ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/25aug450

Comparative Study on the Efficacy of IV Iron Sucrose and Oral Ferrous Fumarate in Managing Moderate to Severe Anemia in Pregnant Women

Dr. Rita D[1]; Dr. Nisha M.S[2]

[1]Professor and Head, Department of Obstetrics and Gynecology,
Navodaya Medical College Hospital and Research Centre, Raichur, India
[2]Junior Resident, Department of Obstetrics and Gynecology,
Navodaya Medical College Hospital and Research Centre, Raichur, India

Publication Date: 2025/08/19

Abstract:

- ***Introduction:***

Anaemia affects 35.5% of the pregnant women globally (WHO, 2023), where the prevalence is notably higher in low and middle income countries.[1] In India, 52.2% of pregnant women are anaemic (NFHS-5), with iron deficiency causing over 60% of cases and contributing to complications like PPH, preeclampsia, sepsis, and up to 40% of maternal deaths.[2]Oral Iron (Ferrous sulphate/fumarate) are the First-line treatment for mild to moderate anaemia because it is Cheap, widely available but limited by Gastrointestinal side effects such as Nausea, constipation, metallic taste, Poor compliance due to intolerance.[3] Intravenous Iron sucrose is indicated when oral iron is not tolerated due to GI side effects. IV Iron sucrose is a water-soluble iron (III)-hydroxide complex allowing slow, safe iron release without a test dose. IV Iron Sucrose is safer with fewer hypersensitivity reactions. It is proven to raise haemoglobin and ferritin faster than oral iron; improves iron stores and fatigue.[3]

- ***Aims and objectives:***

To compare hemoglobin improvement between IV iron sucrose and oral ferrous fumarate in moderately to severely anemic pregnant women. To assess adverse effects, patient compliance, and satisfaction associated with each treatment

- ***Methods:***

This is a prospective comparative study which is conducted at Navodaya Medical College Hospital & Research Centre, Raichur, enrolling 100 antenatal women aged 18–35 years with moderate to severe iron-deficiency anemia (Hb 7.0–10.0 g/dL) between 14–28 weeks of gestation. Participants were allocated into two groups:

- **Group I (n=50) received IV iron sucrose, administered on alternate days, with total dose calculated using the standard formula.**
- **Group II (n=50) received oral ferrous fumarate (100 mg elemental iron) twice daily for four weeks.**

Baseline and follow-up hematological parameters (hemoglobin, ferritin, serum iron, TIBC, and hematocrit) were measured at 0, 2, and 4 weeks. Adverse effects, patient compliance, and maternal and neonatal outcomes were also recorded

- ***Results:***

Both groups showed significant improvement in hemoglobin and iron indices, but the group I demonstrated superior outcomes: Hemoglobin levels at 4 weeks: Group I showed an rise in haemoglobin value by 2.1 g/dL vs Group II showed an rise in hemoglobin by 1.1 g/dL which showed statistical significance ($p<0.001$). Serum ferritin increased by 221.8% in the Group I versus 96.4% in the Group II which is statistically significant ($p < 0.001$). Adverse events were more frequent in the Group I (e.g., nausea, constipation), while the Group II had minimal side effects (e.g., mild staining, myalgia).

- ***Conclusion:***

Intravenous iron sucrose is significantly more effective than oral ferrous fumarate in improving hemoglobin levels, replenishing iron stores, and achieving better maternal and neonatal outcomes in pregnant women with moderate to

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severe anemia. It also has a better tolerability profile. IV iron therapy should be considered the preferred modality in cases where rapid correction of anemia is necessary or when oral iron is poorly tolerated, particularly in resource-limited antenatal settings.

Keywords: *Iron Deficiency Anemia; Intravenous Iron Sucrose; Oral Ferrous Fumarate.*

How to Cite: Dr. Rita D; Dr. Nisha M.S (2025) Comparative Study on the Efficacy of IV Iron Sucrose and Oral Ferrous Fumarate in Managing Moderate to Severe Anemia in Pregnant Women. *International Journal of Innovative Science and Research Technology*, 10(8), 645-650. https://doi.org/10.38124/ijisrt/25aug450

I. INTRODUCTION

Anemia during pregnancy poses a significant challenge to global health, contributing substantially to both maternal and fetal morbidity and mortality. The World Health Organization (WHO) reports that anemia affects approximately 35.5% of women worldwide as of 2023, with higher rates found in low and middle income countries [1]. The condition is characterized by a decrease in the oxygen-carrying capacity of blood, primarily due to reduced hemoglobin concentration, and is associated with adverse pregnancy outcomes such as preterm birth, intrauterine growth restriction, low birth weight, and increased perinatal mortality[2].

In India, anemia remains a pervasive public health concern. Data from the National Family Health Survey (NFHS-5) indicate that 52.2% of pregnant women were anemic, with moderate to severe forms of anemia affecting 40–60% of cases depending on the region [3]. Iron deficiency accounts for more than 60% of anemia in pregnancy, making it the most common nutritional deficiency in Indian women of reproductive age [4]. Beyond increasing the risk of complications such as postpartum hemorrhage, preeclampsia, and sepsis, anemia is also responsible for approximately 20% of direct maternal deaths and another 20% through its contribution to indirect causes [5].

The conventional method for addressing iron deficiency anemia during pregnancy involves oral iron supplementation, often administered a ferrous salts such as ferrous sulfate or ferrous fumarate. Oral iron therapy is inexpensive, widely available, and effective in correcting mild to moderate anemia when compliance is adequate [6]. However, the success of oral iron therapy is often limited by poor gastrointestinal tolerability, which includes adverse effects like nausea, vomiting, abdominal discomfort, constipation, and metallic taste. These side effects can significantly reduce patient adherence, compromising treatment efficacy [7].

In recent years, intravenous (IV) iron formulations have emerged as viable alternatives, particularly in cases of moderate to severe anemia, when there is poor response to oral iron, or intolerance to gastrointestinal side effects. Among various IV formulations, iron sucrose has gained popularity due to its improved safety profile, low risk of anaphylaxis, and effectiveness in rapidly correcting iron deficiency [8]. Originally introduced for anemia in patients with chronic kidney disease, iron sucrose is now widely adopted in obstetric practice, especially in hospital-based antenatal care settings.

Iron sucrose is a water-soluble complex of polynuclear iron(III)-hydroxide in sucrose, which allows slow and sustained release of iron, enabling safe administration without the need for a test dose. Compared to older parenteral iron formulations such as iron dextran and iron sucrose has a much lower incidence of severe hypersensitivity reactions [9]. Several randomized controlled trials and systematic reviews have shown that IV iron sucrose leads to a more significant and faster increase in hemoglobin and ferritin levels compared to oral iron [10,11]. It also achieves higher replenishment of iron stores and improves fatigue and functional status in pregnant women.

Despite these advantages, the use of IV iron is still limited in many low-resource settings due to concerns for the need of hospital-based administration, and perceived risks. Moreover, while hematological improvements have been well-documented, evidence on clinical endpoints such as maternal and fetal outcomes, patient satisfaction, and cost-effectiveness remains inadequate.

Due to significant prevalence of anemia among Indian pregnant women and the clinical uncertainties surrounding the optimal treatment modality, this study was undertaken to evaluate and compare the effectiveness of IV iron sucrose and oral ferrous fumarate in the treatment of moderate to severe anemia in pregnancy. The objectives were to assess improvements in hematological parameters (hemoglobin and serum ferritin), monitor adverse effects, evaluate patient compliance and satisfaction, and explore preliminary maternal and neonatal outcomes associated with each treatment modality. The findings are intended to offer guide to evidence-based decisions in antenatal anemia management, particularly in resource-constrained settings where optimizing maternal health is of paramount importance.

II. MATERIALS AND METHODS

A total of 100 antenatal women diagnosed with moderate to severe iron deficiency anemia were enrolled for this randomized controlled study from the Outpatient and Inpatient Departments of Obstetrics and Gynecology, Navodaya Medical College Hospital and Research Centre (NMCH & RC), Raichur.

- **Study Site:** Navodaya Medical College Hospital and Research Centre, Raichur
- **Study Design :** Prospective comparative Study
- **Study Period**: 1 year
- **Sample size**: 100 samples

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/25aug450

➢ *Inclusion Criteria:*

- Age: 18–35 years
- Gestational age: 14–28 weeks (2nd trimester)
- Hemoglobin level: 7.0–10.0 g/dL
- Patients who are willing to participate in the study.

➢ *Exclusion Criteria:*

- Hemoglobinopathies, severe systemic illness
- Multiple pregnancy, recent iron therapy/transfusion
- Hypersensitivity to IV iron.
- Women who did not give consent

III. METHODOLOGY

All participants were provided written informed consent in a language they understood. Confidentiality and anonymity were strictly maintained. The study was carried out following the guidelines and approval of the Institutional Ethics Committee of NMCH & RC, Raichur.

➢ *Sample Size: Study Sample =100, 50 Participants Per Group*

- Group A (n=50) - received IV iron sucrose, administered on alternate days after calculating the iron requirement.

Total Iron Requirement (mg) = 2.4 × Pre-pregnancy weight (kg) × (11 - Actual Hb) + 500

Iron sucrose was administered at a dose of 200 mg, diluted in 100 ml of normal saline infused over a period of 30 minutes on alternate days under medical supervision until the calculated iron requirement was achieved.

- Group B (n = 50) received oral ferrous fumarate (100 mg elemental iron) tablets twice daily for 4 weeks along with 5 mg folic acid once daily.

Baseline investigations including complete blood count (CBC), serum ferritin, serum iron, total iron-binding capacity (TIBC) and peripheral smear were performed before initiation of therapy.

Follow-up assessments were done at 2 and 4 weeks post-initiation, including measurement of hemoglobin, hematocrit, serum ferritin, and documentation of any adverse effects, patient compliance and symptomatic improvement.

➢ *Assessment of Adverse Effects and Compliance*

All participants were instructed to report any side effects immediately. For oral iron, gastrointestinal side effects such as nausea, vomiting, constipation, or metallic taste were noted using a structured checklist. For IV iron, infusion-related reactions including fever, chills, rash, hypotension, or chest discomfort were documented.

Compliance in the oral group was assessed by pill count and participant diary review. In the IV group, compliance was monitored by completion of scheduled infusions under supervision. Non-compliance was defined as missing more than 20% of the prescribed dose.

➢ *Maternal and Fetal Outcome Monitoring*

Maternal outcomes included rise in hemoglobin and ferritin levels, need for additional iron supplementation or blood transfusion, and presence of anemia-related symptoms at follow-up. Delivery-related parameters such as mode of delivery, blood loss, and duration of hospital stay were recorded.

Fetal outcomes assessed included birth weight, gestational age at the time of delivery, APGAR scores at 1 and 5 minutes, and the need for admission to the neonatal intensive care unit (NICU). Neonatal complications such as low birth weight (defined as <2500 grams), preterm delivery (defined as <37 weeks of gestation), and clinical indicators of hypoxia or infection were also evaluated.

➢ *Statistical Analysis*

Data entry was performed using Microsoft Excel, and statistical analyses were conducted using SPSS software version 20.0 for Windows (IBM Corp., Armonk, NY, USA). The Shapiro-Wilk test was applied to evaluate the normality of distribution for continuous variables. Depending on the data distribution, continuous variables were summarized as mean ± standard deviation (SD) or as median with interquartile range (IQR). For comparisons between groups, either the independent samples t-test or the Mann-Whitney U test was utilized, as appropriate. Categorical data were assessed using the Chi-square test or Fisher's exact test.Within-group changes in hemoglobin and serum ferritin levels from baseline to 2 and 4 weeks were examined using the paired t-test or the Wilcoxon signed-rank test, depending on normality. A p-value of less than 0.05 was considered statistically significant. For key clinical outcomes, odds ratios (OR) along with 95% confidence intervals (CI) were calculated

IV. RESULTS

➢ *General Demographic and Baseline Characteristics*

The mean age of participants was 25.84 ± 4.25 years in the Group I and 24.92 ± 3.98 years in the Group II. The mean gestational age at the time of enrollment was 24.2 ± 3.4 weeks in the Group I and 23.9 ± 3.1 weeks in the Group II. The average BMI was slightly higher in the Group I (22.5 ± 2.1 kg/m²) compared to the Group II (21.9 ± 2.3 kg/m²), though not statistically significant (p = 0.182).

A prior history of anemia was reported in 10% of the Group I and 12% of the Group II, while obstetric complications and previous iron therapy were documented in a small subset of participants without significant intergroup differences. These observations confirm that the groups were well matched at baseline (Table 1).

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/25aug450

Table 1 General Demographic and Obstetric History

Parameter	Group I	Group II
Gestational Age (weeks)	24.2 ± 3.4	23.9 ± 3.1
BMI (kg/m²)	22.5 ± 2.1	21.9 ± 2.3
Previous Anemia	5 (10%)	6 (12%)
Obstetric Complications	3 (6%)	4 (8%)
Previous Iron Therapy	4(8%)	5(10%)

➢ *Hematological Response Over Time*

There was a statistically significant rise in hemoglobin levels in both groups over the 4-week study period. At 2 weeks, the mean hemoglobin increased to 9.64 ± 0.54 g/dL in the Group I and 8.91 ± 0.61 g/dL in the Group II ($p < 0.01$). At 4 weeks, hemoglobin levels further increased to 10.32 ± 0.57 g/dL in the Group I and 9.31 ± 0.59 g/dL in the Group II. The difference between the groups at 4 weeks was statistically significant ($p < 0.001$). The percentage increase in hemoglobin from baseline to 4 weeks was 25.55% in the Group I and 14.37% in the Group II ($p < 0.001$) which is statistically significant (Table 2).

Table 2 Hemoglobin Levels at Different Visits

Visits	Group II	Group II	*p value*
Baseline	8.22 ± 0.58	8.14 ± 0.62	0.237
2 Weeks	9.64 ± 0.54	8.91 ± 0.61	<0.01**
4 Weeks	10.32 ± 0.57	9.31 ± 0.59	<0.001**
% Increase	25.55%	14.37%	<0.001**

➢ *Improvement in Iron Stores*

Serum ferritin levels increased significantly in both groups. In the Group I, ferritin rose from 24.3 ± 3.9 ng/mL at baseline to 78.2 ± 6.4 ng/mL at 4 weeks, while in the Group II, it increased from 25.1 ± 4.1 ng/mL to 49.3 ± 5.2 ng/mL ($p < 0.001$). The percentage increase in serum ferritin was 221.8% in the Group I and 96.4% in the Group II which is statistically significant (Table 3).

Table 3 Serum Ferritin Levels

Visits	Group I (ng/mL)	GroupII (ng/mL)	*p value*
Baseline	24.3 ± 3.9	25.1 ± 4.1	0.298
2 Weeks	56.5 ± 5.2	41.8 ± 4.6	<0.01**
4 Weeks	78.2 ± 6.4	49.3 ± 5.2	<0.001**
% Increase	221.8%	96.4%	<0.001**

➢ *Comparison of Other Iron Parameters*

Serum iron levels improved significantly in the Group I, from 47.8 ± 8.5 mcg/dL at baseline to 81.5 ± 8.2 mcg/dL at 4 weeks. In the Group II, levels rose from 45.2 ± 7.6 mcg/dL to 66.9 ± 7.5 mcg/dL ($p < 0.001$). TIBC showed a greater decrease in the Group I (375 ± 30 to 328 ± 22 mcg/dL) compared to the Group II (382 ± 28 to 345 ± 26 mcg/dL) which is significant with $p<0.001$, indicating improved iron availability. Hematocrit also increased more in the Group I (28.5%) than in the Group II (19.3%) with $p<0.001$ which is statistically significant.(Table 4).

Table 4 Iron Parameters and Hematocrit

Parameter	Visit	Group I	Group II	% Change	*p value*
Serum Iron (mcg/dL)	Baseline	47.8 ± 8.5	45.2 ± 7.6	-	0.246
	2 Weeks	68.2 ± 7.1	57.6 ± 6.4	-	<0.01**
	4 Weeks	81.5 ± 8.2	66.9 ± 7.5	70.7% vs 48.0%	<0.001**
TIBC (mcg/dL)	Baseline	375 ± 30	382 ± 28	-	0.317
	2 Weeks	345 ± 26	361 ± 24	-	<0.05**
	4 Weeks	328 ± 22	345 ± 26	-12.5% vs -9.7%	<0.001**
Hematocrit (%)	Baseline	26.3 ± 2.4	25.9 ± 2.1	-	0.418
	2 Weeks	30.1 ± 2.3	28.2 ± 2.0	-	<0.05**
	4 Weeks	33.8 ± 2.5	30.9 ± 2.2	28.5% vs 19.3%	<0.001**

➢ *Adverse Events*

Adverse events were reported in both groups, though they were more frequent and clinically bothersome in the Group II. Five patients in the oral group reported nausea and vomiting, four experienced constipation, and three had epigastric discomfort. In contrast, the Group I reported minimal side effects, including nausea in two patients, fever, chills and rash in three, and mild myalgia in one patient. No severe hypersensitivity or infusion-related complications were observed (Table 5).

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/25aug450

Table 5 Adverse Events

Side Effect	Group I	Group II
Nausea& Vomiting	2	5
Epigastric Pain	1	3
Constipation	1	4
Fever, chills, rash	3	0
Myalgia	1	1

➢ *Maternal and Fetal Outcomes*

Group I had significantly higher birth weight (P<0.05), maternal complications like GI upset were significantly lower in the Group I (2%) compared to the Group II (36%) with p=0.001-which is significant, other outcomes like APGAR core and NICU admissions were not significant (Table 6)

Table 6 Maternal and Fetal Outcome

Parameter	Group I	Group II	*p value*
Need for Additional Iron Therapy	2 (4%)	6 (12%)	0.174
Need for Blood Transfusion	1 (2%)	2 (4%)	0.556
Maternal Complications	Minor – 2%	GI upset – 36%	<0.001*
Duration of Hospital Stay (days)	3.2 ± 0.9	3.5 ± 1.1	0.217
Gestational Age at Delivery	38.2 ± 1.3	37.8 ± 1.5	0.102
Birth Weight (grams)	2876 ± 310	2702 ± 295	<0.05*
APGAR Score (1 min, 5 min)	7.9 / 8.9	7.6 / 8.7	0.086
NICU Admission	3 (6%)	5 (10%)	0.456
Neonatal Complications	Resp. distress – 1	Infection – 2	0.492

V. DISCUSSION

In the present study, table 1 shows age, parity and gestational age were comparable between the group I and Group II p>0.05-which is not significant, this findings align with tonge et al[4] and anjum et al[5] also reported no statistically significant demographic differences between groups before intervention (P>0.05 – not significant)

In the present study, table 2, IV group showed an increase in hemoglobin by 2.1 g/dL and Group II showed an increase in hemoglobin by 1.1 g/dL p<0.001-which is significant aligning with Anjum et al[5] p = 0.001-which is significant showed Significantly higher Hb gain in Group I (p =0.001) which showed it was significant.

In the present study, table 3, Group I showed an increase in 221% of serum ferritin and Group II showed an increase in 96% p<0.001 which is significant. Tonge et al[4] : serum Ferritin post-treatment: Group I vs Group II< 0.001 which is significant. and is consistent with the present study.

In the present study,in table 4,Hematocrit and TIBC improved more significantly in the Group II p < 0.05 which is significant. Soni et al[5] :Total iron-binding capacity reduced significantly with IV therapy and significant haematocrit (p<0.001 – significant)

In the present study, table 5, Group II had more GI side effects (nausea, vomiting, constipation) which is Consistent with Tonge et al[4] Nausea and vomiting in 38% of Group II vs 4% infusion pain in Group I p < 0.01 which is significant and Anjum et al[4] Poor compliance with oral Iron due to GI symptoms in 36% patients.

In the present study, Group I showed better symptom relief, lower transfusion requirement, higher birth weights (2876 g vs. 2702 g; p < 0.05 which is significant). Supports findings by Prajapati & Patel et al[6] Group I showed higher birth weights (mean ~2800g vs 2600g) (p = 0.03- significant) and which is significant.

Limitations of the current study include the relatively short duration of follow-up, limited to four weeks, and the absence of postpartum follow-up to assess sustained correction of anemia and neonatal developmental outcomes. Additionally, biochemical markers beyond ferritin—such as hepcidin or reticulocyte hemoglobin—were not included but could provide additional insights into iron metabolism.

VI. CONCLUSION

Intravenous iron sucrose is significantly more effective than oral ferrous fumarate in treating moderate to severe anemia in pregnant women. While oral iron remains the first-line treatment for mild anemia due to its ease of administration and wide availability, its effectiveness is often limited by poor absorption and gastrointestinal intolerance, leading to suboptimal outcomes in moderate to severe cases whereas IV iron therapy resulted in greater improvements in hemoglobin levels, serum ferritin, hematocrit, and TIBC, with fewer gastrointestinal side effects and better patient compliance.

The Government of India provide free intravenous iron sucrose under national programs like Anemia Mukt Bharat, strengthening for its broader implementation in antenatal care, particularly in resource-limited and high-burden settings. Incorporating IV iron sucrose into routine practice can significantly improve the effectiveness of anemia management in pregnancy and contribute to national goals of reducing maternal and perinatal morbidity and mortality.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/25aug450

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