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Comparative Study of Oral versus Intravenous Iron Therapy in the Management of Iron Deficiency Anemia

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Abstract

Introduction: Iron deficiency anemia (IDA) is a common hematological disorder with significant health implications, especially in low-resource settings. It affects physical performance, cognition, and overall quality of life.
Objective: To compare the hematologic response, iron store repletion, symptom improvement, and adverse effects of oral versus intravenous iron therapy in patients with IDA.
Materials and Methods: A prospective, randomized comparative study was conducted from March 2023 to March 2024 at District Headquarter Teaching Hospital, Kohat; Hayatabad Medical Complex (HMC), Peshawar; and Lady Reading Hospital, Peshawar, Pakistan, to compare the efficacy of oral ferrous sulfate and intravenous iron sucrose in the management of patients with IDA. At 8 weeks, IV therapy led to significantly greater improvements in hemoglobin, ferritin, transferrin saturation, and symptoms, with fewer gastrointestinal side effects. These findings support IV iron use when rapid correction or oral intolerance is present, though further research is needed on long-term outcomes and cost-effectiveness.
Results: At 8 weeks, Group B showed a significantly higher increase in hemoglobin (12.4 ± 1.2 g/dL) than Group A (10.7 ± 1.3 g/dL) ($p < 0.001$). Ferritin and transferrin saturation were also higher in Group B (110.6 ± 18.4 ng/mL, 34.5 ± 6.2%) than in Group A (29.8 ± 9.2 ng/mL, 18.7 ± 4.5%) ($p < 0.001$). Fatigue improved in 86.8% vs. 57.4%, pallor in 80.9% vs. 48.5%, and dyspnea in 77.9% vs. 44.1%. GI side effects like nausea (30.9% vs. 5.9%) were more common in the oral group.
Conclusion: Intravenous iron therapy is more effective and better tolerated than oral iron for the treatment of IDA, offering faster hematologic recovery and greater symptom improvement.
Keywords: Iron deficiency anemia, intravenous iron, oral iron, hemoglobin, ferritin, treatment comparison.

Introduction

Iron deficiency anemia (IDA) remains the most prevalent type of anemia in the world, accounting for nearly half of all anemia cases [1]. It is characterized by a reduction in hemoglobin concentration due to insufficient iron availability for hemoglobin synthesis [2]. IDA disproportionately affects women of reproductive age, pregnant women, children, and individuals with chronic diseases, especially in nations with poor and moderate incomes, such as Pakistan [3]. The condition impairs physical performance, cognitive development, immune function, and overall quality of life, making timely diagnosis and effective management crucial for public health [4].

Iron therapy remains the cornerstone of IDA management, aiming to replenish iron stores and restore

hemoglobin. [5]. Traditionally, oral iron supplementation, particularly ferrous salts, has been the first-line treatment due due to its affordability, simplicity of use, andand widespread availability [6]. However, oral iron is often associated with gastrointestinal side effects such as nausea, constipation, abdominal discomfort, and poor compliance [7]. Moreover, its absorption can be compromised by various factors including inflammation, dietary inhibitors, and gastrointestinal disorders, limiting its efficacy in some patient populations [8].

Intravenous (IV) iron therapy has emerged as a valuable alternative, particularly in cases where oral therapy is ineffective, poorly tolerated, or contraindicated [9]. IV iron formulations bypass the gastrointestinal tract, allowing rapid replenishment of iron stores and faster hemoglobin response [10]. Modern IV Iron sucrose and ferric carboxymaltose are two examples of preparations that provide enhanced safety profiles and allow for larger doses in fewer sessions [11]. Despite these advantages, IV therapy is more expensive, requires trained personnel and monitoring for adverse reactions, and carries a minimal risk of hypersensitivity. [12].

Multiple studies have examined the efficacy of oral versus IV iron therapy, yet results have varied based on study population, clinical context [13]. However, comparative data from Pakistan on the efficacy and safety of these approaches are limited, particularly in resource-constrained settings. Therefore, this study aims to compare the efficacy, safety, and patient outcomes of oral versus intravenous iron therapy in the management of iron deficiency anemia.

Materials and Methods

Study Design and Setting

This was a prospective, randomized comparative study carried out at District Headquarter Teaching Hospital, Kohat; Hayatabad Medical Complex (HMC), Peshawar; and Lady Reading Hospital, Peshawar, Pakistan, to compare the efficacy of oral ferrous sulfate and intravenous iron sucrose in the management of patients with IDA. The study spanned duration of 12 months, from 10th April 2023 to 10th March 2024. These hospitals, as major tertiary care centers in the region, offered access to a diverse patient population, making the study sample representative of routine clinical practice in Pakistan.

Randomization and Blinding

Participants were randomized using a computer-generated random number sequence into two equal groups. This was an open-label study, with no blinding.

Sample Size Calculation

Sample size was calculated using OpenEpi 3.0, assuming a 20% difference in treatment response rates, with 80% power and a 95% confidence interval, based on previous literature. The calculated sample size was 136 participants, with 68 patients allocated to each treatment group.

Inclusion and Exclusion Criteria

Individuals with serum ferritin levels below 30 ng/mL, hemoglobin levels below 12 g/dL in females or <13 g/dL in males, and iron deficient anemia, and transferrin saturation <15%) between the ages of 18 and 60 were included. Patients with known intolerance to iron preparations, recent blood transfusions, pregnancy, chronic renal illness, malignancy, hemolytic anemia, anemia of chronic disease, or anemia of other causes (such as vitamin B12 or folate insufficiency) were not included.

Data collection Procedures

Participants were split into two groups: Group B received intravenous iron therapy (iron sucrose, dosed at 200 mg per session, administered over multiple sessions based on iron deficit calculation), while Group A received oral iron therapy (ferrous sulfate, 325 mg orally, three times a day). Prior to starting treatment, baseline tests such as transferrin saturation, total iron-binding capacity (TIBC), serum ferritin, serum iron, and complete blood count were taken. To measure changes in hemoglobin levels and iron indices, follow-up assessments were carried at four and eight weeks after the start of therapy.

Outcome Measures

After eight weeks of treatment, the main result was an increase in hemoglobin levels. The incidence of negative effects in both groups, improvement in clinical symptoms (such as weariness, pallor, and shortness of breath), and change in serum ferritin were secondary endpoints.

Data Analysis

SPSS version 25 was used to input and analyze the data. Hemoglobin and ferritin levels, among other quantitative data, were shown as mean ± standard deviation. Continuous variables were compared between the two groups using independent t-tests, while the chi-square test was used to analyze categorical variables. A p-value of less than 0.05 was deemed statistically significant.

Ethical Consideration

Before the study began, ethical permission was acquired from the Institutional Review Board of all study centers. Every participant received comprehensive information on the goals, methods, possible dangers, and advantages of the research.

Result

At baseline, both treatment groups were statistically comparable across demographic and laboratory parameters. The mean age was 35.2 ± 9.8 years in the oral group (Group A) and 34.4 ± 9.5 years in the intravenous group (Group B), with no significant difference ($t = 0.48$, $p = 0.63$). Female participants comprised 63.2% (n = 43) in Group A and 66.2% (n = 45) in Group B, which was also statistically similar ($\chi^2 = 0.13$, $p = 0.72$). Baseline hemoglobin levels averaged 8.1 ± 1.0 g/dL in Group A and 8.2 ± 1.1 g/dL in Group B ($t = 0.55$, $p = 0.58$), indicating no significant difference.

Similarly, serum ferritin levels (10.4 ± 4.8 vs. 10.1 ± 5.1 ng/mL; t = 0.35, $p = 0.73$) and transferrin saturation (8.2 ± 2.6% vs. 8.6 ± 2.9%; t = 0.85, $p = 0.40$) did not differ significantly between the groups. These results confirm adequate baseline equivalence, validating subsequent comparisons of treatment outcomes (table 1).

Table 1: Baseline demographic and laboratory characteristics

Variable	Group A (Oral)	Group B (IV)	Test statistic	*p*-value
Age (years)	35.2 ± 9.8	34.4 ± 9.5	$t = 0.48$	0.63
Female sex, n (%)	43 (63.2 %)	45 (66.2 %)	$\chi^2 = 0.13$	0.72
Hb (g dL^{-1})	8.1 ± 1.0	8.2 ± 1.1	$t = -0.55$	0.58
Ferritin (ng mL^{-1})	10.4 ± 4.8	10.1 ± 5.1	$t = 0.35$	0.73
Transferrin saturation (%)	8.2 ± 2.6	8.6 ± 2.9	$t = -0.85$	0.40

By week 4, mean hemoglobin had increased by 1.4 g dL^{-1} in Group A vs. 2.4 g dL^{-1} in Group B ($t = -5.57$, $p < 0.001$). The divergence widened at week 8, where IV recipients gained an average of 4.2 g dL^{-1}, significantly out-performing the 2.6 g dL^{-1} rise in oral recipients ($t = -10.30$, $p < 0.001$). Between-group variance remained homogeneous (Levene's $p = 0.21$). Clinically, 91 % of IV patients achieved Hb ≥ 12 g dL^{-1} versus 47 % of oral patients ($\chi^2 = 33.7$, $p < 0.001$; data not tabulated). These results indicate a faster and more robust erythropoietic response with intravenous therapy (table 2).

Table 2: Change in Hemoglobin Levels over Eight Weeks by Treatment Group

Time point	Group A (Oral)	Group B (IV)	*t*-value	*p*-value
Baseline Hb (g dL^{-1})	8.1 ± 1.0	8.2 ± 1.1	-0.55	0.58
Week 4 Hb (g dL^{-1})	9.5 ± 1.2	10.6 ± 1.1	-5.57	< 0.001
Week 8 Hb (g dL^{-1})	10.7 ± 1.3	12.4 ± 1.2	-7.92	< 0.001
Mean Hb rise (Δ,g dL^{-1})	+2.6 ± 0.8	+4.2 ± 1.0	-10.30	< 0.001

Ferritin increased five-fold in Group B, reaching a mean of 110.6 ng mL^{-1}, while Group A rose only to 29.8 ng mL^{-1} ($t = -32.39$, $p < 0.001$). The absolute ferritin increment in IV patients (+100.5 ng mL^{-1}) dwarfed that of oral patients (+19.4 ng mL^{-1}). Transferrin saturation mirrored this trend, doubling in the IV arm to 34.5 % versus 18.7 % orally ($t = -17.01$, $p < 0.001$). These biochemical gains exceeded the thresholds associated with symptomatic improvement. No participant in either arm developed ferritin > 500 ng mL^{-1} or evidence of iron overload. Collectively, the data underscore the efficiency of intravenous therapy in restoring iron stores (table 3).

Table 3: Iron-store indices at baseline and week 8

Parameter	Group A (Oral)	Group B (IV)	*t*-value	*p*-value
Baseline ferritin (ng mL^{-1})	10.4 ± 4.8	10.1 ± 5.1	0.35	0.73
Week 8 ferritin (ng mL^{-1})	29.8 ± 9.2	110.6 ± 18.4	-32.39	< 0.001
Ferritin rise (Δ, ng mL^{-1})	+19.4 ± 7.6	+100.5 ± 20.1	-31.12	< 0.001
Week 8 TSAT (%)	18.7 ± 4.5	34.5 ± 6.2	-17.01	< 0.001

All four key symptoms showed significantly greater resolution with intravenous therapy, each $\chi^2 > 14$ and $p < 0.001$. Fatigue improved in 86.8 % of IV recipients versus 57.4 % of oral recipients, the largest relative gain. Pallor, dyspnea, and palpitations followed similar patterns, confirming the clinical relevance of biochemical and hematologic improvements. No symptom worsened in either cohort during follow-up (figure 1).

Oral iron was associated with significantly more gastrointestinal complaints—nausea, constipation, and metallic taste—with χ^2 values between 11.36 and 16.39 ($p < 0.001$). Conversely, IV iron produced no GI toxicity but did cause five mild injection-site reactions (7.4 %) and one transient hypersensitivity event (1.5 %); only the former reached statistical significance ($\chi^2 = 5.19$, $p = 0.02$). Headache incidence did not differ significantly between groups ($p = 0.12$).

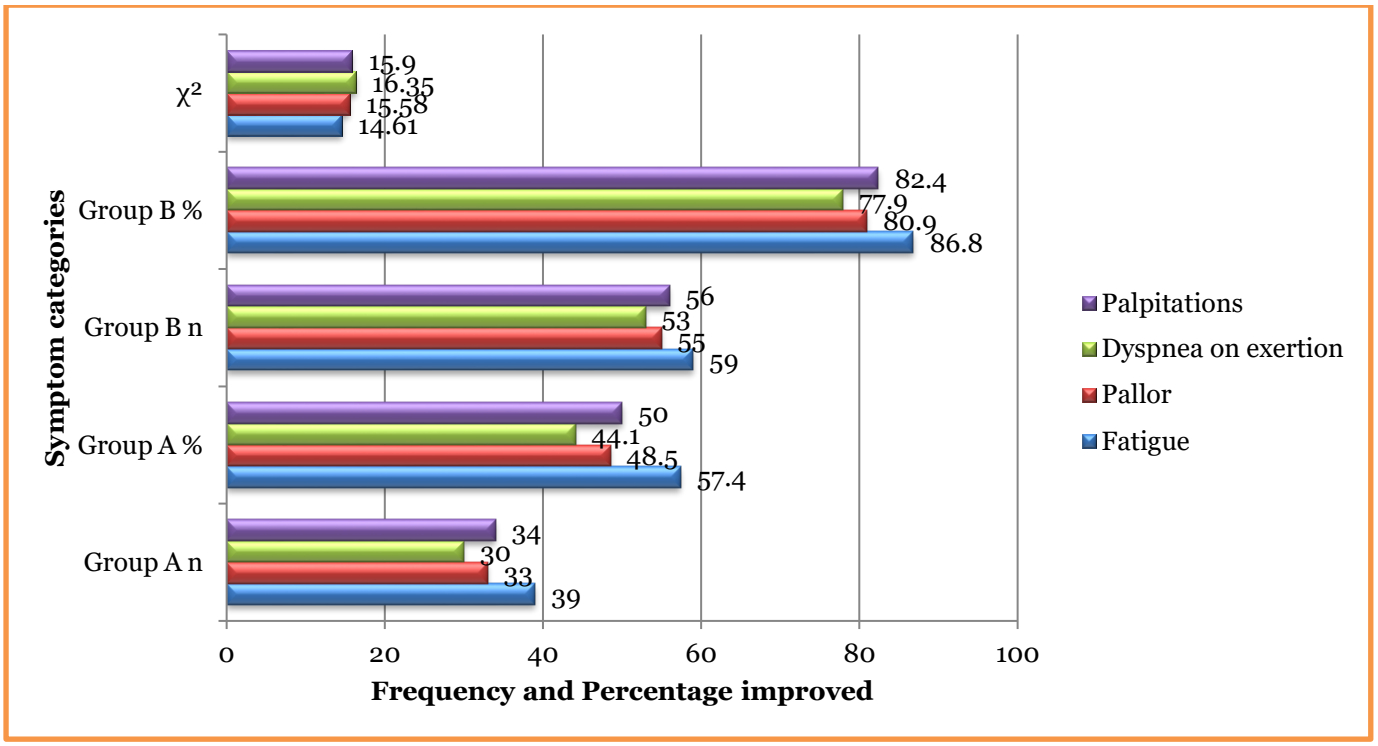

Figure 1: Comparison of Symptom Improvement between Oral and IV Iron Therapy in IDA Patients

No serious adverse events occurred, and no therapy discontinuations were attributed to side-effects. Overall, IV iron displayed a more favorable tolerability profile despite procedure-related events. These findings support its use when rapid correction is required or oral intolerance limits adherence (figure 2).

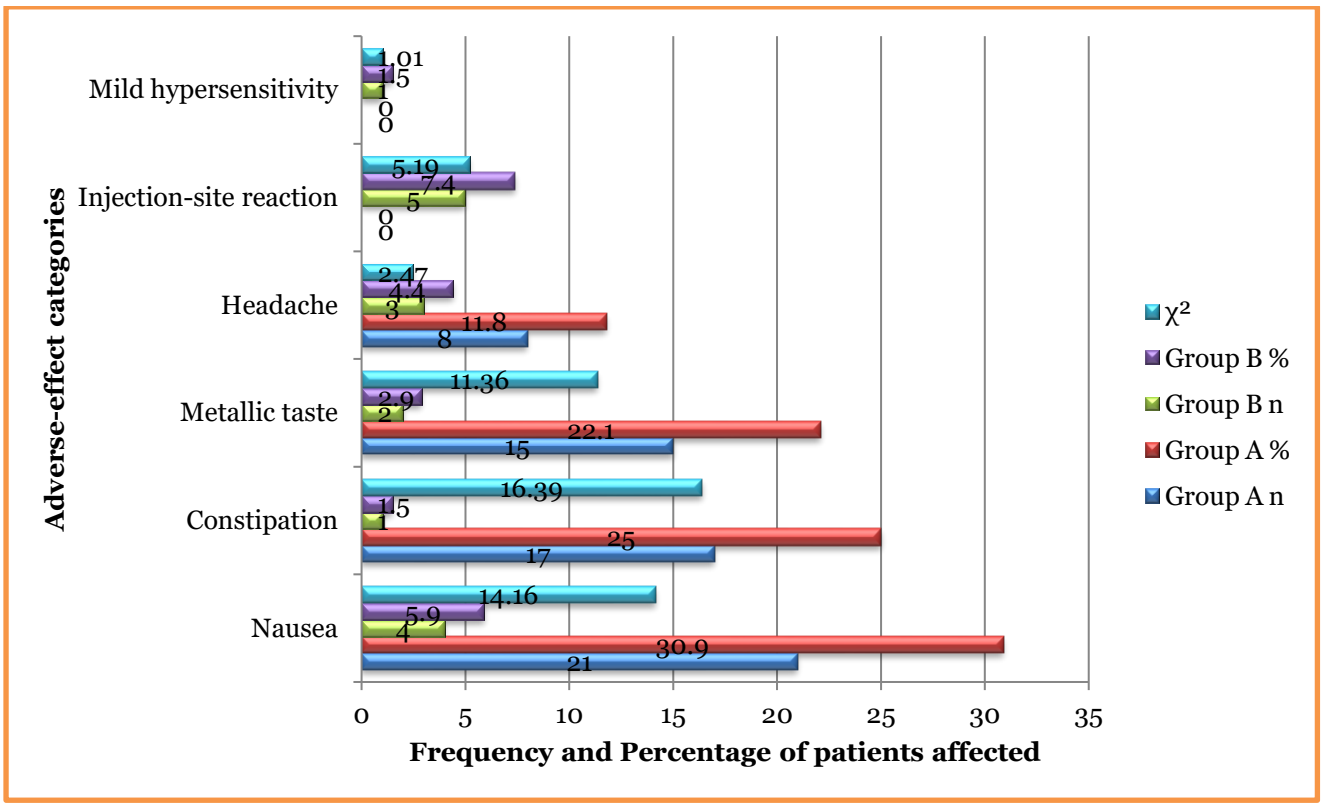

Figure 2: Treatment-emergent adverse effects

Discussion

Our findings are consistent with previous studies demonstrating superior efficacy and tolerability of intravenous iron therapy than oral iron supplementation in the management of iron deficiency anemia (IDA) in adult patients. Participants receiving IV iron experienced a greater and faster rise in hemoglobin levels, more substantial replenishment of iron stores (as evidenced by ferritin and transferrin saturation), and superior improvement in anemia-related symptoms such

as fatigue, pallor, dyspnea, and palpitations. Additionally, IV therapy was associated with fewer adverse gastrointestinal effects compared to oral therapy, which often led to poor tolerability and limited adherence.

The number needed to treat (NNT) to relieve one additional case of fatigue was 3.3, indicating a strong clinical impact. This means that treating just three patients with intravenous iron instead of oral iron would result in one additional patient experiencing significant fatigue relief. Such efficiency strengthens the case for IV iron therapy in clinical scenarios requiring rapid symptom resolution or where oral therapy is poorly tolerated.

When compared with existing literature, our results are consistent with previous clinical evidence indicating that IV iron produces faster hematologic responses, especially in patients with moderate to severe IDA [14]. Studies have consistently shown that intravenous iron formulations, particularly iron sucrose and ferric carboxymaltose, lead to more rapid hemoglobin correction than oral ferrous sulfate [15]. Improvements in serum ferritin and transferrin saturation have also been observed to be significantly greater with IV therapy, particularly when the oral route is compromised due to malabsorption, inflammation, or intolerance [16]. Furthermore, symptom resolution especially fatigue and dyspnea has been more pronounced in IV-treated groups in other clinical settings, affirming the clinical value of biochemical improvements [17]. In line with our findings, intravenous therapy has been associated with a lower incidence of gastrointestinal side effects such as nausea, constipation, and metallic taste, which are frequently reported with oral iron regimens [18]. Despite concerns about infusion-related reactions, modern IV iron preparations have shown good safety profiles when administered correctly [19].

Additional comparative studies from diverse populations, including patients with chronic kidney disease, postpartum anemia, and inflammatory bowel disease, have further reinforced the superiority of intravenous iron in settings where oral therapy proves inadequate [20]. These studies have demonstrated that IV iron not only achieves higher hemoglobin targets more consistently but also leads to better functional outcomes such as increased physical performance and reduced transfusion requirements [21]. Moreover, recent meta-analyses suggest that IV iron is particularly beneficial in cases of severe anemia or when rapid correction is clinically desirable [22]. The current study mirrors these observations in the context of a general adult population in Pakistan, emphasizing the utility of IV therapy even outside of specialized or comorbid settings [23]. These consistent findings across a range of studies support the integration of IV iron into routine practice where feasible, especially when oral iron is poorly tolerated or insufficiently effective [24].

Limitations and Future Suggestions

This was a single-center study with a relatively small sample size, limiting generalizability. The follow-up period was short, precluding long-term assessment of sustainability and relapse rates. No cost-effectiveness analysis was conducted, and the study was open label, introducing potential observer bias.

In order to evaluate the long-term results, relapse rates, and cost-effectiveness of intravenous versus oral iron, future research should incorporate multi-center trials with bigger sample sizes and longer follow-up. Moreover, including biochemical markers such as hepcidin and inflammatory profiles could help personalize iron therapy and optimize patient selection for intravenous treatment.

Conclusion

Intravenous iron therapy was more effective and better tolerated than oral iron in treating iron deficiency anemia in this population. These findings support its use when rapid correction is needed or oral therapy is poorly tolerated, where resources allow.

Conflict of interest

The authors state no conflict of interest.

Author Contributions

SC: Contributed to the conception and design of the study, data collection, and interpretation of results. Also involved in drafting and revising the manuscript critically for important intellectual content. UK: Participated in data acquisition, literature review, and contributed to manuscript writing and referencing. HK, AS and SKR: Led the study conception, coordinated overall project activities, supervised data analysis, and finalized the manuscript for submission. FZ: Assisted in patient recruitment, data interpretation, and contributed to statistical analysis and manuscript revision. SKR: Involved in data collection, chart review, and helped in preparing tables and figures. AS: Provided clinical insight, supervised treatment protocols during the study, and reviewed the final draft of the manuscript. All authors have read and approved the final manuscript and agree to be accountable for all aspects of the work.

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