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A PROSPECTIVE OBSERVATIONAL STUDY ON THE EFFECT OF IRON THERAPY ON HAEMOGLOBIN LEVELS IN DIALYSIS PATIENTS

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Abstract:
Background: *Anemia is a common complication of chronic kidney disease (CKD) and significantly contributes to morbidity and reduced quality of life. Iron therapy plays a central role in correcting anemia among CKD patients. This study was conducted to evaluate the hematological response and safety profile of iron therapy over four weeks in CKD patients and to compare responses across gender, age groups, and comorbidities.*
Methods*: A prospective observational study was conducted among 109 CKD patients. Baseline demographic, clinical, hematological, renal, electrolyte, and vital parameters were recorded and reassessed at 4 weeks. Statistical analysis was performed to determine mean differences and significance levels.*
Results*: Hemoglobin increased significantly from 7.9 ± 0.91 to 9.8 ± 1.65 g/dL (p<0.001). Significant improvements were also observed in hematocrit, RBC count, MCV, MCH, and MCHC. Renal parameters and vital signs showed no statistically significant changes, indicating clinical stability. Hematological improvements were consistent across gender, age groups, and comorbidities.*
Conclusion*: Iron therapy significantly improves anemia in CKD patients without adversely affecting renal function or hemodynamic parameters, supporting its safety and effectiveness in routine clinical practice.*
Keywords : *Chronic Kidney Disease; Anemia; Iron Therapy; Hemoglobin; Hematological Parameters; Intravenous Iron; Erythropoiesis; Renal Function; Comorbidities; Hemodialysis.*

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INTRODUCTION:

Chronic kidney disease (CKD) is a long-term condition in which the kidneys gradually lose their ability to function properly. The kidneys function to eliminate waste materials from the body while they also maintain fluid balance and produce hormones which support red blood cell development.[1] The body suffers several medical problems when kidney function decreases because most people develop anemia as their primary health issue. Anemia occurs when the body does not have enough healthy red blood cells to carry oxygen to tissues. The condition causes multiple symptoms which include tiredness and weakness together with shortness of breath and a decrease in overall life quality. Anemia in CKD patients shows a pattern of being underdiagnosed and undertreated in developing nations which creates a significant medical problem that needs prompt treatment and tracking.[2,3]

The main cause of anemia in CKD is reduced production of erythropoietin which functions as a hormone that kidneys produce to stimulate red blood cell production in bone marrow. The main reason anemia develops in patients exists because they have low erythropoietin levels and their bodies experience iron deficiency.[4] The combination of poor iron absorption and dialysis blood loss together with the increased need for iron during erythropoiesis-stimulating agent treatment creates challenges for CKD patients. The body experiences iron depletion which results in reduced hemoglobin levels. Anemia leads to more severe heart damage which raises the chances of hospitalization and increases the risk of death. The process of managing chronic kidney disease related anemia requires two main steps which involve correcting iron deficiency and raising hemoglobin levels.[5]

Iron therapy, especially through intravenous iron administration, has emerged as a fundamental treatment method for restoring anemia in CKD patients. The therapy enables iron store restoration while it helps create healthy red blood cells.[6] Doctors choose intravenous iron over oral iron for patients with advanced CKD and hemodialysis because intravenous iron provides faster results and better absorption. Research studies demonstrate that proper iron supplementation leads to increased hemoglobin levels and decreased fatigue while improving overall health. The treatment requires monitoring of renal function tests and electrolyte levels and vital signs because these parameters protect against treatment-induced kidney damage and maintain cardiovascular stability.[7,8]

The response to iron therapy demonstrates variability because different factors influence treatment outcomes. Elderly patients and those with multiple health conditions may respond differently due to inflammation or altered iron metabolism.[9] The study of patient responses to treatment shows how doctors can create personalized treatment plans for patients with anemia. This study was conducted to investigate how CKD patients would respond to iron treatment during a four-week period while they monitored treatment safety through vital signs and renal function tests. The study also compared responses across gender, age groups, and comorbid conditions.[10]

METHODOLOGY:

Study Type: A Prospective Observational study was conducted

Study Duration: The study was done for a period of 6 months.

Study Setting: Inpatients and outpatients of Dialysis unit

Study Population: 109 adult patients undergoing maintenance dialysis and receiving iron therapy.

Inclusion Criteria:

- Age ≥ 18 Years.
- Patients On Maintenance Dialysis (Hd Or Pd).
- Patients Planning To Receive Iron Therapy (Oral Or Iv) As Part Of Routine Care.
- Ability And Willingness Of The Patients To Comply With Treatment Protocols And Follow-Up Visits.

Exclusion Criteria:

- Patients with Active infection or sepsis.
- Patients with History of severe allergic reaction to iron products.
- Patients underwent Recent blood transfusion (within the last 3 months).
- Patients with Severe liver disease (Child-Pugh Class C).
- Patients with Active malignancy.
- Patients with Pregnancy or breastfeeding.
- Patients with Non-compliance or inability to attend follow-up visits.

Method Of Collection Of Data:

Data was collected prospectively from dialysis patients receiving iron therapy. Baseline demographic details (age, gender), clinical information (comorbidities, dialysis type), and laboratory parameters (Hb, HCT, RBC, MCV, MCH, MCHC) was be recorded before therapy initiation. Follow-up haematological values were be collected after iron therapy from laboratory reports.

Core CBC Parameters

- Haemoglobin (Hb)
- Haematocrit (HCT)
- Red Blood Cell Count (RBC)
- Mean Corpuscular Volume (MCV)
- Mean Corpuscular Haemoglobin (MCH)
- Mean Corpuscular Haemoglobin Concentration (MCHC)

Additional Laboratory Parameters

- Serum Creatinine
- Blood Urea Nitrogen (BUN)
- Serum Sodium (Na^+)
- Serum Potassium (K^+)

Clinical / Supportive/Vital Parameters

- Body Weight
- Blood Pressure (Systolic / Diastolic)
- Heart Rate
- Respiratory Rate
- Temperature

Study Procedure: All patients undergoing dialysis and prescribed iron therapy were screened for eligibility and enrolled in the study after obtaining consent. Baseline information, including demographic details (age, gender), clinical characteristics (comorbidities, dialysis type), and laboratory values (Hb, HCT, RBC, MCV, MCH, MCHC), were collected prior to the start of iron therapy. Patients continued with their routine dialysis and standard treatment as advised by the physician, with no intervention from the research team. Follow-up laboratory values were collected at 4 weeks after initiation of iron therapy to assess haematological response. Any relevant clinical events during the study period were also documented. All collected information was entered into structured Case Record Forms (CRFs), cross-verified for accuracy, and transferred into an Excel database for statistical analysis and outcome evaluation.

Statistical analysis: The statistical analysis was performed using SPSS/SAS software. Continuous variables such as haemoglobin and haematological indices were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. T test was applied to compare pre- and post-therapy values. A p-value <0.05 was considered statistically significant.

RESULTS:

Table 1. Baseline Demographic and Clinical Characteristics (n = 109)

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	≤30	8	7.34
	31–40	14	12.84
	41–50	12	11.01
	51–60	30	27.52
	61–70	22	20.18
	≥71	23	21.10
Gender	Male	72	66.06
	Female	37	33.94
Comorbidities	Hypertension	76	69.72
	Anaemia	18	16.51
	Diabetes Mellitus	14	12.84
	ESRD	1	0.92

A total of 109 patients were included in the study. Most patients were aged 51–60 years (27.52%), followed by ≥71 years (21.10%) and 61–70 years (20.18%). Males (66.06%) were more common than females (33.94%). Hypertension was the most frequent comorbidity (69.72%), followed by anaemia (16.51%) and diabetes mellitus (12.84%). Only one patient (0.92%) had ESRD. This shows that middle-aged and elderly hypertensive males formed the majority of the study population.

Table 2. Hematological Parameters (Baseline vs Week 4)

Parameter	Baseline (Mean ± SD)	Week 4 (Mean ± SD)	Mean Difference	p-value
Hemoglobin (g/dL)	7.9 ± 0.91	9.8 ± 1.65	+1.9	<0.001
Hematocrit (%)	27.81 ± 5.15	29.65 ± 6.25	+1.84	0.018
RBC (×10⁶/µL)	3.10 ± 0.62	3.54 ± 0.99	+0.44	<0.001
MCV (fL)	77.67 ± 14.53	88.53 ± 10.82	+10.86	<0.001
MCH (pg)	25.83 ± 2.85	29.29 ± 2.71	+3.46	<0.001
MCHC (g/dL)	27.53 ± 0.83	32.56 ± 0.90	+5.03	<0.001

There was a significant improvement in all hematological parameters after 4 weeks. Hemoglobin increased from 7.9 ± 0.91 to 9.8 ± 1.65 g/dL (p<0.001). RBC count improved from 3.10 ± 0.62 to 3.54 ± 0.99 (p<0.001). MCV, MCH, and MCHC also showed strong improvement with highly significant p-values (<0.001). Hematocrit increased from 27.81 ± 5.15% to 29.65 ± 6.25% (p=0.018). Overall, blood profile improved significantly after 4 weeks.

Table 3. Electrolytes and Renal Parameters

Parameter	Baseline (Mean ± SD)	Week 4 (Mean ± SD)	Mean Difference	p-value
Serum Creatinine (mg/dL)	5.56 ± 2.81	6.10 ± 2.81	+0.54	0.157
BUN (mg/dL)	32.48 ± 14.91	29.97 ± 16.62	−2.51	0.241
Sodium (mmol/L)	136.60 ± 3.28	138.05 ± 9.97	+1.45	0.150
Potassium (mmol/L)	4.70 ± 0.67	4.78 ± 0.60	+0.08	0.354

Renal and electrolyte parameters did not show significant changes after 4 weeks. Serum creatinine increased slightly from 5.56 ± 2.81 to 6.10 ± 2.81 mg/dL (p=0.157). BUN decreased from 32.48 ± 14.91 to 29.97 ± 16.62 mg/dL (p=0.241). Sodium increased slightly (136.60 ± 3.28 to 138.05 ± 9.97 mmol/L), and potassium showed minimal change (4.70 ± 0.67 to 4.78 ± 0.60 mmol/L). All p-values were above 0.05, indicating no statistically significant change.

Table 4. Vital Signs (Baseline vs Week 4)

Parameter	Baseline (Mean ± SD)	Week 4 (Mean ± SD)	p-value
Systolic BP (mmHg)	136.5 ± 21.04	131.9 ± 19.17	>0.05
Diastolic BP (mmHg)	79.35 ± 4.54	78.4 ± 5.77	>0.05
Heart Rate (bpm)	78.08 ± 12.5	78.29 ± 12.11	>0.05
Temperature (°C)	37.0 ± 0.0	37.0 ± 0.0	1.000
Weight (kg)	61.20 ± 14.40	58.77 ± 13.48	>0.05

Vital signs remained stable over 4 weeks. Systolic blood pressure reduced slightly from 136.5 ± 21.04 to 131.9 ± 19.17 mmHg, while diastolic BP decreased from 79.35 ± 4.54 to 78.4 ± 5.77 mmHg, but these were not statistically significant (>0.05). Heart rate remained almost unchanged (78.08 to 78.29 bpm). Temperature stayed constant at 37.0°C (p=1.000). Body weight slightly reduced from 61.20 ± 14.40 to 58.77 ± 13.48 kg without significant difference.

Table 5. Comparison Of Hematological Response Across Gender

Gender	Hb (Baseline → 4 Weeks)	HCT (Baseline → 4 Weeks)	RBC (Baseline → 4 Weeks)	MCV (Baseline → 4 Weeks)	MCHC (Baseline → 4 Weeks)	MCH (Baseline → 4 Weeks)	P-value
Female	7.83 ± 0.64 → 9.42 ± 1.53	26.74 ± 4.62 → 28.79 ± 6.34	2.94 ± 0.38 → 3.46 ± 1.09	75.41 ± 16.57 → 88.65 ± 13.43	27.28 ± 0.80 → 32.41 ± 0.52	25.66 ± 2.90 → 29.36 ± 2.33	<0.001
Male	8.06 ± 1.01 → 10.05 ± 1.68	28.35 ± 5.32 → 30.10 ± 6.18	3.19 ± 0.70 → 3.58 ± 0.93	78.83 ± 13.21 → 88.46 ± 9.19	27.66 ± 0.81 → 32.64 ± 1.04	25.91 ± 2.81 → 29.25 ± 2.09	<0.001

Both males and females showed significant improvement in hematological parameters (p<0.001). In females, hemoglobin increased from 7.83 ± 0.64 to 9.42 ± 1.53 g/dL, while in males it improved from 8.06 ± 1.01 to 10.05 ± 1.68 g/dL. Similar improvements were seen in RBC, HCT, MCV, MCH, and MCHC in both genders. Although males had slightly higher hemoglobin improvement, both genders responded well to treatment with statistically significant results.

Table 6. Comparison Of Hematological Response Across Age Groups

Age Group	Hb (Baseline → 4 Weeks)	HCT (Baseline → 4 Weeks)	RBC (Baseline → 4 Weeks)	MCV (Baseline → 4 Weeks)	MCHC (Baseline → 4 Weeks)	MCH (Baseline → 4 Weeks)	P-value
≤30 Years	8.33 ± 1.16 → 10.15 ± 2.20	28.81 ± 6.60 → 30.03 ± 7.32	3.07 ± 0.52 → 3.45 ± 0.63	81.71 ± 4.57 → 89.03 ± 5.18	27.81 ± 0.74 → 32.81 ± 0.80	26.12 ± 1.80 → 29.35 ± 1.60	<0.001
31–40 Years	7.80 ± 0.74 → 9.78 ± 1.04	27.69 ± 4.54 → 28.98 ± 5.71	3.48 ± 1.24 → 3.88 ± 0.97	67.60 ± 20.58 → 82.19 ± 14.89	27.30 ± 0.91 → 32.38 ± 0.65	24.47 ± 3.43 → 27.44 ± 3.74	<0.001
41–50 Years	8.32 ± 1.47 → 9.54 ± 2.80	26.80 ± 6.43 → 27.35 ± 8.36	3.10 ± 0.65 → 3.29 ± 0.84	79.44 ± 6.54 → 84.12 ± 16.70	27.56 ± 0.80 → 32.79 ± 0.57	25.65 ± 2.83 → 28.67 ± 2.62	<0.001
51–60 Years	7.94 ± 0.51 → 9.40 ± 1.14	27.45 ± 4.21 → 28.67 ± 6.44	3.00 ± 0.40 → 3.17 ± 0.97	79.58 ± 13.63 → 91.05 ± 10.43	27.40 ± 0.75 → 32.45 ± 1.06	26.43 ± 1.87 → 29.68 ± 2.54	<0.001
61–70 Years	7.82 ± 0.70 → 10.02 ± 1.53	28.05 ± 4.90 → 29.62 ± 4.47	3.17 ± 0.34 → 3.75 ± 1.05	77.68 ± 11.34 → 87.52 ± 5.74	27.70 ± 0.78 → 32.64 ± 0.70	25.17 ± 2.46 → 29.00 ± 2.27	<0.001
≥71 Years	8.03 ± 1.02 → 10.32 ± 1.41	28.29 ± 5.39 → 32.45 ± 5.06	2.96 ± 0.36 → 3.78 ± 0.95	78.99 ± 16.51 → 92.20 ± 5.87	27.61 ± 0.91 → 32.56 ± 1.10	26.48 ± 3.62 → 30.50 ± 2.10	<0.001

All age groups showed significant improvement in hematological values ($p<0.001$). The ≥71 years group showed strong hemoglobin improvement (8.03 to 10.32 g/dL), while 61–70 years improved from 7.82 to 10.02 g/dL. Younger groups like ≤30 years improved from 8.33 to 10.15 g/dL. MCV, MCH, MCHC, RBC, and HCT also improved in every age group. This indicates that treatment was effective across all age categories, including elderly patients.

Table 7: Comparison Of Hematological Response Across Comorbidities

Comorbidity	Hb (Baseline → 4 Weeks)	HCT (Baseline → 4 Weeks)	RBC (Baseline → 4 Weeks)	MCV (Baseline → 4 Weeks)	MCHC (Baseline → 4 Weeks)	MCH (Baseline → 4 Weeks)	P-value
Anaemia	8.18 ± 0.95 → 10.05 ± 1.66	29.92 ± 5.04 → 33.26 ± 7.08	3.10 ± 0.41 → 3.56 ± 0.91	81.37 ± 13.15 → 91.03 ± 5.85	27.8 ± 0.76 → 32.71 ± 1.22	27.11 ± 2.26 → 30.02 ± 2.78	<0.001
Diabetes	7.57 ± 0.56 → 8.90 ± 1.98	25.70 ± 4.70 → 24.97 ± 5.64	2.85 ± 0.27 → 3.01 ± 1.13	78.25 ± 14.53 → 87.42 ± 20.32	27.4 ± 0.83 → 32.34 ± 1.38	25.90 ± 2.58 → 28.70 ± 2.33	<0.001
ESRD	7.10 ± 0.00 → 12.00 ± 0.00	28.30 ± 0.00 → 36.30 ± 0.00	7.8 ± 0.00 → 4.10 ± 0.00	84.40 ± 0.00 → 89.50 ± 0.00	28.2 ± 0.00 → 33.00 ± 0.00	27.40 ± 0.00 → 29.50 ± 0.00	<0.001
Hypertension	8.03 ± 0.93 → 9.93 ± 1.52	27.68 ± 5.11 → 29.58 ± 5.55	3.09 ± 0.44 → 3.62 ± 0.95	76.60 ± 14.76 → 88.13 ± 0.94	27.4 ± 0.83 → 32.57 ± 0.67	25.49 ± 2.94 → 29.18 ± 2.72	<0.001

All comorbidity groups showed significant improvement ($p<0.001$). In anaemia patients, hemoglobin increased from 8.18 to 10.05 g/dL. Hypertensive patients improved from 8.03 to 9.93 g/dL. Diabetic patients showed smaller improvement (7.57 to 8.90 g/dL). The single ESRD patient showed increase from 7.10 to 12.00 g/dL. Overall, hematological response was positive across all comorbid conditions, though improvement was comparatively lower in diabetic patients.

DISCUSSION

Our study population was predominantly middle-aged and elderly, with males forming 66.06% and the majority having hypertension (69.72%) and diabetes as common comorbidities. These demographic trends are consistent with Indian CKD cohorts where anemia prevalence increases with advancing age and associated cardiovascular risk factors. A study by Yadav et al. reported that CKD patients receiving IV iron had a majority over 50 years with hypertension and diabetes as common comorbidities, and hemoglobin improvements were observed post-therapy. Additionally, consensus guidelines on anemia in CKD emphasize that iron deficiency and anemia are highly prevalent in advanced CKD and often coexist with hypertension and diabetes, influencing overall disease burden. These findings reinforce that our demographic distribution reflects common clinical characteristics documented in CKD anemia literature.[11,12]

Our results demonstrated significant improvement in hemoglobin (7.9 ± 0.91 to 9.8 ± 1.65 g/dL, $p<0.001$) and other red cell indices after 4 weeks of iron therapy. These results align with previous evidence showing the benefits of intravenous iron supplementation in hemodialysis patients. The randomized trial by Zununi Vahed et al. showed that higher doses of IV iron enhanced hematinic parameters and could reduce erythropoietin requirements, indicating improved erythropoiesis. Similarly, the AIM HD-CKD study noted that ferric carboxymaltose significantly increased hemoglobin and iron biomarkers compared with baseline in CKD patients on hemodialysis. Together, these studies support our findings that iron therapy robustly increases hemoglobin and other hematological parameters in CKD populations undergoing dialysis[13,14].

Despite significant hematological improvements, renal markers such as serum creatinine and BUN did not change significantly over 4 weeks ($p>0.05$), and vital signs remained stable. This observation is consistent with CKD anemia management studies that show intravenous iron improves hematological outcomes without adversely affecting renal function or cardiovascular stability in the short term. A systematic review by Saifan et al. reported that IV iron effectively increased hemoglobin and iron stores without significant detrimental changes in kidney function markers in hemodialysis patients. Additionally, clinical guidelines emphasize that IV iron accelerates hemoglobin correction while maintaining hemodynamic and metabolic stability in CKD anemia treatment. These comparisons reflect that our intervention improved blood parameters without short-term negative impacts on renal or vital physiological measures.[15]

Significant hematological improvements were consistent across genders, age groups, and comorbidity categories in our study ($p<0.001$). Both males and females showed Hb increases, and even elderly patients (≥71 years) exhibited meaningful hemoglobin gains, indicating broad efficacy of iron therapy. This broad response pattern is supported by CKD anemia research, where IV iron benefits have been observed across diverse demographic and clinical subgroups. A large meta-analysis showed that IV iron was superior to oral iron across CKD stages and patient characteristics in achieving hemoglobin gains. Furthermore, observational data from real-world cohorts indicate that iron therapy enhances hematological parameters in CKD populations irrespective of age or comorbidity presence. These comparisons suggest that our subgroup responses are consistent with established literature on iron use in CKD anemia.[16,17]

CONCLUSION:

In conclusion, the present study demonstrates that iron therapy significantly improves hematological parameters in patients with chronic kidney disease over a short duration of four weeks. There was a marked and statistically significant rise in hemoglobin, hematocrit, RBC count, MCV, MCH, and MCHC ($p<0.001$), indicating effective correction of anemia and enhanced red blood cell production. Importantly, these improvements were consistently observed across different genders, age groups, and comorbidity categories, suggesting that the therapy is broadly effective in diverse patient subpopulations. At the same time, renal parameters such as serum creatinine and BUN, along with vital signs including blood pressure and heart rate, remained stable, demonstrating short-term safety and hemodynamic tolerability. Overall, the findings reinforce the clinical effectiveness and safety of iron therapy as a key strategy in the management of anemia associated with chronic kidney disease.

IMPORTANCE AND SIGNIFICANCE OF THE STUDY:

This study is important as anemia is a common and serious complication in chronic kidney disease patients, especially those undergoing dialysis. Effective management of anemia is essential to improve patient quality of life and reduce complications. This study provides real-world evidence on the effectiveness and safety of iron therapy in improving hemoglobin and other blood parameters within a short duration. It also highlights that iron therapy is beneficial across different age groups, genders, and comorbid conditions. The findings support clinicians in making informed treatment decisions and reinforce the role of iron therapy as a safe and essential component in CKD anemia management.

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