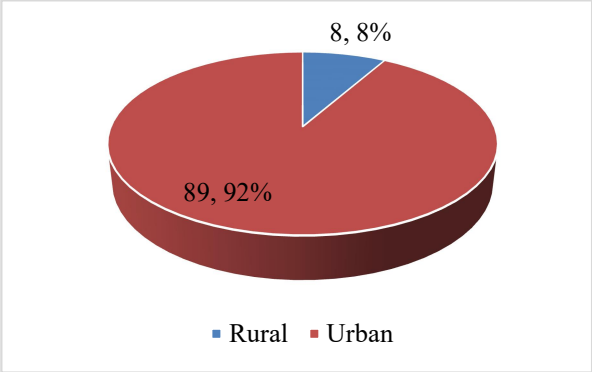

Figure 2. Residential Status of Participants

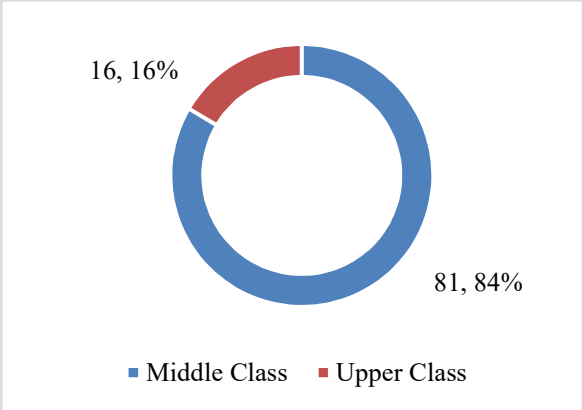

Figure 3. Socio-economic Status of Participants

Table I: Comorbidities and Disease Duration

Comorbidity	n (%)	Duration (years), median (IQR)
Hypertension	97 (100)	12 (8-17)
Diabetes Mellitus	52 (53.6)	16 (10-25)
Kidney Disease (CKD)	97 (100)	5 (4-12)
Stroke	22 (22.7)	1 (1-2)
Cardiac Disease	32 (33.0)	1 (0.5-5)
Hyperparathyroidism	21 (21.6)	2 (1-2)

Table II: Dialysis-Related Parameters

Parameter	Category	Value
Dialysis mode, n (%)	Conventional	97 (100)
Weekly sessions, n (%)	Two	69 (71.1)
	Three	28 (28.9)
Dialyzer type, n (%)	High Flux	49 (50.5)
	Low Flux	48 (49.5)
Blood flow (minutes), mean ± SD		210 ± 28
EPO use, n (%)	Yes	97 (100)
IV/Iron use, n (%)	Yes	97 (100)
Phosphate binder, n (%)	Yes	62 (63.9)
Dialysis duration (years), median (IQR)		3 (2-8)

Table III**:** Biochemical Parameters at Baseline, 6 Months, and 12 Months (Mean ± SD)

Parameter	Baseline (n=97)	6 Months (n=97)	12 Months (n=97)
Hemoglobin (g/dL)	9.1 ± 1.9	10.0 ± 1.8	10.2 ± 2.0
ESR (mm/hr)	66 ± 24	58 ± 22	55 ± 26
Serum Creatinine (µmol/L)	892 ± 268	851 ± 201	863 ± 215
Blood Urea (mmol/L)	22.4 ± 7.5	19.8 ± 6.2	20.1 ± 6.8
Serum Calcium (mg/dL)	9.0 ± 0.9	9.1 ± 1.0	9.2 ± 0.9
Serum Phosphate (mg/dL)	5.0 ± 1.2	4.8 ± 1.1	4.9 ± 1.3
Intact PTH (pg/mL), median (IQR)	317 (65-995)	409 (78-952)	425 (135-975)
Serum Albumin (g/dL)	3.7 ± 0.5	3.8 ± 0.5	3.8 ± 0.6
Uric Acid (mg/dL)	6.8 ± 1.7	6.5 ± 1.9	6.6 ± 1.8
HbA1c (%)	7.6 ± 2.5	7.8 ± 2.0	7.5 ± 2.2
CRP (mg/L), median (IQR)	11.8 (7.2-21.3)	10.5 (7.7-20.0)	9.5 (6.6-14.2)
Kt/V	1.21 ± 0.14	1.28 ± 0.16	1.29 ± 0.15
URR (%)	62 ± 10	68 ± 8	69 ± 9

Note: Intact PTH and CRP reported as median (IQR) due to non-normal distribution.

Table IV: Clinical Outcomes and Symptoms

Outcome	n (%)
Restless sleep	74 (76.3)
Muscle cramps	62 (63.9)
Skin allergy	12 (12.4)
Leg cramp (during dialysis)	19 (19.6)
Pruritus (any)	52 (53.6)
Pruritus frequency: Daily	28 (28.9)
Weekly	19 (19.6)
Monthly	5 (5.2)
Dry skin	60 (61.9)
VAS score: Mild (0-3)	36 (37.1)
Moderate (4-7)	16 (16.5)
Severe (8-10)	0 (0)

Table V: Multivariate Regression Analysis of Biochemical Parameters Associated with Clinical Outcomes

Outcome	Biochemical Parameter	Adjusted OR / β	95% CI	p-value*
Pruritus (present)	Hemoglobin (g/dL)	aOR 0.68	0.48-0.96	0.030
	Serum Phosphate (mg/dL)	aOR 1.52	1.02-2.27	0.040
	Intact PTH (pg/mL)†	aOR 1.96	1.04-3.69	0.040
	Serum Albumin (g/dL)	aOR 0.41	0.18-0.93	0.030
Muscle cramps (present)	Serum Phosphate (mg/dL)	aOR 1.76	1.10-2.82	0.020
Dry skin (present)	Serum Albumin (g/dL)	β -0.41	-0.68 to -0.14	0.003

*Multivariate logistic regression for binary outcomes (aOR); multivariate linear regression for dry skin (β).
†Log-transformed for analysis.
All models adjusted for age, gender, and dialysis duration.
Statistical tests: Logistic regression (Wald test) and linear regression (t-test). A two-tailed $p<0.05$ was considered significant.

Discussion

In this prospective observational study of 97 patients undergoing maintenance hemodialysis, we observed that biochemical derangements—particularly hyperphosphatemia, elevated intact PTH, anemia, and hypoalbuminemia—were independently associated with adverse clinical outcomes including pruritus, muscle cramps, and dry skin. These findings underscore the importance of systematic biochemical monitoring beyond traditional adequacy parameters such as Kt/V. The prevalence of pruritus in our cohort (53.6%) aligns with previously reported ranges of 46-65% among hemodialysis populations.[5,6] On multivariate analysis, lower hemoglobin, higher serum phosphate, higher intact PTH, and lower serum albumin independently predicted pruritus. The association between hyperphosphatemia and pruritus has been attributed to calcium-phosphate deposition in the skin, which may activate peripheral sensory nerves.[6,14] Elevated PTH contributes to pruritus through multiple mechanisms, including increased mast cell proliferation and histamine release, as well as enhanced cutaneous calcium deposition.[4,14] Our finding

that each log-unit increase in PTH nearly doubled the odds of pruritus (aOR 1.96) is clinically significant and supports the role of parathyroid hormone as a key mediator of uremic pruritus.[4,20] The independent association of lower hemoglobin with pruritus merits particular attention. Anemia in hemodialysis patients results from relative erythropoietin deficiency, iron dysregulation, and chronic inflammation.[6,15] Anemia-induced tissue hypoxia may lower the pruritus threshold, while the inflammatory milieu common to both anemia and pruritus could represent a shared pathogenic pathway.[15,20] Interestingly, we found no independent association between CRP and pruritus after multivariate adjustment, suggesting that inflammation may exert its effects indirectly through other mediators such as hepcidin or PTH.[16,20] Muscle cramps occurred in 63.9% of our patients, consistent with published estimates of 50-80%.[8] Higher serum phosphate independently predicted muscle cramps (aOR 1.76). This association may reflect the role of phosphate in intracellular calcium homeostasis and neuromuscular excitability.[14,17] Patients with hyperphosphatemia often require higher calcium loads from phosphate binders, potentially exacerbating intradialytic electrolyte shifts that trigger cramping.[17,22] Alternatively, hyperphosphatemia may serve as a marker for non-adherence to dietary and medication regimens, which could also contribute to cramping through other metabolic disturbances.[7,20] Dry skin affected 61.9% of participants and was strongly associated with lower serum albumin (β -0.41, p=0.003). Hypoalbuminemia in hemodialysis patients reflects the protein-energy wasting (PEW) syndrome, characterized by loss of somatic protein stores and reduced visceral protein pools.[11,20] Low albumin compromises skin barrier integrity by reducing oncotic pressure and impairing tissue repair mechanisms.[11,18] Furthermore, albumin serves as a carrier for essential fatty acids and micronutrients critical for skin hydration and barrier function.[18,20] The strong association we observed suggests that nutritional assessment and intervention targeting serum albumin may improve dermatological outcomes in this population.[23,21] Restless sleep affected 76.3% of patients but showed no significant association with any biochemical parameter in our regression models. This negative finding is noteworthy, as previous studies have linked sleep disturbances to pruritus, cramps, and periodic limb movements rather than directly to specific biochemical markers.[9,19] The multifactorial nature of sleep disturbance in hemodialysis patients—encompassing uremic neuropathy, psychological distress, and dialysis-related discomfort—may explain why no single biochemical parameter emerged as an independent predictor.[19,25] Dialysis adequacy, as measured by Kt/V and URR, improved modestly over 12 months but did not independently predict any clinical outcome. This observation aligns with emerging evidence that conventional small-molecule clearance metrics incompletely capture the clinical benefits related to middle-molecule removal.[13,20] Enhanced removal of medium-molecular-weight substances through hemodiafiltration has been associated with significant improvement in pruritus, restless legs, and muscle cramps, suggesting that future research should focus on middle-molecule clearance rather than urea kinetics alone.[2,7] The independent predictive value of serum phosphate and PTH for both pruritus and muscle cramps highlights the importance of strict mineral metabolism control in hemodialysis patients.[14,21] Current guidelines recommend maintaining serum phosphate within 3.5-5.5 mg/dL and PTH within 2-9 times the upper normal limit.[10,14] Our data suggest that patients with values at the higher end of these ranges remain at significantly increased risk for adverse

symptoms, supporting a more individualized, symptom-guided approach to mineral metabolism management.[3,21] The association of lower hemoglobin with pruritus adds a new dimension to the clinical implications of anemia management.[6,15] While current anemia guidelines focus primarily on cardiovascular outcomes and transfusion avoidance, our findings suggest that achieving higher hemoglobin targets (within recommended limits) may confer additional symptomatic benefits through pruritus reduction.[15,20] Further randomized studies are needed to confirm whether hemoglobin optimization directly improves pruritus severity. Finally, the robust association between hypoalbuminemia and dry skin reinforces the concept that protein-energy wasting manifests not only as systemic morbidity but also as clinically significant dermatological impairment.[11] Early identification of patients with declining serum albumin using validated nutritional screening tools could enable timely dietary interventions that may improve both systemic and cutaneous outcomes.[10,22]

Limitations

This single-center study limits generalizability. The absence of severe pruritus reduced statistical power. Subjective outcome assessments are susceptible to recall bias. Unmeasured confounders such as dialysate composition and medication adherence may have influenced results. Residual confounding cannot be excluded.

Conclusion

Hyperphosphatemia, elevated parathyroid hormone (PTH), anemia, and hypoalbuminemia were identified as independent predictors of pruritus, muscle cramps, and xerosis (dry skin) among patients undergoing maintenance hemodialysis. In contrast, conventional dialysis adequacy measures, such as Kt/V, were not significantly associated with these symptom burdens. These findings highlight the importance of comprehensive biochemical monitoring and targeted management of mineral metabolism, anemia, and nutritional status to alleviate symptom burden and improve health-related quality of life in this population. Further prospective and interventional studies are warranted to evaluate the impact of enhanced middle-molecule clearance strategies and other novel therapeutic approaches on patient-centered outcomes.

Recommendation

Routine monitoring and appropriate management of serum phosphate, parathyroid hormone (PTH), hemoglobin, and serum albumin should be incorporated into the standard care of patients receiving maintenance hemodialysis. Achieving optimal biochemical control may reduce the prevalence and severity of pruritus, muscle cramps, and xerosis, ultimately improving patients' quality of life and overall clinical outcomes.

Ai Declaration

Artificial intelligence tools contributed marginally to manuscript preparation and development. All core scientific content was human-verified.

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