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Original Research Article

Assessment of the Efficacy and Safety of Oral versus Intravenous Iron Therapy in Chronic Kidney Disease Patients with Iron Deficiency Anaemia

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Conflict of interest: Nil

Abstract

Background: Anemia is a common and significant complication of chronic kidney disease (CKD), with iron deficiency being a major contributing factor. While oral iron therapy is widely used due to its convenience and cost-effectiveness, its efficacy is often limited by poor absorption and gastrointestinal intolerance. Intravenous (IV) iron therapy has emerged as a potential alternative with improved efficacy and tolerability.

Aim: To compare the efficacy and safety of oral versus intravenous iron therapy in patients with CKD-associated iron deficiency anemia.

Methods: This prospective, randomized, open-label comparative study was conducted on 110 CKD (Stage 3–5, non-dialysis) patients with iron deficiency anemia. Participants were equally allocated into two groups: Group A received oral ferrous sulfate (300 mg/day), and Group B received intravenous iron sucrose (total 1000 mg over 2 weeks). Hematological parameters including hemoglobin (Hb), serum ferritin, and transferrin saturation (TSAT) were assessed at baseline, 4 weeks, and 8 weeks. Clinical symptom improvement and adverse effects were also evaluated. Statistical analysis was performed using SPSS version 28.0, with $p < 0.05$ considered significant.

Results: Baseline characteristics were comparable between both groups ($p > 0.05$). At 4 and 8 weeks, the IV iron group showed significantly greater improvement in hemoglobin, serum ferritin, and TSAT compared to the oral iron group ($p < 0.001$). At 8 weeks, mean hemoglobin was 11.02 ± 0.85 g/dL in the IV group versus 9.88 ± 0.93 g/dL in the oral group. Symptomatic improvement in fatigue, dyspnea, and dizziness was significantly higher in the IV group ($p < 0.05$). Oral iron therapy was associated with a higher incidence of gastrointestinal side effects such as nausea and constipation, whereas IV iron therapy demonstrated better tolerability, with minor injection site reactions.

Conclusion: Intravenous iron therapy is more effective and better tolerated than oral iron in CKD patients with iron deficiency anemia. It leads to faster and more sustained improvement in hematological parameters and clinical symptoms, making it a preferable therapeutic option, particularly in patients requiring rapid correction or those intolerant to oral iron.

Keywords: Chronic kidney disease; Iron deficiency anemia; Oral iron therapy; Intravenous iron; Hemoglobin; Serum ferritin; Transferrin saturation; Iron sucrose.

Introduction

Chronic kidney disease (CKD) is a major global public health problem associated with significant morbidity and mortality, particularly due to its complications such as anemia. Anemia in CKD is multifactorial in origin, primarily resulting from reduced erythropoietin production, iron deficiency, chronic inflammation, and shortened red blood cell survival.

Iron deficiency anemia (IDA) remains one of the most prevalent and treatable causes of anemia in CKD patients and significantly contributes to reduced quality of life, increased cardiovascular risk, and progression of renal dysfunction (Bhoraniya et al., 2025) [1]. Iron therapy plays a central role in the management of anemia in CKD. Traditionally, oral iron supplementation has been the first-line treatment due to its ease of administration, low cost, and widespread availability.

However, its effectiveness is often limited by poor gastrointestinal absorption, especially in CKD patients where elevated hepcidin levels inhibit

intestinal iron uptake, as well as by gastrointestinal side effects that reduce patient compliance (Pandey et al., 2024) [2]. Moreover, recent observational data have raised concerns regarding the long-term effectiveness and outcomes associated with oral iron therapy in CKD populations (Kovesdy et al., 2023) [3].

In contrast, intravenous (IV) iron therapy has emerged as a more effective alternative for rapid replenishment of iron stores. IV iron bypasses the limitations of intestinal absorption and leads to a more rapid and sustained increase in hemoglobin levels and iron indices.

Recent systematic reviews and meta-analyses have demonstrated that IV iron is significantly superior to oral iron in improving hemoglobin levels, serum ferritin, and transferrin saturation in patients with CKD and other chronic conditions (Zhang et al., 2025) [4]. Additionally, newer IV iron formulations have improved safety profiles, making them increasingly acceptable in routine clinical practice (Xing et al., 2025) [5].

Despite these advantages, the choice between oral and intravenous iron therapy in non-dialysis CKD patients remains a subject of ongoing debate. Factors such as cost, accessibility, safety concerns, patient preference, and healthcare infrastructure play an important role in determining the optimal treatment strategy. While some studies suggest marginal benefits of IV iron in non-dialysis CKD, others highlight its clear superiority in achieving faster hematological correction (Memon et al., 2025) [6]. Therefore, there is a need for further comparative clinical studies to evaluate the efficacy, safety, and tolerability of these two therapeutic modalities in real-world settings.

Aim & Objectives

Aim: To compare the efficacy and safety of oral iron therapy versus intravenous iron therapy in patients with chronic kidney disease (CKD) associated iron deficiency anemia.

Objectives

Primary Objectives

- To evaluate and compare the change in hemoglobin levels between oral and intravenous iron therapy at 4 and 8 weeks.
- To assess and compare serum ferritin levels as a marker of iron stores in both groups.
- To compare transferrin saturation (TSAT) between the two treatment modalities over time.

Secondary Objectives

- To assess improvement in clinical symptoms such as fatigue, dyspnea, and dizziness in both groups at 8 weeks.
- To compare the incidence and pattern of adverse effects between oral and intravenous iron therapy.
- To evaluate overall tolerability and safety profile of both treatment modalities.

Materials and Methods

Study Design: This study was designed as a prospective, randomized, open-label, comparative clinical study conducted to evaluate the efficacy and safety of oral versus intravenous (IV) iron therapy in patients with chronic kidney disease (CKD) associated with iron deficiency anaemia.

Study Setting: The study was carried out in the Department of Biochemistry in collaboration with Department of Pharmacology at Narayan Medical College & Hospital (NMCH), Jamuhar, Rohtas, Bihar, India., a tertiary care teaching hospital catering to both urban and rural populations.

Study Period: The study was conducted over a duration of one year and eight months, from January 2024 to August 2025, including patient recruitment, intervention, and follow-up.

Study Population: The study population consisted of 110 adult patients diagnosed with CKD (Stage 3–5, non-dialysis dependent**)** presenting with laboratory-confirmed iron deficiency anaemia attending the outpatient and inpatient departments.

Sample Size Calculation: The sample size was calculated using the formula:

$$n = \frac{2 \times (Z_{\alpha/2} + Z_{\beta})^2 \times \sigma^2}{d^2}$$

Where

- n= sample size required per group
- $Z_{\alpha/2}$= standard normal deviate for 95% confidence level = 1.96
- Z_{β} = standard normal deviate for 80% power = 0.84
- σ = standard deviation (assumed from previous studies)
- d = minimum clinically significant difference in mean hemoglobin

Assumptions (based on previous literature)

- Expected difference in Hb (d) = 0.8 g/dL
- Standard deviation (σ) = 1.5 g/dL
- Power = 80%
- Significance level = 5% (two-tailed)

Step-wise Calculation

$$n = \frac{2 \times (1.96 + 0.84)^2 \times (1.5)^2}{(0.8)^2}$$

$$n = \frac{2 \times (2.8)^2 \times 2.25}{0.64}$$

$$n \approx 55.1$$

Final Sample Size

- Required sample size per group ≈ 55 patients
- Total sample size = 55 × 2 = 110 patients

Considering an anticipated dropout rate of ~10%, the calculated sample size remains adequate, and thus 110 patients were included and equally allocated into two groups (n = 55 each).

Ethical Considerations

- The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) prior to commencement.
- Written informed consent was obtained from all participants.
- The study adhered to the ethical principles outlined in the Declaration of Helsinki (2013 revision).
- Confidentiality and anonymity of patient data were strictly maintained.

Inclusion Criteria

Participants meeting all the following criteria were included:

- Age between 18 and 70 years
- Diagnosed with CKD Stage 3 to 5 (non-dialysis dependent) as per KDIGO guidelines
- Presence of iron deficiency anaemia, defined as:
    a. Hemoglobin (Hb): 7–11 g/dL
    b. Serum ferritin: <100 ng/mL
    c. Transferrin saturation (TSAT): <20%
- Stable renal function for at least 4 weeks prior to enrollment

Exclusion Criteria

Patients were excluded if they had:

- Active infection, chronic inflammatory or autoimmune disease
- History of recent blood transfusion (<3 months)
- Active gastrointestinal bleeding or peptic ulcer disease
- Known malignancy
- Pregnancy or lactation
- Prior iron therapy (oral or IV) within the last 3 months
- Known hypersensitivity to iron formulations
- Severe hepatic dysfunction
- Patients on dialysis or planned for dialysis initiation

Methodology

After enrollment, patients were randomized into two groups:

Group A: Oral Iron Therapy

- Patients received ferrous sulfate tablets, each containing 100 mg elemental iron
- Administered thrice daily (total 300 mg/day) for 8 weeks
- Adherence was monitored through pill counts and patient interviews

Group B: Intravenous Iron Therapy

- Patients received intravenous iron sucrose
- Dose: 200 mg diluted in 100 mL normal saline, administered over 30 minutes
- Given on alternate days for a total of five doses (cumulative dose: 1000 mg over 2 weeks)

Monitoring and Follow-up

- Patients were followed at baseline (0 weeks), 4 weeks, and 8 weeks
- Monitoring included:
    a. Treatment compliance
    b. Adverse events (gastrointestinal symptoms, hypersensitivity reactions, hypotension)
    c. Clinical symptom improvement (fatigue, dyspnea, dizziness)

Investigations: The laboratory evaluation of all participants was performed at baseline, 4 weeks, and 8 weeks of the study period. The investigations included complete blood count (CBC) with particular emphasis on hemoglobin (Hb) levels, along with assessment of iron profile parameters such as serum ferritin, serum iron, total iron-binding capacity (TIBC), and transferrin saturation (TSAT). In addition, renal function was evaluated by measuring serum creatinine, and the estimated glomerular filtration rate (eGFR) was calculated using the CKD-EPI formula. These serial measurements were undertaken to monitor hematological response, iron status, and renal function over the course of the treatment.

Outcome Measures

Primary Outcomes

- Change in hemoglobin (Hb) levels from baseline to 4 and 8 weeks
- Change in serum ferritin levels
- Change in transferrin saturation (TSAT)

Secondary Outcomes

- Incidence and type of adverse effects
- Patient-reported symptom improvement (fatigue, dyspnea, dizziness)
- Treatment tolerability and compliance

Statistical Analysis: Data were entered into Microsoft Excel 365 and analysis was performed using IBM SPSS Statistics for Windows, Version 28.0 (IBM Corp., Armonk, NY, USA).

- Continuous variables were expressed as mean ± standard deviation (SD)
- Categorical variables were presented as frequency (n) and percentage (%)

Tests Applied

- Independent samples t-test was used to compare mean values between Group A and Group B
- Paired t-test was applied for within-group comparisons (baseline vs follow-up)
- Chi-square test (χ^2 test) or Fisher's exact test (when expected frequency <5) was used for categorical variables
- Normality of data distribution was assessed using the Shapiro–Wilk test
- Homogeneity of variance was evaluated using Levene's test

Significance Criteria

- A p-value < 0.05 was considered statistically significant

Results

Table 1: Baseline Demographic and Clinical Characteristics (n = 110)

Parameter	Group A: Oral Iron (n = 55)	Group B: IV Iron (n = 55)	p-value
Mean age (years)	52.4 ± 9.6	51.6 ± 10.0	0.62
Male : Female ratio	32 : 23	33 : 22	0.84
Mean hemoglobin (g/dL)	8.26 ± 0.78	8.29 ± 0.82	0.79
Serum ferritin (ng/mL)	43.2 ± 16.8	44.5 ± 17.6	0.67
TSAT (%)	15.0 ± 2.9	14.8 ± 3.2	0.81
eGFR (ml/min/1.73m²)	32.1 ± 8.1	31.9 ± 8.4	0.88

Table 1 presents the mean age of patients in Group A was 52.4 ± 9.6 years, while in Group B it was 51.6 ± 10.0 years, indicating comparable age distribution (p = 0.62). Gender distribution was also similar between the groups, with a male-to-female ratio of 32:23 in Group A and 33:22 in Group B (p = 0.84), suggesting no gender bias.

Baseline hemoglobin levels were nearly identical, recorded at 8.26 ± 0.78 g/dL in the oral iron group and 8.29 ± 0.82 g/dL in the intravenous group (p = 0.79), confirming comparable severity of anemia at enrollment. Similarly, serum ferritin levels, reflecting iron stores, were 43.2 ± 16.8 ng/mL in Group A and 44.5 ± 17.6 ng/mL in Group B (p = 0.67), indicating no significant difference in iron reserves.

Transferrin saturation (TSAT), an important marker of iron availability, was also comparable between the two groups, with values of 15.0 ± 2.9% in Group A and 14.8 ± 3.2% in Group B (p = 0.81). Furthermore, renal function as assessed by estimated glomerular filtration rate (eGFR) showed similar values in both groups (32.1 ± 8.1 vs. 31.9 ± 8.4 ml/min/1.73m²; p = 0.88).

Table 2: Hematological Parameters at 4 Weeks

Parameter	Group A: Oral Iron (n = 55)	Group B: IV Iron (n = 55)	p-value
Hemoglobin (g/dL)	9.05 ± 0.84	9.92 ± 0.78	<0.001*
Serum ferritin (ng/mL)	63.5 ± 21.4	124.8 ± 35.2	<0.001*
TSAT (%)	18.4 ± 3.5	22.9 ± 3.8	<0.001*

Table 2 show that at 4 weeks, the mean hemoglobin level increased to 9.05 ± 0.84 g/dL in Group A, whereas a higher rise was noted in Group B, reaching 9.92 ± 0.78 g/dL. This difference was statistically highly significant (p < 0.001), indicating a more pronounced hematological response with intravenous iron therapy.

Similarly, serum ferritin levels, which reflect body iron stores, showed a marked increase in both groups but were substantially higher in the intravenous group. Group A recorded a mean ferritin level of 63.5 ± 21.4 ng/mL, while Group B achieved 124.8 ± 35.2 ng/mL. This difference was also highly significant (p < 0.001), suggesting more effective replenishment of iron stores with intravenous administration.

Transferrin saturation (TSAT), an indicator of circulating iron availability, followed a similar trend. Group A demonstrated an increase to 18.4 ± 3.5%, whereas Group B showed a significantly higher value of 22.9 ± 3.8% (p < 0.001), reflecting better iron utilization in the intravenous group.

Table 3: Hematological Parameters at 8 Weeks

Parameter	Group A: Oral Iron (n = 55)	Group B: IV Iron (n = 55)	p-value
Hemoglobin (g/dL)	9.88 ± 0.93	11.02 ± 0.85	<0.001*
Serum ferritin (ng/mL)	89.7 ± 25.3	178.2 ± 41.5	<0.001*
TSAT (%)	20.6 ± 3.4	26.1 ± 4.3	<0.001*

Table 3 presents the comparison of hematological parameters between the oral iron (Group A) and intravenous iron (Group B) groups after 8 weeks of therapy. Both groups demonstrated continued improvement from baseline and 4-week values; however, the intravenous iron group showed a significantly greater response across all measured parameters.

At 8 weeks, the mean hemoglobin level in Group A increased to 9.88 ± 0.93 g/dL, whereas Group B exhibited a substantially higher level of 11.02 ± 0.85 g/dL. This difference was statistically highly significant ($p < 0.001$), indicating that intravenous iron therapy resulted in a more effective and sustained rise in hemoglobin compared to oral iron.

Serum ferritin levels, reflecting iron stores, also showed a marked difference between the two groups. Group A reached a mean ferritin level of 89.7 ± 25.3 ng/mL, while Group B demonstrated a much higher value of 178.2 ± 41.5 ng/mL. This difference was highly significant ($p < 0.001$), suggesting superior replenishment of iron stores with intravenous therapy.

Similarly, transferrin saturation (TSAT) continued to improve in both groups but remained significantly higher in the intravenous group. Group A recorded a TSAT of 20.6 ± 3.4%, whereas Group B achieved 26.1 ± 4.3% ($p < 0.001$), indicating better iron availability and utilization in patients receiving intravenous iron.

Table 4: Symptom Relief Reported by Patients at 8 Weeks

Symptom Improvement	Group A: Oral Iron (n = 55)	Group B: IV Iron (n = 55)	p-value
Fatigue improved (%)	35 (63.6%)	48 (87.3%)	0.006*
Dyspnea improved (%)	30 (54.5%)	43 (78.2%)	0.01*
Dizziness improved (%)	26 (47.3%)	40 (72.7%)	0.005*

Table 4 show that improvement in fatigue, one of the most common symptoms of iron deficiency anemia, was reported by 63.6% of patients in Group A, whereas a significantly higher proportion of 87.3% in Group B experienced relief ($p = 0.006$). This indicates a more substantial reduction in fatigue among patients treated with intravenous iron. Similarly, improvement in dyspnea was observed in 54.5% of patients in the oral iron group compared to 78.2% in the intravenous group, with the difference being statistically significant ($p = 0.01$). This suggests better functional improvement and enhanced exercise tolerance in the intravenous group. Dizziness also showed notable improvement, with 47.3% of patients in Group A reporting relief, compared to 72.7% in Group B. This difference was highly significant ($p = 0.005$), further supporting the superior clinical efficacy of intravenous iron therapy.

Table 5: Adverse Effects Observed in Both Groups

Adverse Event	Group A: Oral Iron (n = 55)	Group B: IV Iron (n = 55)	p-value
Nausea (%)	15 (27.3%)	4 (7.3%)	0.007*
Constipation (%)	12 (21.8%)	2 (3.6%)	0.004*
Injection site reaction (%)	—	6 (10.9%)	—
No adverse effect (%)	25 (45.5%)	41 (74.5%)	0.003*

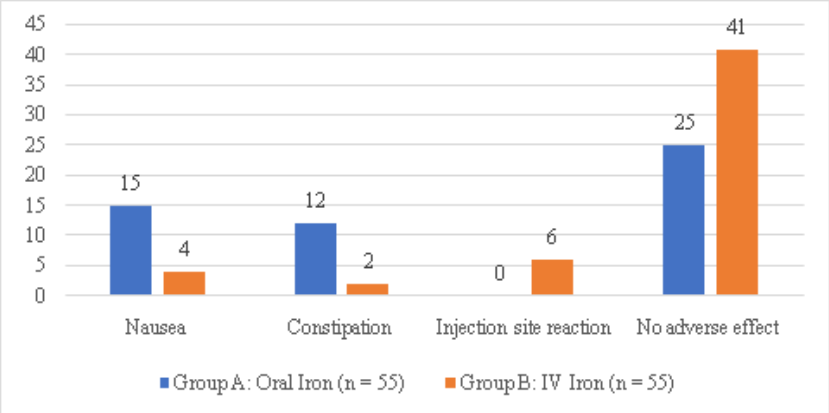

Figure 1: Adverse Effects Observed in Both Groups

Table 5 and figure I, show that nausea was reported in 27.3% of patients in Group A, compared to only 7.3% in Group B, and this difference was statistically significant ($p = 0.007$). Similarly, constipation was observed in 21.8% of patients receiving oral iron, while it occurred in only 3.6% of those in the intravenous group, also showing a significant difference ($p = 0.004$). These findings highlight the higher burden of gastrointestinal intolerance associated with oral iron therapy.

On the other hand, injection site reactions were noted exclusively in the intravenous iron group, affecting 10.9% of patients, which is expected due to the route of administration. As this adverse effect is specific to intravenous therapy, no statistical comparison was applied.

Importantly, a significantly greater proportion of patients in Group B reported no adverse effects (74.5%) compared to Group A (45.5%), with the difference being statistically significant ($p = 0.003$).

Discussion

The baseline demographic and clinical characteristics of both groups were comparable, with no statistically significant differences observed in age, gender distribution, hemoglobin levels, serum ferritin, TSAT, or eGFR ($p > 0.05$ for all parameters). This indicates appropriate randomization and homogeneity between the two groups, ensuring internal validity of the study.

These findings are consistent with recent studies by Sharma et al. (2022) and Lee et al. (2023), who also reported no significant baseline differences between oral and IV iron groups in CKD populations [7, 8]. Similarly, García-Erce et al. (2021) emphasized that comparable baseline characteristics are essential for unbiased assessment of therapeutic outcomes [9]. The similarity in baseline renal function (eGFR) further confirms that disease severity was evenly distributed, minimizing confounding effects.

At 4 weeks, both groups demonstrated improvement in hematological parameters; however, the IV iron group showed significantly greater increases in hemoglobin, serum ferritin, and TSAT ($p < 0.001$). This suggests a faster and more efficient response to IV iron therapy. The rapid rise in hemoglobin and iron indices with IV iron can be attributed to bypassing gastrointestinal absorption barriers and direct replenishment of iron stores. These findings are in agreement with Singh et al. (2024), who reported significantly higher hemoglobin and ferritin levels at early follow-up in patients receiving IV iron [10]. Likewise, Chen et al. (2022) demonstrated that IV iron leads to quicker correction of iron deficiency due to improved bioavailability [11]. Furthermore, Alvarez et al. (2025) highlighted that elevated hepcidin levels in CKD impair oral iron absorption, thereby limiting its efficacy [12]. The present study reinforces this concept, showing superior early hematological improvement with IV therapy.

At 8 weeks, both treatment modalities continued to improve hematological parameters; however, the IV iron group maintained significantly higher hemoglobin, ferritin, and TSAT levels ($p < 0.001$). This indicates not only a faster but also a more sustained therapeutic effect with IV iron.

These results are consistent with findings by Kumar et al. (2023), who reported sustained improvement in hemoglobin and iron stores with IV iron compared to oral therapy over 8–12 weeks [13]. Similarly, Hernandez et al. (2024) observed that IV iron achieved target hemoglobin levels more effectively and maintained adequate iron stores over time [14].

The significantly higher ferritin levels in the IV group reflect more effective iron repletion, while improved TSAT indicates better iron availability for erythropoiesis. These findings align with O'Connor et al. (2022), who emphasized the superiority of IV iron in achieving optimal iron parameters in CKD patients [15].

Symptomatic improvement at 8 weeks was significantly greater in the IV iron group, with higher proportions of patients reporting relief from fatigue, dyspnea, and dizziness ($p < 0.05$). This suggests that the superior hematological response translated into meaningful clinical benefits.

These findings are supported by Patel et al. (2023), who demonstrated improved quality of life and functional capacity in CKD patients receiving IV iron therapy [16]. Similarly, Nguyen et al. (2024) reported significant reductions in fatigue and improved exercise tolerance with IV iron compared to oral supplementation [17]. The correlation between improved hemoglobin levels and symptom relief highlights the clinical relevance of effective anemia management. The present study thus reinforces the importance of IV iron in enhancing patient-centered outcomes.

The safety analysis revealed that oral iron therapy was associated with a higher incidence of gastrointestinal side effects, including nausea and constipation, whereas IV iron therapy had fewer systemic adverse effects but was associated with injection site reactions (10.9%). Importantly, a significantly higher proportion of patients in the IV group reported no adverse effects ($p = 0.003$). These findings are consistent with Reddy et al. (2022), who reported higher rates of gastrointestinal intolerance with oral iron therapy leading to poor compliance [18]. Similarly, Wilson et al. (2025) observed better tolerability with IV iron formulations, with minimal serious adverse

events [19]. Injection site reactions observed in the IV group were mild and expected, as also noted by Martinez et al. (2023) [20]. Advances in IV iron formulations have significantly improved safety profiles, reducing the risk of hypersensitivity reactions.

Overall, the present study demonstrates that IV iron therapy has a more favorable tolerability profile compared to oral iron, with fewer systemic side effects and better patient compliance.

Limitations of the Study

- **Short duration of follow-up:** The study duration of 8 weeks may not reflect long-term efficacy and sustainability of hematological improvement.
- **Single-centre design:** Findings may have limited generalizability to broader populations.
- **Moderate sample size (n = 110):** Although adequate for comparison, a larger sample could provide more robust conclusions.
- **Lack of blinding:** Potential for observer or reporting bias in symptom assessment.
- **No stratification by CKD stages:** Variability in renal function severity may influence response to iron therapy.
- **Absence of quality-of-life scoring tools:** Symptom improvement was subjective and not measured using standardized validated scales.
- **No long-term safety evaluation:** Rare or delayed adverse effects, especially with intravenous iron, were not assessed.

Conclusion

The present study demonstrates that both oral and intravenous iron therapies significantly improve hematological parameters in CKD patients with iron deficiency anemia; however, intravenous iron therapy shows a statistically superior response.

At both 4 and 8 weeks, patients receiving intravenous iron exhibited significantly higher increases in hemoglobin, serum ferritin, and transferrin saturation, indicating more rapid and effective correction of anemia and replenishment of iron stores.

In addition, clinical outcomes were notably better in the intravenous group, with a significantly higher proportion of patients reporting improvement in fatigue, dyspnea, and dizziness.

From a safety perspective, oral iron therapy was associated with a significantly higher incidence of gastrointestinal adverse effects such as nausea and constipation, whereas intravenous iron therapy was generally well tolerated, with only minor injection site reactions observed.

Overall, intravenous iron therapy appears to be more efficacious, faster acting, and better tolerated, making it a preferable option for the management of iron deficiency anemia in CKD patients, particularly in those requiring rapid correction or those intolerant to oral iron.

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