International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Real-World Effectiveness and Safety of Ferrous Glycine Sulfate in the Management of Iron Deficiency Anemia: A Multicenter Retrospective Observational Study from India

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OPEN ACCESS

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Received: 22-06-2026
Accepted: 10-07-2026
Available online: 27-07-2026

ABSTRACT

Background: Iron deficiency anemia (IDA) remains the most prevalent nutritional deficiency worldwide and represents a major public health challenge, particularly in low- and middle-income countries. Oral iron supplementation is recommended as first-line therapy for most patients with uncomplicated IDA; however, gastrointestinal intolerance and poor adherence frequently limit treatment success with conventional iron salts. Ferrous glycine sulfate (FGS) is a chelated oral iron formulation used in routine clinical practice, but evidence describing its effectiveness and safety under real-world conditions in India remains limited. This study evaluated the clinical outcomes with FGS treatment in patients with IDA in real-world clinical practice.

Methods: This multicenter, retrospective, observational study included patients diagnosed with IDA treated with FGS between November 2024 and December 2025 at participating centers across India. Data were extracted from anonymized medical records. Baseline demographic and clinical characteristics, treatment details, laboratory parameters, and safety outcomes were collected. Effectiveness was assessed using baseline and follow-up measurements of hemoglobin and other hematological indices, whereas safety analyses included all patients with documented follow-up. Continuous variables were summarized using descriptive statistics, and paired comparisons were performed using appropriate statistical tests.

Results: A total of 4,270 patient records were screened. The effectiveness analysis included 457 patients with paired hemoglobin measurements available at baseline and follow-up. Most documented cases of IDA were attributed to nutritional deficiency and abnormal blood loss. Treatment with FGS resulted in a significant increase in mean hemoglobin from 9.05 ± 1.34 g/dL at baseline to 12.35 ± 1.44 g/dL at follow-up (mean increase 3.30 g/dL; $p<0.001$). Significant improvements were also observed across hematological indices and iron-related biochemical parameters, indicating effective correction of anemia and replenishment of iron stores. No treatment-related adverse events were documented during the study period.

Conclusions: In this multicenter retrospective real-world study, treatment with FGS led to statistically significant improvement in hematological parameters in patients with IDA managed in routine clinical practice. The formulation demonstrated a favorable documented safety profile. Prospective comparative long-term studies are warranted to further characterize the long-term effectiveness and safety of FSG in diverse patient populations.

Keywords: *Iron deficiency anemia; Ferrous glycine sulfate; Oral iron therapy; Real-world evidence; Retrospective observational study; India.*

INTRODUCTION

Iron deficiency anemia (IDA) remains the most common nutritional deficiency worldwide and constitutes a major cause of morbidity across all age groups. According to the World Health Organization (WHO), anemia affects nearly one-third of the global population, with one in three non-pregnant women, more than a third of pregnant women, and approximately 40% of children under five years of age affected. Although anemia has diverse etiologies, including malaria, thalassemia, and chronic illnesses, iron deficiency (ID) accounts for approximately half of all anemia cases, rendering IDA the single most common form of anemia globally.[1,2] Despite considerable progress in public health initiatives, IDA continues to impose a substantial burden on healthcare systems, particularly in low- and middle-income countries where nutritional deficiencies, chronic blood loss, recurrent infections, and limited healthcare access remain common contributing factors.[2,3] India bears one of the highest burdens of IDA globally. National surveys consistently demonstrate a high prevalence of anemia among women of reproductive age, pregnant women, adolescents, and young children.[4,5] Although nutritional iron deficiency remains the predominant cause, other factors including menstrual blood loss, pregnancy, gastrointestinal disorders, parasitic infections, chronic kidney disease, and malabsorption syndromes also contribute significantly to disease burden.[3,6] Beyond hematological abnormalities, untreated IDA adversely affects physical performance, cognitive function, work productivity, pregnancy outcomes, immune competence, and overall quality of life.[6,7]

The primary objective of IDA management is restoration of hemoglobin concentration together with replenishment of body iron stores and correction of the underlying etiology whenever feasible. Current international and national guidelines recommend oral iron supplementation as first-line therapy for most patients with uncomplicated IDA because of its established efficacy, widespread availability, ease of administration, and relatively low cost.[8–11] Intravenous iron therapy is generally reserved for selected clinical situations including severe anemia requiring rapid iron replacement, intolerance to oral iron preparations, malabsorption syndromes, inflammatory bowel disease, or persistent ongoing blood loss.[8–11]

Conventional oral iron preparations, including ferrous sulfate, ferrous fumarate, and ferrous gluconate, have been used extensively for several decades. International guidelines including those from the International Consensus Conference on Anemia Management in Surgical Patients (ICCAMS), British Society of Gastroenterology (BSG) and the American Gastroenterological Association (AGA) consistently recommend oral ferrous preparations as the initial treatment of choice.[8,9] A conventional course lasting 3–6 months is generally required to normalize hematological parameters and ensure iron repletion.[8] Although these formulations are generally effective, their clinical utility may be compromised by gastrointestinal adverse effects such as nausea, abdominal discomfort, constipation, diarrhea, metallic taste, and epigastric irritation. These adverse effects frequently contribute to poor treatment adherence, premature discontinuation, and incomplete correction of iron deficiency in routine clinical practice.[12,13] Consequently, alternative oral iron formulations designed to improve gastrointestinal tolerability while maintaining adequate iron absorption have received increasing clinical interest.

Ferrous glycine sulfate (FGS) is a chelated oral iron formulation in which elemental iron is complexed with glycine. The formulation has been incorporated into routine clinical practice for the management of IDA in several patient populations. While randomized clinical trials have demonstrated the efficacy of oral iron therapy in correcting anemia, evidence describing the performance of FGS under routine clinical practice conditions remains relatively limited, particularly in the Indian setting. Real-world evidence complements findings from randomized controlled trials by evaluating treatment outcomes in heterogeneous patient populations encountered during everyday clinical practice, including patients with multiple comorbidities, varying disease severity, and differences in treatment adherence that may not be fully represented in controlled clinical studies.[14,15]

Retrospective observational studies provide an opportunity to evaluate treatment patterns, effectiveness, and safety using routinely collected healthcare data while reflecting actual physician prescribing behavior and patient management practices. Such studies are particularly valuable in countries with a high burden of iron deficiency anemia, where treatment decisions are frequently influenced by patient characteristics, physician preference, healthcare accessibility, and socioeconomic factors.[15,16]

The present multicenter retrospective observational study was therefore undertaken to evaluate the real-world effectiveness and safety of FGS in patients with IDA treated across multiple centers in India. By analyzing routinely collected clinical data from patients managed in everyday practice, this study aims to provide additional evidence regarding the clinical outcomes associated with FGS while acknowledging the inherent strengths and limitations of retrospective real-world research.

MATERIALS AND METHODS

Study Design

This was a multicenter, retrospective, observational, real-world evidence study conducted across multiple healthcare centers in India. The study evaluated the effectiveness and safety of FGS in patients diagnosed with IDA who received treatment as part of routine clinical practice. Medical records of eligible patients treated between November 2024 and December 2025 were retrospectively reviewed according to a predefined study protocol. As treatment decisions were made

independently by the treating physicians before initiation of the study, no intervention or modification of routine clinical care occurred. The study was designed to reflect routine clinical practice and to evaluate treatment outcomes under real-world conditions rather than under the controlled environment of a randomized clinical trial.

Study Setting and Data Source

Data were obtained from anonymized patient medical records maintained at participating study centers distributed across India. Clinical information was abstracted using a standardized Case Report Form (CRF) developed specifically for the study to ensure uniform data collection across participating investigators. Information collected included demographic characteristics, medical history, underlying causes of IDA, treatment details, laboratory investigations, physician assessments, and safety outcomes documented during routine follow-up visits.

Study Population

Patients diagnosed with IDA with baseline hemoglobin concentration between 4.0 g/dL and <12.0 g/dL treated with FGS as a part of routine clinical practice were eligible, provided there was an availability of baseline clinical evaluation together with at least one documented follow-up visit approximately 4 ± 1 weeks after treatment initiation. Patients were excluded if they had anemia attributable to causes other than iron deficiency, incomplete medical records preventing assessment of study endpoints, and/or active inflammatory or infectious conditions considered likely to substantially influence hematological parameters.

Ethical Considerations

The study protocol and corresponding case record form (CRF) template were reviewed and approved by a registered Institutional Ethics Committee (IEC) prior to study initiation. The study was conducted in accordance with the Ethical Guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Research (ICMR).

Study Methods

Demographic and clinical parameters of patients treated with FGS or other oral iron supplements were collected. At baseline (Assessment 1), data on demographic details (age, gender, height, weight), medical history, presenting complaints, clinical signs, underlying cause of IDA, hematological parameters (Hb, red blood cell [RBC] count, hematocrit, mean corpuscular volume [MCV], mean corpuscular hemoglobin [MCH], mean corpuscular hemoglobin concentration [MCHC], etc.), iron indices (serum iron, ferritin, TIBC, transferrin, transferrin saturation, and soluble transferrin receptor), concomitant medications, comorbidities, and prescribed treatment details (dose, duration, and frequency) were recorded.

At Assessment 2 (first follow-up visit; 4 ± 1 weeks), data on duration of therapy, clinical signs and symptoms, hematological parameters, iron indices, and the physician's assessment of treatment efficacy, safety, tolerability, and compliance (graded as very good, good, average, or poor) were captured. Any adverse events reported during treatment were also documented. Because laboratory investigations were performed according to routine clinical practice rather than a predefined protocol schedule, availability of individual laboratory variables differed across participating centers. Concomitant medications considered necessary for patient management were permitted throughout the observation period.

Outcome Measures

The primary endpoint was to evaluate the clinical response; defined by symptomatic improvement in hemoglobin concentration from baseline to the first available follow-up assessment, changes in hematological parameters and iron indices, treatment duration, compliance and physician's assessment of effectiveness and tolerability. The secondary endpoint was to assess the incidence and nature of adverse events reported during treatment.

Statistical Analysis

The Full Analysis Population comprised all eligible patients who received FGS and had available follow-up documentation after treatment initiation. The safety population included all patients with documented follow-up information available for review. Safety analyses were based on adverse events documented in routine clinical records during the observation period. Statistical analyses were performed using validated statistical software. Continuous variables are presented as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate according to data distribution. Categorical variables are summarized as frequencies and percentages. For patients with paired baseline and follow-up measurements, within-patient changes were evaluated using paired Student's *t*-test for normally distributed variables. When assumptions of normality were not satisfied, the Wilcoxon signed-rank test was considered as a non-parametric sensitivity analysis. All statistical tests were two-sided, and a p-value <0.05 was considered statistically significant.

No imputation was performed for missing data. Analyses were conducted using available cases for each individual endpoint because missing laboratory values reflected routine clinical practice rather than protocol deviations.

Ethical Considerations

The study protocol, case report form, and associated study documents were reviewed and approved by an appropriately constituted Institutional Ethics Committee before study initiation. As this investigation involved retrospective analysis of

anonymized medical records without any patient contact or modification of treatment, informed consent requirements were managed in accordance with applicable national ethical guidelines and Institutional Ethics Committee recommendations. Patient confidentiality was maintained throughout the study. All data were anonymized before analysis, and no patient-identifiable information was accessible to investigators performing the statistical analyses.

RESULTS

Patient Disposition

A total of 4,270 patient records from participating centers were screened for eligibility. Of these, 457 patients had paired baseline and follow-up hemoglobin measurements available and constituted the effectiveness analysis population. Safety analyses included all patients with documented follow-up information available in the medical records.

Baseline Demographic and Clinical Characteristics

The baseline demographic and clinical characteristics of the effectiveness population are summarized in Table 1**.** The mean age of patients was 40.2 ± 11.4 years (range: 12–72 years). Female patients constituted a slight majority of the study population (52.7%**),** higher than the male patients (47.3%). The mean body mass index (BMI) was 23.9 ± 4.4 kg/m²**,** while the average duration of iron therapy was 2.6 ± 0.8 months. Overall, the study population represented a broad spectrum of patients encountered in routine clinical practice, including adolescents and older adults, thereby reflecting the heterogeneous nature of IDA managed in real-world settings.

Table 1. Baseline demographic characteristics (N = 457)

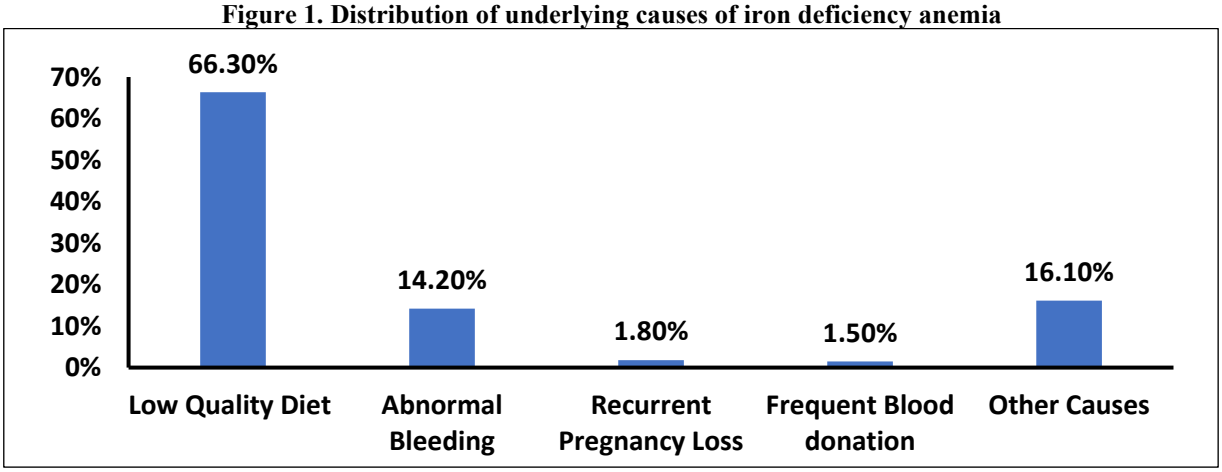
Characteristic	Value
Age (years), mean ± SD	40.23 ± 11.43
Female, n (%)	241 (52.7)
Male, n (%)	216 (47.3)
Height (cm), mean ± SD*	158.24 ± 9.09
Weight (kg), mean ± SD*	59.89 ± 10.30
BMI (kg/m²), mean ± SD*	23.94 ± 4.43
Duration of therapy (months), mean ± SD	2.56 ± 0.80

**Available for patients with recorded measurements*

Underlying Causes of Iron Deficiency Anemia

The underlying causes of IDA are presented in Figure 1. Nutritional deficiency was the most frequently documented underlying cause, accounting for approximately two-thirds of patients (66.3%)**.** Abnormal blood loss represented the second most common etiological category, including irregular menstrual bleeding and other bleeding disorders. Less frequently reported causes included frequent blood donation, chronic kidney disease, urinary tract bleeding, tuberculosis, and other miscellaneous conditions. These findings are consistent with the multifactorial etiology of IDA commonly encountered in routine clinical practice in India.

Figure 1. Distribution of underlying causes of iron deficiency anemia



**Other causes include acute diarrhea, aging and poor absorption, chronic kidney disease, diabetic, inherited disorders.*

Treatment Exposure

Patients received FGS according to routine physician prescribing practices. The average treatment duration was 2.6 months, although treatment duration varied according to individual patient characteristics and physician discretion. The majority of

patients completed the planned treatment period without documented treatment discontinuation attributable to adverse events.

Effectiveness Outcomes

Change in Hemoglobin

Treatment with FGS was associated with a statistically significant improvement in hemoglobin concentration from baseline to follow-up (Table 2). Mean hemoglobin increased from 9.05 ± 1.34 g/dL at baseline to 12.35 ± 1.44 g/dL at follow-up, representing a mean increase of approximately 3.30 g/dL **(**$p < 0.001$**)**. The magnitude of hemoglobin improvement was clinically meaningful and reflected effective correction of anemia in the majority of evaluable patients.

Changes in Hematological Parameters

Significant improvements were also observed in available hematological indices following treatment. Red blood cell count increased significantly between baseline and follow-up (4.26 x 10^{12}/L to 5.14 x 10^{12}/L, $p < 0.001$). Similarly, improvements were observed in hematocrit from 44.74% at baseline to 48.45% at follow-up ($p < 0.001$). Erythrocyte indices also improved significantly, with MCV rising from 88.25 fL to 92.95 fL ($p < 0.001$), MCH from 25.64 pg to 29.23 pg ($p < 0.001$), and MCHC from 27.07 g/dL to 34.02 g/dL ($p < 0.001$), indicating progressive correction of iron-deficient erythropoiesis.

Iron-related Biochemical Parameters

Among patients with available laboratory data, serum iron concentrations increased from 87.80 µg/dL to 136.15 µg/dL ($p < 0.001$), while serum ferritin rose from 122.96 ng/mL to 193.48 ng/mL ($p < 0.001$). Total iron-binding capacity and transferrin also increased significantly (214.51 µg/dL to 334.16 µg/dL and 141.35 mg/dL to 213.84 mg/dL, respectively; both $p < 0.001$), suggesting replenishment of iron stores (Table 2). Because these laboratory investigations were not routinely performed for all patients, the number of evaluable observations differed between individual parameters.

Table 2. Mean Changes in Hematological and Biochemical Parameters from Baseline to Follow-Up

Parameter (units)	N	Baseline mean (SD)	Follow-up mean (SD)	T (df)	P- value*
Hemoglobin (g/dL)	457	9.05 (1.09)	12.35 (1.04)	-53.18 (456)	<0.001
Red blood cells (10^{12}/l)	49	4.26 (0.27)	5.14 (0.38)	-23.85 (48)	<0.001
Hematocrit (%)	305	44.74 (9.12)	48.45 (9.86)	-12.83 (304)	<0.001
Mean corpuscular volume (femtoliters)	44	88.25 (3.78)	92.95 (6.44)	-8.17 (43)	<0.001
Mean corpuscular hemoglobin (picograms)	44	25.64 (1.48)	29.23 (1.31)	-11.03 (43)	<0.001
Mean corpuscular hemoglobin concentration (g/dL)	44	27.07 (0.33)	34.02 (1.69)	-25.76 (43)	<0.001
Serum iron (µg/dL)	310	87.80 (35.16)	136.15 (33.40)	-27.56 (309)	<0.001
Ferritin (ng/ml)	307	122.96 (62.88)	193.48 (80.51)	-17.87 (306)	<0.001
Total iron binding capacity (TIBC) (µg/dL)	43	214.51 (45.04)	334.16 (40.63)	-14.41 (42)	<0.001
Transferrin (mg/dL)	43	141.35 (78.52)	213.84 (113.19)	-13.68 (42)	<0.001
Transferrin saturation (%)	299	21.61 (7.72)	35.68 (9.83)	-27.43 (298)	<0.001
Soluble transferrin receptor (mg/l)	32	2.81 (0.47)	3.59 (0.84)	-8.00 (31)	<0.001

*p-values are significant where indicated, DF: Degrees of Freedom, SD: Standard Deviation, #Mean change (From Baseline to Follow Up) reflects increase in respective value from baseline.

Clinical Response

Among patients with documented follow-up clinical assessments, improvement in symptoms such as generalized weakness, fatigue, dizziness, and reduced exercise tolerance were observed following treatment. Although physician assessments of treatment response were not consistently documented across all participating centers, the available records indicated favorable clinical improvement in the majority of patients.

Safety Outcomes

Safety was evaluated using all patients with available follow-up documentation. No treatment-related adverse events were documented in the medical records during the observation period. Similarly, no serious adverse events, treatment discontinuations due to adverse events, or clinically significant safety concerns attributable to FGS were identified.

DISCUSSION

IDA remains one of the leading causes of morbidity worldwide despite the widespread availability of effective iron replacement therapies.[1-3] Although oral iron supplementation remains the recommended first-line treatment for most

patients with uncomplicated IDA, treatment success in routine clinical practice depends not only on the efficacy of the formulation but also on patient adherence, tolerability, and persistence with therapy.[8-13] Real-world evidence therefore plays an important role in complementing findings from randomized controlled trials by evaluating treatment effectiveness in heterogeneous patient populations managed under routine clinical conditions.[14-16]

In this multicenter retrospective observational study involving patients with IDA treated across multiple centers in India, treatment with FGS was associated with significant improvement in hemoglobin concentration during routine clinical practice. Improvement was also observed in available hematological indices and iron-related biochemical parameters, suggesting recovery from iron deficiency following treatment. These findings support the effectiveness of FGS as an oral iron replacement option in patients with IDA managed in everyday clinical settings.

The demographic characteristics of the study population were consistent with the known epidemiology of iron deficiency anemia. Adult women represented a slight majority of the cohort, reflecting the higher burden of iron deficiency among females attributable to menstrual blood loss, increased iron requirements during pregnancy and lactation, and nutritional deficiencies. Nutritional iron deficiency was the most frequently documented underlying cause of anemia, followed by abnormal blood loss, highlighting the multifactorial etiology of IDA encountered in routine clinical practice. These observations are broadly consistent with national epidemiological surveys and reinforce the continuing public health burden of IDA in India. [4-7]

A clinically meaningful increase in hemoglobin concentration was observed following treatment with FGS. The magnitude of improvement is comparable to the expected hematological response reported for oral iron therapy in appropriately treated patients with iron deficiency anemia. Current clinical guidelines generally recommend an increase in hemoglobin of approximately 1–2 g/dL within the first few weeks of effective oral iron therapy, with continued improvement over subsequent weeks depending on baseline severity, treatment adherence, ongoing blood loss, and correction of the underlying cause of iron deficiency.[8-11] The improvement observed in the present study therefore appears consistent with the expected therapeutic response reported in previous clinical studies of oral iron supplementation.[12,13]

In addition to improvement in hemoglobin concentration, favorable changes were observed in other available hematological indices, including red blood cell count, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, and mean corpuscular hemoglobin concentration. Improvement in these indices reflects correction of iron-deficient erythropoiesis and restoration of normal red blood cell production. Similarly, improvement in serum iron and ferritin concentrations among patients with available laboratory measurements suggests replenishment of body iron stores, which is an important therapeutic objective beyond normalization of hemoglobin alone. [8,11]

The findings of the present study should be interpreted within the context of routine clinical practice. Unlike randomized clinical trials, patients included in this retrospective analysis represented a heterogeneous population with varying disease severity, comorbidities, underlying etiologies of anemia, and treatment patterns. Such heterogeneity enhances the external validity of the findings and provides insight into the effectiveness of FGS under conditions that more closely resemble everyday clinical care.[14–16] At the same time, variability in follow-up schedules and laboratory assessments reflects the realities of routine practice and should be considered when interpreting the results.

No treatment-related adverse events were documented during the observation period. Although this finding suggests that FGS was generally well tolerated in routine clinical use, it should be interpreted cautiously. Because the study relied on retrospective review of routinely maintained medical records, adverse event reporting depended entirely on physician documentation and may not capture mild gastrointestinal symptoms that patients did not report or clinicians did not record. Consequently, the absence of documented adverse events should not be interpreted as evidence that adverse events did not occur but rather as an indication that no clinically documented safety concerns were identified during the study period. Moreover, the favorable tolerability profile of FGS may be related to its chelated formulation. Experimental and pharmacological studies have suggested that chelation of ferrous iron with glycine stabilizes ferrous (Fe^{2+}) iron in the gastric environment, potentially reducing oxidation and gastrointestinal mucosal irritation while facilitating intestinal absorption. [17-19] These properties may contribute to improved gastrointestinal tolerability and treatment adherence compared with conventional ferrous salts; however, this hypothesis was not directly evaluated in the present study.

The strengths of this study include its multicenter design, inclusion of patients treated in routine clinical practice, and evaluation of outcomes in a heterogeneous population representative of patients commonly encountered in outpatient settings. By incorporating data from multiple participating centers, the study reflects diverse prescribing practices and patient characteristics, thereby enhancing the generalizability of the findings within the Indian healthcare setting. Furthermore, the relatively large number of screened patient records contributes valuable real-world evidence regarding the clinical use of FGS, an area in which published data remain limited.[14-16]

Nevertheless, several limitations should be acknowledged. First, the retrospective observational design precludes establishment of a causal relationship between treatment and observed outcomes and is inherently susceptible to selection

bias, information bias, and residual confounding.[16] Second, laboratory investigations were performed according to routine clinical practice rather than a standardized protocol, resulting in incomplete availability of paired laboratory measurements for some variables. Consequently, effectiveness analyses were restricted to patients with available paired data, which may introduce selection bias if these patients differed systematically from those without complete laboratory follow-up. Third, the study did not include a concurrent comparator group receiving an alternative oral iron preparation; therefore, comparative effectiveness between FGS and other oral iron formulations cannot be determined from the present data. Finally, the duration of follow-up was relatively short and may not fully capture long-term maintenance of hematological response, replenishment of iron stores, treatment adherence, recurrence of anemia, or delayed adverse events.

Despite these limitations, the study provides clinically relevant evidence regarding the use of FGS in routine practice. The findings demonstrate that patients receiving FGS experienced improvement in hematological parameters during the observation period, while no new safety concerns were identified from the available medical records. These observations complement existing evidence supporting oral iron therapy in the management of IDA and contribute additional real-world data from the Indian clinical setting. [8-16]

Future prospective studies with long-term follow-up, comprehensive assessment of iron biomarkers, systematic collection of patient-reported outcomes, and direct comparison with other oral iron formulations would further strengthen the evidence base for FGS. Such studies would also help define the patient populations most likely to benefit from this formulation and clarify its role within contemporary strategies for the management of iron deficiency anemia.

CONCLUSION

In this multicenter retrospective real-world observational study conducted across India, treatment with FGS was associated with significant improvement in hemoglobin concentration and favorable changes in available hematological parameters among patients with IDA. No treatment-related adverse events were documented during the study period, although the retrospective nature of the analysis should be considered when interpreting safety findings. Overall, the results support the use of FGS as an effective oral iron replacement option in routine clinical practice. Prospective comparative studies with long-term follow-up are warranted to further characterize its long-term effectiveness, safety, and comparative clinical utility.

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