ORIGINAL ARTICLE

Comparison of Oral Versus Intravenous Iron Therapy for The Treatment of Anemia in Patients with End-Stage Renal Disease. An Interventional Study at a Tertiary Care Setting Nowshera

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ABSTRACT

Objective: Our research seeks to compare the efficacy and safety of 'oral' versus 'intravenous' iron therapy in treating anemia in patients suffering from end-stage renal disease (ESRD), with a focus on hemoglobin response and adverse effects profile.

Study Design: An interventional study.

Place and Duration of Study: This study was conducted at the Department of Nephrology, Pak Emirates Military Hospital (PEMH), Rawalpindi, Pakistan, and the Department of Medicine and Otorhinolaryngology (ENT), Combined Military Hospitals (CMH), Nowshera, Pakistan, from September 2024 to September 2025.

Methods: The study included 163 patients with end-stage renal disease (ESRD) and anemia, who received either oral iron (N=69) or intravenous iron (N=94) therapy. Group 1 received oral ferrous sulfate 200 mg elemental iron daily for 8 weeks, while Group 2 received intravenous iron sucrose 200 mg weekly for 5 weeks, totaling 1 g. Hemoglobin levels, iron stores, adverse reactions, and treatment costs were monitored over 6 weeks of therapy.

Results: Weekly intravenous iron therapy showed significantly greater increase in hemoglobin levels (2.87±1.11g/dL vs 1.60±1.26g/dL, *P*<0.001) and ferritin levels (254 ± 32ng/mL vs 112 ± 18ng/mL, *P<0.001*) compared to oral iron therapy in anemic patients of ESRD receiving hemodialysis. Gastrointestinal adverse effects were more common with oral iron (28% vs 8%; *P=0.01*). Hypersensitivity from systemic iron supplementation resulted in 10.52% (N=10) of patients.

Conclusion: Oral iron repletion was cost-effective and safe, yet intravenous iron therapy was more effective and better tolerated than oral iron therapy in treating anemia in ESRD patients. Making it the preferred treatment option. Individualization of therapy must be based on patients' needs and resources.

Keywords: *Anemia, Erythropoietin, Hemodialysis, Hemoglobin, Kidney Failure, Renal Dialysis.*

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Introduction

Anemia is a common and clinically significant complication of end-stage renal disease (ESRD), affecting approximately 70–80% of patients worldwide.[1,2] It is associated with increased cardiovascular morbidity, reduced quality of life, frequent hospitalizations, and higher mortality rates. Iron deficiency, either absolute or functional, is a major contributor to anemia in ESRD and may impair the response to erythropoiesis-stimulating agents (ESAs).[3] The estimated prevalence of ESRD in Pakistan ranges from 12.5% to 31.2%.[4] And in Pakistan, a study reported that 68% of ESRD patients had anemia, with iron deficiency being the most common cause.[5]

Adequate iron supplementation is essential for the effective management of anemia, particularly in

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patients receiving erythropoiesis-stimulating agents (ESAs), as iron deficiency can lead to hypo-responsivity of ESAs. Despite advances in anemia management, there is ongoing debate about the optimal iron supplementation strategy for patients with ESRD. Oral iron therapy is often limited by gastrointestinal side effects and poor absorption, while intravenous iron therapy is associated with higher costs and potential risks of hypersensitivity reactions. Several international studies have demonstrated superior improvements in hemoglobin levels, serum ferritin, and transferrin saturation with IV iron compared with oral iron in patients with ESRD.[6] In Pakistan, limited local data are available comparing the effectiveness and safety of oral versus intravenous iron therapy among ESRD patients.[7] Differences in healthcare resources, patient characteristics, nutritional status, and treatment accessibility necessitate region-specific evidence. Therefore, this study aims to compare the efficacy and safety of oral versus intravenous iron therapy for treating anemia in ESRD patients at a Pakistani tertiary-care postgraduate teaching hospital. Specifically, evaluating the changes in hemoglobin levels, iron stores, and adverse effects associated with each treatment protocol. This study will provide valuable insights into the comparative efficacy and safety of oral and intravenous iron therapy, ultimately informing evidence-based practice and improving patient outcomes. It will provide 'region-specific' evidence in order to be included in a later meta-analysis. Our findings have the potential to significantly contribute to and shape the future of nephrology research at a national level, serving as a valuable resource for policymakers, researchers, and healthcare professionals.

Methods

This prospective, open-label, clinical trial was conducted at the Department of Nephrology, Pak Emirates Military Hospital (PEMH), Rawalpindi, Pakistan, and the Department of Medicine and Otorhinolaryngology (ENT), Combined Military Hospital (CMH), Nowshera, Khyber Pakhtunkhwa, Pakistan, from September 2024 to September 2025. After acquiring approval from the Institutional Ethics Review Board, vide letter number: A/28/ERC/552/23, dated 1st August 2024, and letter no: E-1102-YFHSOXA, dated 19 August 2024. Written informed consent was obtained from all participants. Trial ID 91115, IRCT ID IRCT20260617069855N1, registered at https://www.irct.ir/user/trial/91115/. A total of 163 patients were included in the study, with 69 allocated to the oral iron group and 94 to the intravenous iron group. The minimum sample size was calculated applying the formula N=c2Np(1-p)/(A2N) + (c2p[1-p]), where the margin of error was 0.05, and the confidence interval was 95%. A detailed medical history and physical examination were performed for every participant at baseline. Information regarding age, sex, duration of chronic kidney disease, hemodialysis sessions per week, hypertension, diabetes mellitus, cardiovascular disease, chronic infections, previous blood transfusions, gastrointestinal symptoms, menstrual history (where applicable), medication history, and nutritional status was recorded. Baseline blood pressure, body weight, and clinical examination findings were documented. All patients of ESRD receiving maintenance hemodialysis between the ages 18 and 65 years, who had pretreatment hemoglobin <10g/dL; serum ferritin <500ng/mL, and/or transferrin saturation (TSAT) <30% were included, according to the Kidney Disease: Improving Global Outcomes (KDIGO) recommendations for anemia management in chronic kidney disease.[8] Patients having active and prolonged infection or inflammatory disease, recipients of blood transfusion (within last 3 months), having known iron overload disorders, hypersensitivity to iron preparations, and suffering from malignancy or chronic liver disease were excluded. Those belonging to Group 1 were advised to take oral ferrous sulfate, providing 200mg of elemental iron daily with a glass of water on an empty stomach for 8 weeks. Subjects in Group-2 were advised to receive intravenous iron sucrose 1g in total (200mg intravenous infusion, diluted in 100 ml of 0.9% normal saline, given over 60-90 minutes once a week for 5 weeks). Compliance with oral iron therapy was ensured through pill counts at each follow-up visit, patient treatment diaries, and telephonic reminders. Patients who consumed less than 80% of the prescribed medication were considered non-compliant and identified in both intention-to-treat and per-protocol analyses. The patients were managed for hemodialysis with the Fresenius 5008S Hemodialysis

System. ESA treatment was initiated after correction of reversible causes of anemia, including iron deficiency, when hemoglobin concentration was ≤9.0–10.0 g/dL and iron stores were adequate, with dose adjustments targeting hemoglobin levels below 11.5 g/dL according to KDIGO recommendations. Using the Beckman Colter Hematology Analyzer LH780, which worked mainly on the Colter Principle, combined with volume conductivity and scatter (VCS) technology.[9] We recorded change in hemoglobin from baseline to end of treatment, achieving target hemoglobin (i.e.,>10g/dL), change in serum ferritin (ng/mL), change in transferrin saturation (TSAT %), ESA dose adjustments (units/biweekly), and adverse events (gastrointestinal side effects and hypersensitivity reactions. Additional transfusion requirements (if any) would also be taken into account. In view of 'switchers' who inadvertently or deliberately remained non-compliant with their specified therapeutic plan, we conducted intention-to-treat (ITT) and per-protocol (PP) analyses to identify and adjust for missing values when analyzing the research outcome variables. Potential confounding factors and effect modifiers included age, gender, duration of dialysis, hypertension, diabetes mellitus, baseline hemoglobin concentration, baseline serum ferritin, baseline TSAT, and ESA dose.

Later, at the Departments of Medicine and Otorhinolaryngology (ENT) of the tertiary care teaching hospital Nowshera, Khyber Pakhtunkhwa, the data were recorded for analysis using the International Business Machines Corporation Statistical Package for the Social Sciences (SPSS®) version 27. We applied descriptive statistics for the frequency of demographic variables. An independent-samples t-test was used to compare normally distributed continuous variables, including change in hemoglobin, change in serum ferritin, TSAT, and ESA dose adjustment, between the two study groups. The Chi-Square test was employed to compare categorical variables, including the measure of achievement of the target hemoglobin level. Patients were analyzed in an intention-to-treat (ITT) and per-protocol (PP) manner, maintaining comparability of groups reflecting real-world versus ideal efficacy outcomes. *P-value* of <0.05 was arbitrarily considered significant, and we used 95% confidence interval for all estimates.

Results

Our research population comprised 72.4% (N=118) males and 27.6% (N=45) female subjects, with a mean age of 54.37±8.914 years. Following treatment, the intravenous group demonstrated a significantly greater improvement in hemoglobin compared to the oral group (mean change: 3.01±1.02 vs 1.44±1.16; *P*<0.001). Similarly, post-treatment serum ferritin levels were significantly higher in the intravenous group (*P*<0.001). TSAT levels were significantly higher in the intravenous group both at baseline and after treatment (*P*<0.001), as shown in Table 1.

10.2% (N=7) of patients ultimately had to switch from group-1 to group-2 during the course of treatment due to intolerance to untoward gastrointestinal symptoms caused by the intervention. A total of 10 (10.52%) patients shifted from group-2 to oral ferrous sulfate due to hypersensitivity reactions, and 5.88% (N=4) patients switched from oral ferrous sulfate to intravenous iron sucrose in the absence of any untoward symptoms. 5.88% (N=4) and 7.36% (N=7) patients from groups 1 and 2, respectively, received blood transfusions in addition to their prescribed treatments. 10.29% (N=7) of patients in the oral ferrous sulfate group experienced gastrointestinal adverse events. 10.52% (N=10) of patients receiving intravenous iron sucrose infusion experienced a drug allergy. Assuming equal variances, the difference of untoward events remained non-significant between the two groups (*P* = 0.171).

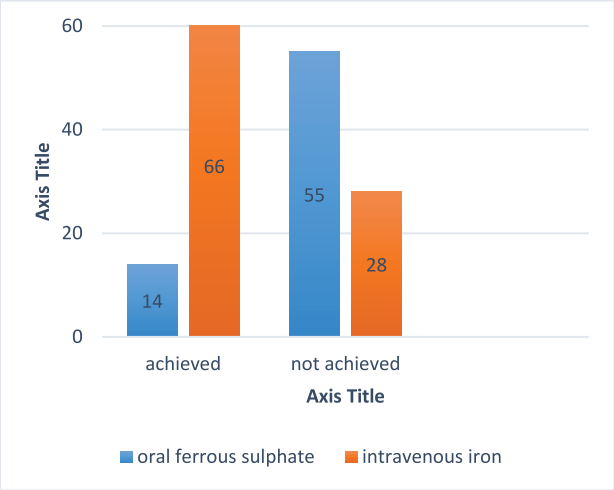

Fig.1: Group-wise achievement of target hemoglobin

Table 1: Comparison of Intervention-Based Outcomes Variables

Outcome Variables and Time Point		Oral (Group-1)	Intravenous (Group-2)	*t*- test value	*P*-value	
		Mean ± SD	Mean ± SD		*ITT analysis	**PP analysis
Hemoglobin (g/dl)	Pre-treatment	7.33±1.17	7.58±1.27	-1.28	0.199	0.199
	Post-treatment	8.94±1.48	10.46±1.23	-9.20	<0.001	<0.001
	Change	1.60±1.26	2.87±1.11	-9.10	<0.001	<0.001
Serum ferritin (ng/L)	Pre-treatment	41.09±14.68	45.68±16.59	-2.19	0.030	0.042
	Post-treatment	71.70±29.94	89.19±29.80	-5.02	<0.001	<0.001
TSAT (%)	Pre-treatment	20.210±3.29	29.56±2.20	-13.82	<0.001	<0.001
	Post-treatment	22.99±4.44	42.79±4.62	-14.80	<0.001	<0.001

**Intention-to-treat (ITT), **Per-protocol (PP)*

Table 2: Erythropoietin-stimulating agent (ESA) biweekly dose adjustments (units per biweekly) in both study groups

	0IU/ml	4000IU/ml	6000IU/ml	8000IU/ml	10000IU/ml	Total
Oral ferrous sulfate	16	27	14	10	3	70
Intravenous iron sucrose	55	35	3	0	0	93
Total	71	62	17	10	3	163

A higher proportion of patients in the intravenous group achieved target hemoglobin compared to the oral group [66 (82.5%) vs 14 (17.5%)], while non-achievement was more common in the oral group [55 (66.23%) vs 28 (33.73%)] (*P*<0.001*)* (Figure 1). We observed a mean biweekly dosage adjustment of 4314.29±2881.94 units in patients receiving oral ferrous sulfate and 1698.92±2084.02 units in the intravenous iron sucrose group, indicating a 43.14% lower requirement for ESA administration in patients in group-2 (*P*<0.001) (Table 2).

Discussion

Anemia is a common complication of end-stage renal disease (ESRD), resulting primarily from erythropoietin deficiency, reduced red blood cell survival, and iron deficiency.[10] Iron is essential for hemoglobin synthesis, with smaller amounts utilized in myoglobin and various enzymes. Hemoglobin reflects oxygen-carrying capacity and overall iron status, with normal levels ranging from 13–17 g/dL in men and 12–16 g/dL in women. Serum ferritin, the most sensitive indicator of iron stores, normally ranges from 30–400 ng/mL in men and 13–150 ng/mL in women; reduced levels indicate iron deficiency. Transferrin saturation (TSAT), calculated as (serum iron/TIBC) × 100, reflects iron available for erythropoiesis. In patients with end-stage renal disease (ESRD), a TSAT of approximately 30% indicates adequate iron availability, whereas values below 20% suggest iron deficiency.[11] These markers aid in the diagnosis of iron deficiency anemia, chronic disease, and iron overload disorders. Unlike acute renal failure, which is potentially reversible, chronic kidney disease progresses over more than three months and may result in irreversible renal damage. Common causes of acute renal failure include acute myocardial infarction, hemolysis, acute glomerulonephritis, and rhabdomyolysis,

whereas chronic kidney disease is most often caused by diabetic nephropathy, hypertension, nephrotic syndrome, and polycystic kidney disease. Although serum creatinine levels vary among individuals, an estimated glomerular filtration rate (eGFR) <15 mL/min/1.73 m² is used to define ESRD. Anemia in ESRD is multifactorial,[12] with erythropoietin deficiency being the primary cause. Chronic inflammation and hemodialysis impair iron mobilization and utilization, leading to absolute or functional iron deficiency. Uremic toxins suppress erythropoiesis and reduce red blood cell survival, while occult blood loss associated with hemodialysis and uremic coagulopathy further aggravates anemia. Therefore, adequate iron supplementation is essential to optimize the response to erythropoiesis-stimulating agents (ESAs). Oral iron therapy is inexpensive and easy to administer, but is often limited by poor gastrointestinal absorption, intolerance, and non-compliance, particularly in ESRD patients. Intravenous (IV) iron bypasses gastrointestinal absorption, rapidly replenishes iron stores, and has been shown to improve hemoglobin levels and ESA responsiveness. However, IV iron is associated with higher costs, the need for venous access, and potential adverse reactions.

While oral iron repletion appears cost-effective and does not necessitate hospitalization, intravenous iron supplementation may offer benefits for early, rapid recovery of hemoglobin and ferritin concentrations.[13] Pandey AK et al. reported a greater quantitative and faster increase in hemoglobin with intravenous iron therapy compared to its oral counterpart, regardless of its impact on maternal and neonatal outcomes.[14] On the contrary, Short V et al. demonstrated no statistically significant benefit in efficacy of one modality over the other while managing a neurological condition, the restless legs syndrome.[15] In another interesting research, De Souza LV et al. established divergent mechanisms in murine models showing an increase in hemoglobin by oral as well as systemic iron in murine models suffering from anemia of chronic disease and iron deficiency anemia.[16] Abuelazm M et al. conducted a meta-analysis and concluded that intravenous iron is superior in improving hemoglobin and ferritin concentrations in patients with gastrointestinal bleeding.[17] However, they demonstrated a varied response in TSAT. Our results are comparable to those of Raju MR et al., who also demonstrated that intravenous iron repletion is superior to oral supplementation in patients with chronic kidney disease.[18] Engel-Nitz NM et al. particularly focused on the cost-effectiveness of patients with malignancies, heart failure, and chronic kidney disease receiving oral versus intravenous iron supplements, and concluded oral repletion to be significantly cost-effective in all three disease populations.[19] Wang D et al. developed a Markov model yielding 19.26 quality-adjusted life years (QALYs) at a cost of $157,500, compared with $19.10 QALYs at $152,900 for intravenous iron dextran versus oral ferrous sulfate among anemic females. They recommended intravenous iron supplementation as first-line treatment in women suffering from anemia due to heavy menstrual bleeding.[20] Figures and statistics from different parts of the country overwhelmingly merit intravenous iron supplementation in ESRD.[21] Chan S et al. demonstrated analogous results, evaluating the efficacy of intravenous iron sucrose compared with oral iron therapy in alleviating anemia, particularly in a resource-constrained region of Pakistan.[22]

Overviewing shortcomings of our research, limited access to intravenous iron therapy in some suburban centers of Pakistan, cost and logistics, prevalence of malaria and parasites like hookworm infestation, and dietary compliance (phytates in tea might reduce iron absorption) could skew the outcome of oral versus systemic iron intake and its metabolism. Selection bias arising from the allocation of oral therapy to more seriously ill patients without proper randomization. We consider it more appropriate to treat malnutrition/inflammation as key confounders and to address them by measuring C-reactive protein and serum albumin in all subjects. Similarly, the use of ESA impacts hemoglobin response; its dose must be standardized. Dialysis influences anemia response. Its adequacy must be assessed by tracking Kt/V and adjusting the dialysis dose accordingly.

Conclusion

While intravenous iron sucrose has demonstrated superior efficacy in correcting anemia in patients with end-stage renal disease, oral iron remains a viable option for those with mild anemia or limited access to intravenous therapy. The trade-off

between efficacy and safety/cost highlights the need for individualized treatment strategies. Further studies should explore optimal dosing regimens and adjunctive therapies to maximize the effectiveness of oral iron in resource-limited settings.

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Author Contributions

MS: Conception, design of the work, and approval for final submission
NAS: Manuscript writing for methodology design, investigation, and approval for final submission
UA: Revising, editing, supervising for intellectual content, and approving for final submission
MTA: Validation of data, interpretation, write-up of results, and approval for final submission
AA: Data acquisition, curation, statistical analysis, and approval for final submission
JN: Writing the original draft, proofreading, and approval for final submission
MS is the nominated guarantor and takes full responsibility for the overall content and integrity of the work