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Clinical and Haematological Improvement Following a 90-Day Oral Iron Supplementation Regimen in Adults with Iron Deficiency Anemia - A Prospective Real-World Observational Study

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ABSTRACT

Introduction: Iron deficiency anemia (IDA) is a prevalent nutritional disorder worldwide and a major contributor to fatigue, impaired physical performance, reduced quality of life, and increased morbidity. Although oral iron supplementation remains the standard first-line therapy for uncomplicated IDA, treatment outcomes may be affected by poor gastrointestinal tolerability, limited absorption, and adherence challenges. This study evaluated the clinical and hematological outcomes of a structured 90-day oral iron supplementation regimen in adults with moderate to severe IDA.

Method: Fifty adults with moderate to severe IDA completed a 90-day supplementation protocol comprising one oral iron tablet twice daily along with dietary counselling. Hemoglobin (Hb), serum iron, total iron-binding capacity (TIBC), and transferrin saturation (TSAT) were assessed at baseline and Day 90. Clinical symptoms, including generalized weakness, hair loss, and dizziness, were monitored along with treatment compliance and adverse events.

Results: Significant improvements were observed across all hematological parameters following supplementation ($p<0.0001$). Mean Hb increased from 8.82 ± 0.60 g/dL to 13.42 ± 0.50 g/dL, with substantial improvements in serum iron and TSAT and normalization of TIBC levels. Complete resolution of baseline clinical symptoms was reported in all participants. No treatment-related adverse events were observed, indicating good tolerability.

Conclusion: A 90-day oral iron supplementation regimen demonstrated significant hematological recovery, symptomatic improvement, and favourable tolerability in adults with moderate to severe IDA. These findings provide real-world evidence supporting its potential role as an effective nutritional approach for IDA management.

Keywords: Iron deficiency anemia, Hemoglobin, serum iron, transferrin saturation, Total Iron-Binding Capacity.

INTRODUCTION

Iron deficiency anemia (IDA) is the most common nutritional deficiency worldwide and remains a major

public health concern, affecting more than one billion individuals globally. It results from insufficient iron availability for erythropoiesis, leading to impaired hemoglobin synthesis and a reduced oxygen-carrying capacity of the blood. Clinically, IDA manifests with symptoms such as fatigue, generalized weakness, dizziness, impaired cognitive performance, reduced exercise tolerance, and hair loss, all of which adversely affect functional status and quality of life. Despite being largely preventable and treatable, IDA continues to contribute substantially to global morbidity, particularly among women of reproductive age, children, and individuals with chronic illnesses, underscoring the need for effective and well-tolerated treatment strategies [1-3].

Oral iron supplementation remains the standard first-line therapy for uncomplicated IDA because of its affordability, ease of administration, and widespread availability. Nevertheless, the effectiveness of oral iron therapy may be compromised by gastrointestinal adverse effects, poor intestinal absorption, suboptimal adherence, and prolonged treatment duration. These limitations highlight the importance of optimizing oral iron formulations and therapeutic regimens to improve patient compliance and clinical outcomes [2-4,7,8].

Although randomized controlled trials have consistently demonstrated the efficacy of oral iron supplementation in improving hematological parameters, evidence from routine clinical practice remains comparatively limited. Real-world studies are valuable because they evaluate treatment effectiveness under everyday clinical conditions, reflecting patient adherence, tolerability, and outcomes in a broader and more representative population. Furthermore, assessment of both objective hematological recovery and patient-reported symptom improvement provides a comprehensive evaluation of therapeutic benefit [5,6].

The present 90-day real-world clinical study was conducted to evaluate the effectiveness of a structured oral iron supplementation regimen in individuals with moderate to severe iron deficiency anemia. Treatment outcomes were assessed using key hematological parameters, including hemoglobin (Hb), serum iron, total iron-binding capacity (TIBC), and transferrin saturation, together with clinically relevant symptoms such as generalized weakness, dizziness, and hair loss. The findings are intended to provide real-world evidence regarding the hematological response and symptomatic improvement associated with oral iron therapy in patients with iron deficiency anemia.

Case Presentation and Methodology

A prospective, real-world observational study employing a before-and-after design was conducted to evaluate the clinical and hematological outcomes of a 90-day oral iron supplementation regimen in adults with moderate to severe iron deficiency anemia (IDA). Only participants who completed the treatment regimen with documented adherence and attended the scheduled follow-up visit were included in the final analysis.

Written informed consent was obtained from all participants prior to enrolment. Eligible participants were adults aged 18 years or older with hemoglobin levels below the normal reference range and a clinical diagnosis of iron deficiency anemia, accompanied by one or more symptoms including generalized weakness, dizziness, or hair loss. Participants were excluded if they were pregnant or lactating, had a known hypersensitivity to any component of the study formulation, were receiving concurrent iron therapy, or were unable to complete the 90-day follow-up period. Additional exclusion criteria included severe chronic systemic illness, active bleeding disorders, hematological conditions other than iron

deficiency anemia, and incomplete clinical or laboratory data. Serum iron and TIBC were measured using automated colorimetric assays, and transferrin saturation was calculated as (Serum Iron/TIBC) ×100.

All participants received the prescribed oral iron supplementation regimen consisting of one tablet administered twice daily for 90 consecutive days. Standardized dietary counseling emphasizing the consumption of iron-rich foods was provided at baseline to support nutritional management. Treatment adherence was assessed throughout the study, and participants were monitored for adverse events during the treatment period.

Clinical effectiveness was evaluated by comparing baseline (Day 0) and post-treatment (Day 90) hematological parameters, including hemoglobin (Hb), serum iron, total iron-binding capacity (TIBC), and transferrin saturation (TSAT). Improvement in iron deficiency anemia-related symptoms, including generalized weakness, dizziness, and hair loss, was also documented during follow-up.

Statistical analyses were performed using GraphPad Prism version 10.0 (GraphPad Software, Boston, MA, USA). Normality was assessed using the Shapiro–Wilk test. Continuous variables were expressed as mean ± standard deviation (SD), whereas categorical variables were summarized as frequencies and percentages. Changes in hemoglobin, TIBC, and TSAT between baseline and Day 90 were analyzed using the paired Student's t-test. As serum iron values were not normally distributed, changes were evaluated using the Wilcoxon signed-rank test. All statistical tests were two-tailed, and a p-value of less than 0.05 was considered statistically significant. Only participants with complete baseline and Day 90 assessments were included in the final analysis; therefore, no imputation for missing data was performed, and all analyses were conducted using a complete-case approach.

Result

Demographic Characteristics

A total of 50 participants completed the 90-day follow-up and were included in the final analysis. The study population comprised 29 males and 21 females, with an overall mean age of 41.8 ± 11.55 years. The mean age was 46.00 ± 11.18 years among males and 36.00 ± 9.54 years among females (Table 1).

Assessment of Improvement in Hematological Parameters

Following 90 days of oral iron supplementation, statistically significant improvements were observed in all evaluated hematological parameters (Table 2 and Figure 1). Mean hemoglobin concentration increased significantly from 8.82 ± 0.60 g/dL at baseline to 13.42 ± 0.50 g/dL at Day 90, representing a mean increase of 4.60 g/dL (52.2%) ($p < 0.0001$). Serum iron levels increased significantly from 42.14 ± 8.85 µg/dL at baseline to 117.44 ± 11.52 µg/dL after 90 days of treatment, corresponding to a mean increase of 75.30 µg/dL (178.7%) ($p < 0.0001$). Mean total iron-binding capacity (TIBC) decreased significantly from 410.50 ± 16.97 µg/dL at baseline to 296.20 ± 13.42 µg/dL at Day 90, representing a mean reduction of 114.30 µg/dL (27.8%) ($p < 0.0001$). Similarly, mean transferrin saturation (TSAT) increased significantly from 13.84 ± 3.01% at baseline to 32.76 ± 2.75% following treatment, corresponding to a mean increase of 18.92 percentage points (136.7%) ($p < 0.0001$). No participants discontinued treatment during the study period, and all enrolled participants completed both baseline and Day 90 assessments. Overall, oral iron supplementation for 90 days was associated with statistically significant improvements in all evaluated hematological parameters.

Assessment of Reduction in Clinical Symptoms

At screening, all participants (100%) reported at least one symptom associated with iron deficiency anemia, including weakness (n = 27), hair fall (n = 18), and dizziness (n = 9). By Day 90, all participants who had reported these symptoms at baseline experienced complete resolution, resulting in the absence of these symptoms across the study cohort. These findings demonstrate complete symptomatic improvement following the 90-day intervention (Table 3 and Figure 2).

Discussion

This real-world observational study demonstrated that a 90-day oral iron supplementation regimen was associated with significant hematological recovery in adults with moderate to severe iron deficiency anemia. Improvement across multiple iron indices, together with resolution of anemia-related symptoms, suggests that the intervention effectively corrected iron deficiency under routine clinical practice. The observed improvement in hemoglobin was accompanied by normalization of serum iron, transferrin saturation, and total iron-binding capacity, indicating restoration of iron availability and erythropoiesis rather than an isolated increase in hemoglobin concentration.

These findings are consistent with previous clinical studies demonstrating that appropriately administered oral iron therapy can effectively replenish iron stores and improve hematological outcomes in patients with IDA. Patel et al. and Hennigar et al. similarly reported significant improvements in hemoglobin and iron indices following oral iron supplementation, supporting the effectiveness of optimized oral iron therapy in routine clinical practice [5,6]. The direction of improvement observed in the present study is comparable with these reports.

An important clinical observation was the improvement in patient-reported symptoms alongside laboratory recovery. Since fatigue, generalized weakness, dizziness, and hair loss substantially affect daily functioning, symptomatic improvement indicates that hematological correction of iron deficiency anemia translated into clinically meaningful benefit. This is particularly relevant as gastrointestinal adverse effects associated with oral iron therapy often affect adherence and clinical effectiveness [2,7].

Moreover, no treatment discontinuations or treatment-related adverse events were observed during the study, suggesting good tolerability of the supplementation regimen. The observed changes in hemoglobin, serum iron, TIBC, and transferrin saturation collectively reflect improved iron metabolism and enhanced availability of iron for erythropoiesis, consistent with established mechanisms underlying IDA management [1-4].

The real-world design of this study is a key strength, as it evaluates treatment effectiveness through both objective hematological improvements and patient-reported clinical outcomes. However, limitations include the small sample size, lack of a comparator group, inability to separate the effect of dietary counseling from supplementation, and absence of long-term follow-up. Future randomized controlled studies with larger populations and extended monitoring are warranted.

Overall, the evaluated 90-day oral iron supplementation regimen demonstrated significant hematological recovery, symptom resolution, and favorable tolerability, supporting its potential role as a practical nutritional approach for managing moderate to severe IDA.

Conclusion

The present 90-day clinical study demonstrates that the evaluated oral iron supplementation regimen was associated with significant hematological recovery and clinical improvement in adults with moderate to

severe iron deficiency anemia. Marked improvements in hemoglobin, serum iron, total iron-binding capacity (TIBC), and transferrin saturation, including an average hemoglobin increase of 4.6 g/dL, indicate effective restoration of iron status and erythropoietic function. Complete resolution of IDA-related symptoms and the absence of treatment-related adverse events further support the favorable tolerability and clinical utility of this approach. These real-world findings suggest that structured oral iron supplementation may serve as an effective therapeutic strategy for IDA management. Further randomized controlled studies with larger populations and longer follow-up are warranted to validate these outcomes.

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Tables

Table 1. Baseline Demographic Characteristics of the Study Population

Characteristic	Male	Female	Total
Number of participants	29	21	50
Age (years), Mean ± SD	46.00 ± 11.18	36.00 ± 9.54	41.8 ± 11.55

8. *Data are presented as mean ± standard deviation (SD).*

Table 2. Changes in Hematological Parameters from Baseline to Day 90 Following Oral Iron Supplementation

Parameter	Baseline	Day 90	p- value
Hemoglobin (g/dl)	8.82 ± 0.60	13.42 ± 0.50 (+ 52.2%)	<0.0001
Serum iron (µg/dL)	42.14 ± 8.85	117.44 ± 11.52	<0.0001
TIBC (µg/dL)	410.50 ± 16.97	296.20 ± 13.42	<0.0001
Transferrin Saturation (%)	13.84 ± 3.01	32.76 ± 2.75	<0.0001

Data are presented as mean ± standard deviation (SD). Hb, TIBC, and TSAT were analyzed using paired Student's t-test, whereas serum iron was analyzed using the Wilcoxon signed-rank test.

Figures

Figure 1. Improvement in Hematological Parameters Following 90 Days of Oral Iron Supplementation.

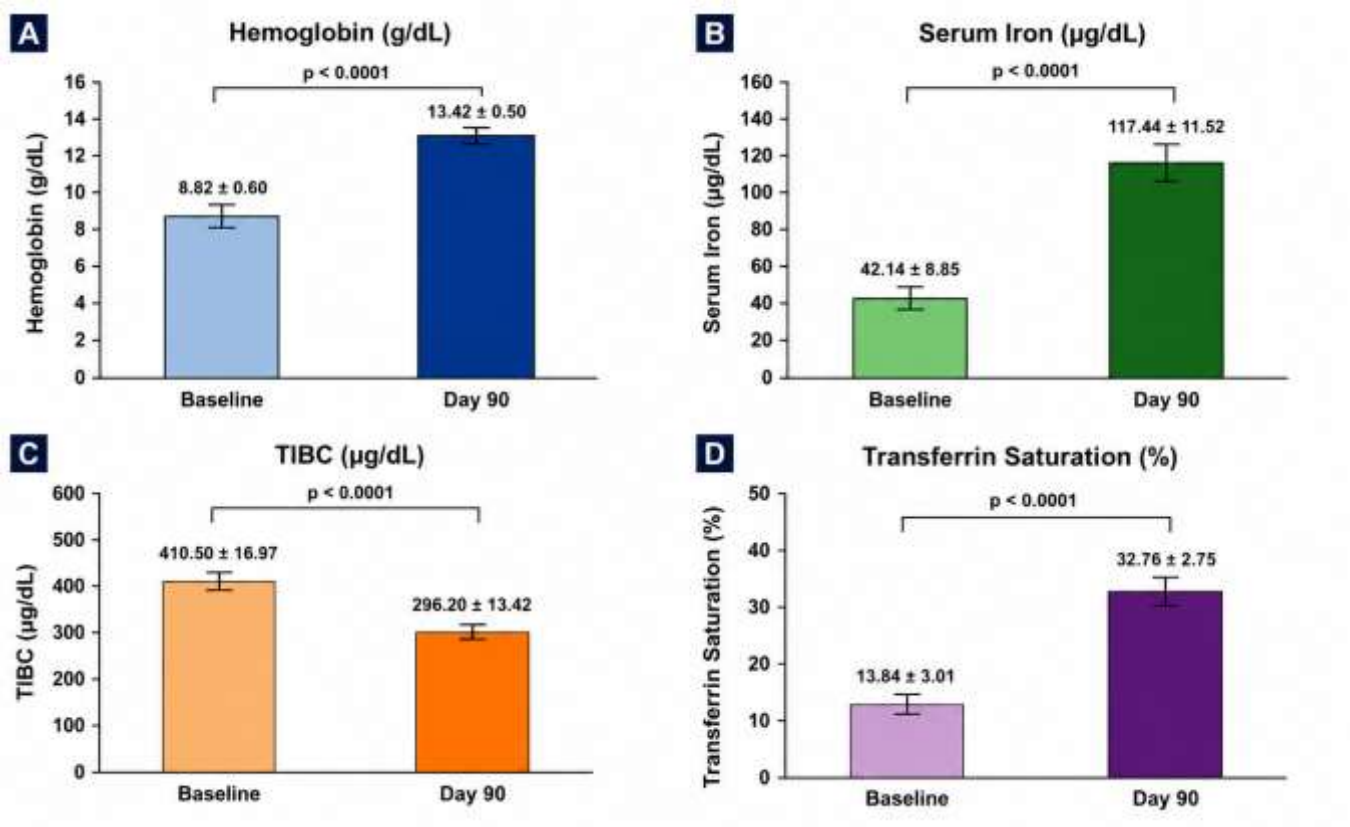

Figure 2: Assessment of Resolution in Clinical Symptoms