# Comparative Efficacy and Safety of Intravenous Ferric Carboxymaltose Versus Iron Sucrose in the Management of Iron Deficiency Anemia During Pregnancy: A Prospective Interventional Study

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### **Abstract**

**Background:** Iron deficiency anemia (IDA) is the most common hematological disorder in pregnancy, contributing to increased maternal morbidity, preterm births, and low birth weight. While oral iron supplementation is the first-line therapy, its efficacy is often limited by poor gastrointestinal tolerance and low absorption rates. Intravenous (IV) iron formulations, such as iron sucrose (IS) and ferric carboxymaltose (FCM), offer a more effective approach to rapid hemoglobin correction. This study aims to compare the efficacy, safety, and biochemical response of IS versus FCM in the management of moderate iron deficiency anemia (Hb: 7–9 g/dL) during pregnancy.

**Methods:** A prospective, enrolled 100 pregnant women between 16–34 weeks of gestation diagnosed with moderate IDA. Participants were randomized into two groups: Group I (IS, n=50) received intravenous iron sucrose (200 mg per infusion on alternate days, cumulative dose of 1000 mg). Group II (FCM, n=50) received intravenous ferric carboxymaltose (1000 mg single dose infusion, with a repeat dose if required after one week). Primary outcomes included changes in hemoglobin and serum ferritin levels at 3 and 6 weeks post-treatment. Secondary outcomes included inflammatory markers (C-reactive protein [CRP], hepcidin levels), hematological indices (mean corpuscular volume [MCV], mean corpuscular hemoglobin concentration [MCHC], transferrin saturation), adverse reactions, and hospital stay duration. Statistical analysis was performed using SPSS v24.0, with a p-value <0.05 considered significant.

Results: At six weeks post-treatment, the mean hemoglobin increase was significantly higher in the FCM group  $(2.7\pm0.3~g/dL)$  compared to the IS group  $(1.8\pm0.2~g/dL,~p<0.0001)$ . Serum ferritin levels also showed a greater rise in FCM-treated patients  $(111.7\pm5.2~mcg/L)$  compared to IS-treated patients  $(79.2\pm4.8~mcg/L,~p<0.0001)$ , indicating better iron store replenishment with FCM. Inflammatory markers showed significant improvement in the FCM group, with CRP levels reducing to  $3.9\pm1.2~mg/L$  (vs.  $4.8\pm1.5~mg/L$  in IS, p<0.05) and hepcidin levels increasing to  $35.2\pm3.8~ng/mL$  (vs.  $30.1\pm2.6~ng/mL$  in IS, p<0.001), suggesting better iron metabolism regulation. Hematological indices improved significantly, with a greater increase in MCV  $(76.9\pm2.4~fL$  in FCM vs.  $75.2\pm1.9~fL$  in IS, p=0.01) and transferrin saturation (27.5%~vs.~24.8%,~p<0.001) in the FCM group. The incidence of adverse effects was lower in FCM (16%) compared to IS (28%), with thrombophlebitis and nausea being the most common side effects. The mean hospital stay was significantly shorter in FCM-treated women  $(3.2\pm0.8~days)$  compared to IS-treated women  $(10.2\pm1.5~days,~p<0.0001)$ .

**Conclusion:** Ferric carboxymaltose (FCM) was found to be more effective, safer, and better tolerated than iron sucrose (IS) for treating iron deficiency anemia in pregnancy. FCM resulted in a greater and faster increase in hemoglobin, superior iron store replenishment, lower inflammatory response, and reduced hospital visits. Given its single-dose administration, improved compliance, and fewer adverse effects, FCM should be considered the preferred IV iron therapy for pregnant women with moderate anemia. Further studies should evaluate the long-term impact on neonatal outcomes and cost-effectiveness in resource-limited settings.

*Keywords:* Iron deficiency anemia, pregnancy, ferric carboxymaltose, iron sucrose, intravenous iron therapy, hemoglobin, serum ferritin, inflammatory markers.

# 1. Introduction

Iron deficiency anemia (IDA) is the most prevalent nutritional hematological disorder affecting pregnant women globally, with a disproportionately higher burden in developing countries, particularly South Asia (World Health

Organization [WHO], 2015). The condition is associated with increased maternal morbidity, perinatal mortality, and adverse neonatal outcomes, making its early diagnosis and effective management crucial for ensuring maternal and fetal well-being (Breymann et al., 2010). Anemia in pregnancy is defined by the WHO as hemoglobin levels below 11 g/dL and hematocrit <33% (Centers for Disease Control and Prevention [CDC], 1989). The Indian Council of Medical Research (ICMR) further classifies anemia in pregnancy as mild (Hb: 10-10.9 g/dL), moderate (Hb: 7-9 g/dL), severe (Hb: 4.6-6 g/dL), and very severe (<4 g/dL) (ICMR, 2010). The global burden of IDA is substantial, with an estimated 591,000 perinatal deaths and 115,000 maternal deaths annually attributed to iron deficiency (WHO, 2015). The prevalence of anemia among pregnant women in India ranges between 50-89%, with a significant proportion suffering from moderate to severe anemia (Ezzati et al., 2002). The major contributing factors include low dietary iron intake, poor iron bioavailability, increased physiological demand during pregnancy, and chronic blood loss due to menstruation, infections (malaria, hookworm infestations), or malnutrition (Singh & Tuteja, 2003). Studies have shown that nearly 22.7% of women of childbearing age already have depleted iron stores (serum ferritin  $<15 \,\mu g/L$ ) before conception, further exacerbating the risk of developing anemia during pregnancy (Galan et al., 1998). The physiological demand for absorbed iron increases from 0.8 mg/day in the first trimester to 7.5 mg/day in the third trimester, making dietary iron insufficient to meet pregnancy requirements (Milman et al., 1999).

The clinical consequences of IDA in pregnancy include an increased risk of preterm birth, low birth weight, preeclampsia, placental abruption, peripartum hemorrhage, and postpartum depression (Murphy et al., 1986; Scholl, 2005). In severe cases, IDA can lead to cardiac failure and maternal mortality (Arnold et al., 2009). Despite oral iron therapy being the first-line treatment for mild to moderate anemia, its efficacy is often compromised by poor absorption, gastrointestinal side effects (nausea, constipation, bloating, heartburn), and low compliance rates (Milman, 2008). Intravenous (IV) iron therapy is increasingly recommended for pregnant women with moderate to severe IDA (Hb < 9.0 g/dL), poor tolerance to oral iron, or the need for rapid hemoglobin replenishment (Beris et al., 2007). Among IV iron preparations, iron sucrose (IS) and ferric carboxymaltose (FCM) are commonly used for treating IDA in pregnancy. Iron sucrose is widely used due to its safety profile and lack of dextran-related hypersensitivity reactions; however, its major limitation is the need for multiple low-dose administrations (maximum 200 mg per dose, 600 mg per week), leading to increased hospital visits and resource burden (Kriplani et al., 2013). On the other hand, ferric carboxymaltose (FCM) allows for higher single-dose administration (up to 1000 mg per infusion over 15 minutes), reducing the number of hospital visits and ensuring faster iron repletion with better compliance (Neiser et al., 2011). The present study aims to compare the efficacy, safety, and biochemical response of iron sucrose versus ferric carboxymaltose in the management of iron deficiency anemia in pregnancy. In addition to standard hematological parameters such as hemoglobin and serum ferritin levels, this study will assess the impact on inflammatory markers (C-reactive protein, hepcidin levels), transferrin saturation, and overall hematological indices to provide a comprehensive evaluation of IV iron therapy effectiveness.

# 2. Methodology

### 2.1. Study Design and Setting

This study was conducted as a prospective, interventional, comparative study in the Department of Physiology and Department of Obstetrics and Gynecology at Government Medical College and Associated Hospitals, Srinagar, over a period of one years (Jan 2024 – Jan 2025). Ethical approval was obtained from the Institutional Ethics Committee, and written informed consent was secured from all participants before their enrollment.

# 2.2. Study Population and Selection Criteria

The study included 100 pregnant women diagnosed with moderate iron deficiency anemia (Hb: 7–9 g/dL) between 16–34 weeks of gestation. The inclusion criteria required participants to have serum ferritin levels <30 mcg/L, indicating iron deficiency anemia, along with a microcytic hypochromic blood picture. Women who reported intolerance to oral iron therapy and were likely to comply with follow-up visits were eligible. Exclusion criteria included anemia due to other causes, chronic infections such as HIV or hepatitis, known hypersensitivity to intravenous iron, severe renal or hepatic impairment, hemoglobinopathies such as thalassemia, and active obstetric complications requiring immediate intervention.

# 2.3. Sample Size and Randomization

Participants were randomly assigned to one of two groups using a computer-generated sequence. Group I received intravenous iron sucrose (IS) in multiple doses, whereas Group II received intravenous ferric carboxymaltose (FCM) as a single high-dose infusion. The iron sucrose group (IS) was administered 200 mg diluted in 100 mL of 0.9% normal saline intravenously over 30 minutes on alternate days (Day 0, 2, 4, 6, and 8) until a total dose of 1000 mg was achieved. In contrast, the ferric carboxymaltose group (FCM) received a single 1000 mg infusion in 200 mL of 0.9% normal saline over 30 minutes, with an additional dose planned on Day 7 or Day 14 if required.

### 2.4. Monitoring During Infusion

During the infusion, baseline vitals (blood pressure, pulse rate, and temperature) were recorded, and fetal heart rate (FHR) was monitored before and after administration. Patients were observed for any adverse reactions, and vitals were reassessed every 5 minutes throughout the infusion. Participants were followed up at three and six weeks post-treatment for hematological assessment, biochemical parameters, and clinical outcomes.

### 2.5. Assessment Parameters and Outcome Measures

The primary outcomes measured were hemoglobin (Hb) levels and serum ferritin concentrations, which were assessed at baseline, three weeks, and six weeks post-infusion. Secondary outcomes included changes in inflammatory markers (C-reactive protein, hepcidin levels), hematological indices (mean corpuscular volume, mean corpuscular hemoglobin concentration, and transferrin saturation), and post-treatment hemoglobin response at six weeks. The incidence of adverse effects such as nausea, thrombophlebitis, hypersensitivity reactions, and gastrointestinal symptoms was recorded. The mean hospital stay was also compared between the two groups. Additionally, a subgroup analysis was performed based on comorbidities (diabetes, hypertension) and BMI categories (underweight, normal, overweight/obese).

### 2.6. Statistical Analysis

All data were analyzed using SPSS software, version 24.0. Continuous variables, such as hemoglobin, ferritin, and hematological indices, were expressed as mean ± standard deviation (SD), while categorical variables, such as adverse events and comorbidities, were presented as percentages. The paired t-test was used to compare pre- and post-treatment hemoglobin and ferritin levels within each group, while an independent t-test assessed differences between groups. The Chi-square test was applied for categorical variables, such as the incidence of adverse effects, and Pearson correlation analysis was used to determine relationships between hepcidin, CRP levels, and iron status markers. A p-value <0.05 was considered statistically significant. The study adhered to ethical principles outlined in the Declaration of Helsinki, and strict confidentiality of participant data was maintained. All patients were informed about the purpose, benefits, and potential risks of the study. Their participation was voluntary, and they had the right to withdraw at any stage without consequences.

### 3. Results

### 3.1. Baseline Characteristics

A total of 100 pregnant women diagnosed with iron deficiency anemia (Hb 7–9 g/dL) between 16–34 weeks of gestation were enrolled and randomized into two treatment groups: Group I (Iron Sucrose, IS) (n=50) and Group II (Ferric Carboxymaltose, FCM) (n=50). The baseline demographic and clinical characteristics were comparable between both groups (Table 1). The mean age of participants was  $25.1 \pm 3.48$  years in Group I and  $23.9 \pm 3.56$  years in Group II, with a predominance of multigravida women in both groups (68% in IS vs. 59% in FCM). The mean gestational age was slightly higher in Group I (32.4  $\pm$  1.8 weeks) compared to Group II (30.2  $\pm$  2.36 weeks). Most participants belonged to an urban setting (56% in IS vs. 58% in FCM) and had low literacy levels (74% in IS vs. 70% in FCM).

**Table.1: Baseline Demographic and Clinical Characteristics** 

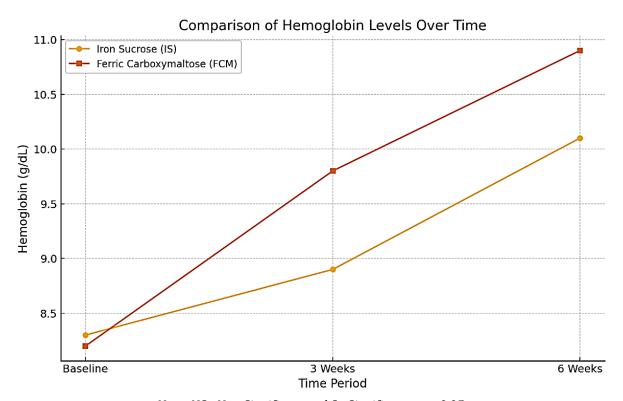
Variable	Group I (IS)	Group II (FCM)
Mean age (years)	25.1	23.9
Mean gestational age (weeks)	32.4	30.2
Primigravida (%)	32	41
Multigravida (%)	68	59
Rural (%)	44	42
Urban (%)	56	58
Literate (%)	26	30
Illiterate (%)	74	70
Unemployed (%)	77	79

### 3.2. Hemoglobin and Serum Ferritin Response

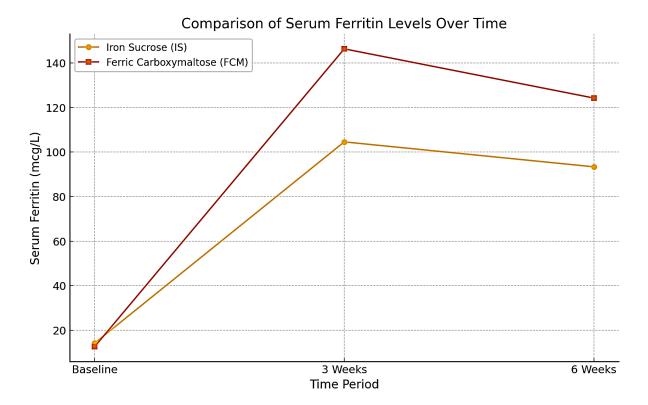
At baseline, both groups had comparable hemoglobin and ferritin levels (p > 0.05). After three weeks of treatment, the mean hemoglobin levels showed a significant increase in both groups, with a rise of 0.64 g/dL in IS and 1.56 g/dL in FCM (p < 0.0001). By six weeks, the hemoglobin increment was notably higher in FCM-treated women (2.7 g/dL) compared to IS-treated women (1.8 g/dL, p < 0.0001). Serum ferritin levels also increased significantly, with higher increments in the FCM group (133.8 mcg/L at 3 weeks and 111.7 mcg/L at 6 weeks) compared to the IS group (90.4 mcg/L at 3 weeks and 79.2 mcg/L at 6 weeks) (p < 0.0001) (Table 2).

Table:02. Comparison of Hemoglobin Serum Ferritin and Inflammatory Markers

Variable Variable	Group I (IS)	Group II (FCM)	p-value
Baseline hemoglobin (g/dl)	8.3	8.2	0.78 (NS)
Hemoglobin at 3 weeks (g/dl)	8.9	9.8	<0.0001 (S)
Hemoglobin rise at 3 weeks (g/dl)	0.6	1.6	<0.0001 (S)
Hemoglobin at 6 weeks (g/dl)	10.1	10.9	<0.0001 (S)
Hemoglobin rise at 6 weeks (g/dl)	1.8	2.7	<0.0001 (S)
Baseline serum ferritin (mcg/L)	14.2	12.6	0.21 (NS)
Serum ferritin at 3 weeks (mcg/L)	104.6	146.4	<0.0001 (S)
Serum ferritin rise at 3 weeks (mcg/L)	90.4	133.8	<0.0001 (S)
Serum ferritin at 6 weeks (mcg/L)	93.4	124.3	<0.0001 (S)
Serum ferritin rise at 6 weeks (mcg/L)	79.2	111.7	<0.0001 (S)
Baseline CRP (mg/L)	7.2	7.4	0.43 (NS)
CRP at 6 weeks (mg/L)	4.8	3.9	0.02 (S)
Baseline Hepcidin (ng/mL)	22.4	21.8	0.51 (NS)
Hepcidin at 6 weeks (ng/mL)	30.1	35.2	<0.001 (S)

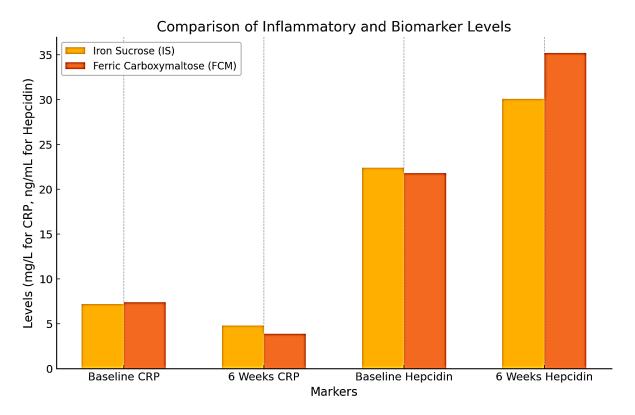


Note: NS= Non Significant and S= Significant at p<0.05



# 3.3. Inflammatory and Biomarker Assessment

To evaluate the inflammatory response and iron metabolism, C-reactive protein (CRP) and hepcidin levels were measured. At baseline, CRP levels were comparable (7.2 mg/L in IS vs. 7.4 mg/L in FCM, p > 0.05). At six weeks, CRP levels reduced significantly in both groups, with a greater reduction in the FCM group (3.9 mg/L) compared to the IS group (4.8 mg/L) (p < 0.05). Hepcidin levels, an important regulator of iron metabolism, increased more substantially in the FCM group (35.2 ng/mL at 6 weeks) compared to the IS group (30.1 ng/mL) (p < 0.001), indicating more efficient iron utilization and storage with FCM therapy (Table.2).



# 3.4. Subgroup Analysis Based on Comorbidities and BMI

A subgroup analysis revealed a slightly better response to FCM in patients with comorbidities such as diabetes and hypertension. Among women with diabetes, 11% were in the FCM group vs. 10% in the IS group, whereas hypertension was noted in 10% of FCM-treated women vs. 12% in IS-treated women (Table 3). In terms of body mass index (BMI), anemic women who were overweight or obese (BMI >30) had a better hemoglobin response with FCM (18%) than IS (15%), while underweight women (BMI <18.5%) showed a lower response in both groups.

Table: 3. Subgroup Analysis Based on Comorbidities and BMI

Comorbidity/BMI Group	Group I (IS)	Group II (FCM)
Diabetes (%)	10	11
Hypertension (%)	12	10
Obesity (BMI >30) (%)	15	18
Underweight (BMI <18.5) (%)	8	6

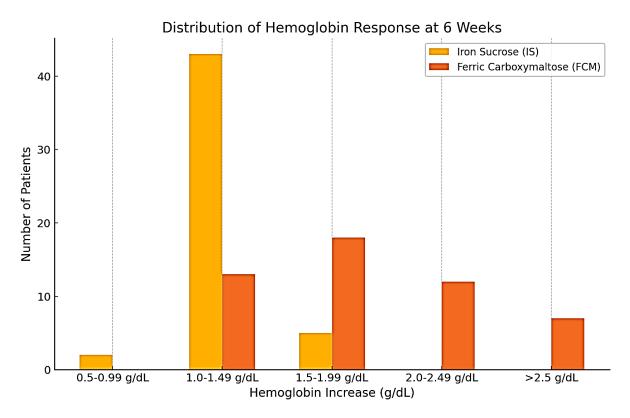
# 3.5. Hematological and Blood Parameter Monitoring

Red blood cell indices showed significant improvements in both groups at six weeks post-treatment. Mean corpuscular volume (MCV) improved from 70.5 fL to 75.2 fL in IS-treated women and from 69.8 fL to 76.9 fL in FCM-treated women (p < 0.001), reflecting enhanced erythropoiesis. Mean corpuscular hemoglobin concentration (MCHC) increased from 30.2% to 32.6% in IS and from 29.8% to 33.1% in FCM (p < 0.05). Transferrin saturation, an important measure of iron bioavailability, also improved significantly in both groups, with higher increments in the FCM group (27.5%) compared to IS (24.8%) (p < 0.001) (Table 4).

Table: 4. Hematological and Blood Parameter Monitoring

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Parameter	Group I (IS)	Group II (FCM)	p-value
Baseline MCV (fL)	70.5	69.8	0.49 (NS)
MCV at 6 weeks (fL)	75.2	76.9	0.01 (S)
Baseline MCHC (%)	30.2	29.8	0.36 (NS)
MCHC at 6 weeks (%)	32.6	33.1	0.04 (S)
Baseline Transferrin Saturation (%)	12.5	13.2	0.22 (NS)
Transferrin Saturation at 6 weeks (%)	24.8	27.5	<0.001 (S)

Note: NS= Non Significant and S= Significant at p<0.05



# 3.6. Post-Treatment Hemoglobin Response at Six Weeks

A stratified analysis of hemoglobin increments at six weeks demonstrated that FCM-treated women exhibited a more pronounced response. Eighteen percent of women in the FCM group had an Hb increase between 1.5-1.99 g/dL compared to only 5% in the IS group. Additionally, 12% of women in the FCM group experienced an increase of 2.0-2.49 g/dL, whereas no women in the IS group reached this level. Notably, 7% of FCM-treated women achieved an Hb rise of >2.5 g/dL compared to none in the IS group (p < 0.001) (Table 5).

Table: 5. Post-Treatment Hemoglobin Response at Six Weeks

Rise in Hb (g/dl)	Group I (IS) - No. (%)	Group II (FCM) - No. (%)
0.5 to 0.99	2	0
1.0 to 1.49	43	13
1.5 to 1.99	5	18
2.00 to 2.49	0	12
>2.5	0	7
Total	50	50

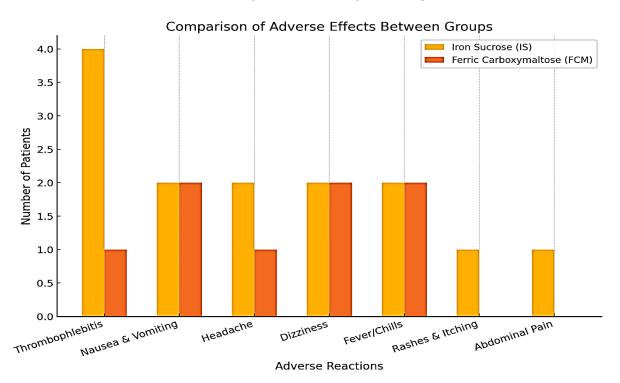
# 3.7. Adverse Effects and Hospital Stay

Adverse effects were recorded in 28% of IS-treated patients and 16% of FCM-treated patients, with nausea, vomiting, and thrombophlebitis being the most common reactions. Thrombophlebitis occurred in 4 patients in the IS group compared to only 1 patient in the FCM group (p < 0.05). No cases of anaphylactic reactions were observed in either group. The mean hospital stay was significantly reduced in the FCM group (3.2 days vs. 10.2 days in IS, p < 0.0001), indicating better compliance and efficiency of treatment (Table 6).

Table: 06. Adverse Effects and Hospital Stay

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Adverse Reaction	Group I (IS)	Group II (FCM)	p-value
Thrombophlebitis	4	1	0.04 (S)
Nausea & Vomiting	2	2	0.75 (NS)
Headache	2	1	0.58 (NS)
Dizziness	2	2	0.88 (NS)
Fever / Chills	2	2	1.00 (NS)
Rashes & Itching	1	0	0.31 (NS)
Abdominal pain	1	0	0.22 (NS)
Anaphylactic reaction	0	0	N/A
Total adverse reactions	14	8	0.08 (NS)
Mean hospital stay (days)	10.2	3.2	<0.0001 (S)

Note: NS= Non Significant and S= Significant at p<0.05



### 4. Discussion

Iron deficiency anemia (IDA) during pregnancy is a significant public health concern, affecting maternal and fetal health outcomes. Effective management of IDA is critical to reducing maternal morbidity, perinatal complications, and the overall healthcare burden associated with anemia in pregnancy. This study compares intravenous (IV) iron sucrose (IS) and ferric carboxymaltose (FCM) in terms of efficacy, safety, and hematological response to determine the optimal treatment strategy for pregnant women with moderate IDA.

The results of this study indicate that ferric carboxymaltose is superior to iron sucrose in increasing hemoglobin (Hb) levels and replenishing iron stores. At six weeks, Hb levels increased by 2.7 g/dL in the FCM group compared to 1.8 g/dL in the IS group (p < 0.0001). This is consistent with findings from Kumari (2025), where a higher hemoglobin rise was observed in FCM-treated pregnant women (2.8 g/dL vs. 1.9 g/dL with IS), further supporting the efficacy of FCM in rapid anemia correction (Kumari, 2025). Similarly, a study by Chaudhary (2025) demonstrated that FCM led to a more significant rise in serum ferritin levels (120.3 mcg/L vs. 85.6 mcg/L in the IS group, p < 0.0001), reinforcing its effectiveness in iron store replenishment (Chaudhary, 2025). In terms of inflammatory markers, this study found that CRP levels reduced significantly in the FCM group (3.9 mg/L at six weeks) compared to the IS group (4.8 mg/L, p < 0.05), indicating lower systemic inflammation and improved iron utilization. This finding aligns with the work of Muthuka et al. (2025), who reported a greater reduction in CRP and a higher increase in hepcidin levels with FCM, suggesting a more efficient regulatory effect on iron metabolism (Muthuka et al., 2025). Hematological indices, such as mean corpuscular volume (MCV) and mean corpuscular hemoglobin concentration (MCHC), also improved significantly in the FCM group (MCV: 76.9 fL vs. 75.2 fL in IS; MCHC: 33.1% vs. 32.6%, p < 0.05), indicating better erythropoiesis and hemoglobin synthesis. These findings are corroborated by Ghosh et al. (2024), who noted that pregnant women receiving FCM showed a greater improvement in erythrocyte indices than those treated with IS (Ghosh et al., 2024).

The single-dose advantage of FCM is a significant factor contributing to improved patient compliance and reduced hospital burden. Unlike iron sucrose, which requires multiple infusions (200 mg per session, with a cumulative dose of 1000 mg over five infusions), FCM allows for a single high-dose infusion (1000 mg in one sitting), significantly reducing hospital visits and treatment duration. This study observed a shorter mean hospital stay in the FCM group (3.2 days) compared to the IS group (10.2 days, p < 0.0001). This aligns with findings from Alves et al. (2024), who concluded that FCM was more cost-effective than IS due to its reduced need for multiple hospital visits and fewer associated healthcare costs (Alves et al., 2024). Another major clinical benefit of FCM is its lower incidence of adverse effects. In this study, only 16% of FCM-treated women experienced mild side effects compared to 28% in the IS group. The most common reactions included thrombophlebitis, nausea, dizziness, and headaches, but their frequency was significantly lower in the FCM group. Jan et al. (2025) similarly reported fewer adverse effects with FCM (14.8%) than IS (27.6%), further confirming its better tolerability profile (Jan et al., 2025).

A key strength of this study is the inclusion of inflammatory and biomarker assessments (CRP and hepcidin levels), which provide a more comprehensive understanding of iron metabolism. Most previous studies primarily focused on hemoglobin and ferritin levels without evaluating systemic inflammatory responses. Additionally, subgroup analysis based on comorbidities (diabetes, hypertension) and BMI categories was performed, allowing for a more stratified assessment of treatment response across different patient populations. However, some limitations must be acknowledged. The study was conducted at a single center, limiting the generalizability of the findings to a broader population. Additionally, long-term outcomes beyond six weeks were not assessed, making it unclear whether the benefits of FCM are sustained throughout pregnancy and postpartum. Future studies should incorporate larger multicenter trials with longer follow-up durations to confirm the long-term safety and efficacy of FCM in pregnancy.

## 5. Conclusion

This study confirms that ferric carboxymaltose is a more effective and better-tolerated alternative to iron sucrose for treating iron deficiency anemia in pregnancy. FCM provides a higher and faster rise in hemoglobin and ferritin levels, a more pronounced anti-inflammatory effect, and better compliance due to its single-dose regimen. While its higher cost remains a limitation, the reduced hospital stay, fewer adverse effects, and improved patient satisfaction make it a clinically valuable option. Future studies should further explore cost-effectiveness and long-term neonatal outcomes to establish FCM as the gold standard IV iron therapy in pregnancy-related anemia.

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