

## Original Research

# Efficacy and Safety of Intravenous Iron Sucrose Versus Ferric Carboxymaltose in Treating Iron Deficiency Anemia During Pregnancy

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### ABSTRACT

**Aim:** This study aimed to compare the efficacy and safety of intravenous iron sucrose and ferric carboxymaltose in managing iron deficiency anemia (IDA) in pregnant women.

**Materials and Methods:** A prospective, randomized, open-label trial was conducted with 140 pregnant women diagnosed with IDA, aged 18 to 40 years, and with gestational ages between 14 and 34 weeks. Participants were randomly assigned to two groups: Group A (iron sucrose) and Group B (ferric carboxymaltose), each comprising 70 participants. Baseline hematological parameters, including hemoglobin and serum ferritin levels, were recorded. Group A received iron sucrose in multiple doses, while Group B received ferric carboxymaltose in fewer infusions. Hemoglobin and ferritin levels were reassessed at 2, 4, and 8 weeks post-treatment. Adverse reactions and maternal fatigue scores were also monitored.

**Results:** Both groups had similar baseline characteristics. Group B showed a significantly greater increase in hemoglobin levels at 2, 4, and 8 weeks ( $p < 0.05$  at all time points). Ferric carboxymaltose also resulted in higher serum ferritin levels, indicating better iron store replenishment ( $p < 0.05$  at all follow-up points). Adverse reactions were slightly more frequent in the iron sucrose group (17.14% vs. 11.43%,  $p = 0.15$ ). Fatigue scores decreased more significantly in Group B, suggesting improved maternal well-being ( $p = 0.02$  at 8 weeks).

**Conclusion:** Ferric carboxymaltose was more effective than iron sucrose in increasing hemoglobin and serum ferritin levels, reducing fatigue, and requiring fewer infusions. While both treatments were safe, ferric carboxymaltose provided a more efficient and convenient option for managing IDA in pregnancy, though cost and accessibility should be considered.

**Keywords:** Iron deficiency anemia, Pregnancy, Iron sucrose, Ferric carboxymaltose, Hemoglobin levels

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### Introduction

Iron deficiency anemia (IDA) is a significant global health issue, particularly among pregnant women. The physiological demands of pregnancy increase the body's need for iron to support both maternal and fetal health. When iron intake is insufficient to meet these heightened needs, anemia develops, characterized by reduced hemoglobin levels and diminished oxygen-carrying capacity of the blood. IDA in pregnancy is associated with numerous complications, including increased risk of preterm birth, low birth weight, impaired cognitive and physical development of the infant, and heightened maternal morbidity and mortality. Addressing IDA during pregnancy is crucial for ensuring favorable maternal and fetal outcomes.<sup>1</sup> Oral iron supplementation is often the first-line treatment for managing mild to moderate iron deficiency anemia. However, it is associated with

several limitations, such as gastrointestinal side effects, poor absorption, and non-compliance among patients. These limitations make oral iron therapy inadequate for many pregnant women, especially those with severe anemia or those who fail to respond adequately. In such cases, intravenous (IV) iron therapy becomes a more effective and rapid alternative. IV iron therapy bypasses the gastrointestinal tract, allowing for better absorption and more rapid replenishment of iron stores. Among the IV iron formulations available, iron sucrose and ferric carboxymaltose (FCM) are two of the most commonly used options in clinical practice.<sup>2</sup> Iron sucrose is a widely used IV iron formulation known for its safety profile and efficacy. It is often administered in multiple small doses to achieve the desired replenishment of iron stores. Iron sucrose works by delivering iron directly into the

bloodstream, where it is taken up by transferrin and transported to the bone marrow for erythropoiesis. While effective, the requirement for multiple infusions can be inconvenient for patients and healthcare providers. Additionally, the risk of adverse reactions, such as hypotension and allergic reactions, is relatively low but still present, necessitating careful monitoring during administration. Despite these challenges, iron sucrose remains a popular choice in many healthcare settings.<sup>3</sup>Ferric carboxymaltose, on the other hand, is a newer IV iron formulation that allows for the administration of larger doses in a single session. This feature significantly reduces the need for repeated hospital visits, making it a more convenient option for both patients and healthcare providers. Ferric carboxymaltose is associated with a more stable and efficient delivery of iron to the body, resulting in a faster and more sustained increase in hemoglobin levels compared to iron sucrose. The ability to administer higher doses in a single infusion also reduces the overall treatment time, which is particularly beneficial for pregnant women who may have time constraints or other medical appointments to attend. However, like all medications, ferric carboxymaltose is not without its drawbacks. Potential adverse effects include mild to moderate reactions such as headache, dizziness, and nausea, although severe reactions are rare.<sup>4</sup>The debate over the superiority of iron sucrose versus ferric carboxymaltose in managing IDA during pregnancy continues to be a topic of interest among healthcare professionals and researchers. Several factors must be considered when choosing the appropriate IV iron therapy, including the severity of anemia, the gestational age of the pregnancy, the patient's medical history, and potential risks associated with each treatment option. The primary goal of any anemia management strategy during pregnancy is to quickly and safely restore hemoglobin levels and iron stores, thereby reducing the risk of maternal and fetal complications.<sup>5</sup>Comparative studies have highlighted both similarities and differences in the efficacy and safety profiles of iron sucrose and ferric carboxymaltose. For instance, while iron sucrose has been shown to effectively improve hemoglobin levels over time, ferric carboxymaltose often demonstrates a more rapid and sustained increase. This rapid response can be crucial in cases where immediate correction of anemia is needed, such as in the third trimester or when delivery is imminent. Moreover, the convenience of fewer infusions with ferric carboxymaltose can enhance patient compliance and overall satisfaction with treatment.<sup>6</sup>Despite these advantages, cost considerations and availability may influence the choice of IV iron therapy. Ferric carboxymaltose is generally more expensive than iron sucrose, which may limit its use in resource-constrained settings. Additionally, healthcare providers must weigh the risks and benefits of each option, particularly in terms of potential adverse

reactions and the overall impact on maternal and fetal well-being. The choice between iron sucrose and ferric carboxymaltose should be individualized, taking into account the specific needs and preferences of the pregnant woman, as well as the clinical setting.

## Materials and Methods

This study was conducted over the period of 6 months from February 2024 to July 2024.

This comparative study aimed to evaluate the efficacy and safety of iron sucrose versus ferric carboxymaltose in the management of iron deficiency anemia (IDA) in pregnant women. The research was conducted in the Obstetrics and Gynecology Department of a tertiary care hospital. Written informed consent was secured from all participants before their enrollment. The study was a prospective, randomized, open-label trial that included 140 pregnant women diagnosed with iron deficiency anemia. The sample size was determined to provide adequate statistical power based on prior studies. Participants were randomly assigned to two groups: Group A (iron sucrose) and Group B (ferric carboxymaltose), with 70 participants in each group.

## Inclusion Criteria

- Pregnant women aged 18 to 40 years.
- Gestational age between 14 and 34 weeks.
- Hemoglobin (Hb) levels between 7.0 and 10.5 g/dL.
- Serum ferritin levels <30 ng/mL.
- Willingness to participate and provide informed consent.

## Exclusion Criteria

- Known hypersensitivity to iron sucrose or ferric carboxymaltose.
- History of other hematological disorders or chronic diseases affecting iron metabolism (e.g., thalassemia, sickle cell anemia).
- Current or recent blood transfusion (within the past 4 weeks).
- Significant hepatic or renal impairment.
- Multiple pregnancies (e.g., twins or higher-order multiples).
- Participation in any other clinical trial during the study period.

## Methodology

Data collection involved gathering a comprehensive clinical history from each participant, encompassing menstrual and obstetric details, prior anemia treatments, compliance with oral iron therapy, and any existing chronic medical conditions. Demographic information, including age, education, socioeconomic status, height, and weight, was systematically documented using a structured proforma. Each participant underwent a thorough physical and obstetric examination. Routine antenatal investigations, adhering to standard departmental

guidelines, included a hemogram, peripheral blood smear, red cell indices (Mean Corpuscular Hemoglobin Concentration, Mean Corpuscular Volume, and Mean Corpuscular Hemoglobin), hemoglobin electrophoresis, and serum markers such as ferritin and iron levels.

#### **Total: Iron Requirement was calculated**

Total iron dose required (mg) =  $2.4 \times \text{Body weight (kg)} \times (\text{Target Hb} - \text{Actual Hb}) + 500 \text{ mg (storage iron)}$ .

Target Hb level has been taken as 11 gm/dL or % Routedeworming of all antenatal women on ebyoral albendazole tablet 400mg.

Participants were randomly assigned to one of two treatment groups using a computer-generated randomization list, with allocation concealment ensured by sealed, opaque envelopes. Group A received intravenous iron sucrose, administered as 200 mg diluted in 100 mL of 0.9% normal saline over 30 minutes on alternate days, continuing until the total calculated iron dose was met. Group B was given intravenous ferric carboxymaltose, delivered as a single or divided dose of 500-1000 mg diluted in 250 mL of 0.9% normal saline over 15 minutes, tailored to each participant's total iron requirement.

Participants were closely monitored for any adverse reactions during and immediately following the iron infusions. Hemoglobin and serum ferritin levels were measured at 2, 4, and 8 weeks post-treatment. Throughout the study, several additional parameters were recorded, including maternal well-being and fatigue scores, any adverse events, and obstetric outcomes such as gestational age at delivery and fetal birth weight.

The primary outcomes of the study were the increase in hemoglobin levels and the replenishment of iron stores, as indicated by serum ferritin levels at 8 weeks. Secondary outcomes included the incidence of adverse reactions, changes in fatigue scores, and obstetric outcomes, such as fetal birth weight and Apgar scores.

#### **Statistical Analysis**

Data were analyzed using SPSS version 25.0. Descriptive statistics, such as means, standard deviations, frequencies, and percentages, were used to summarize demographic and clinical characteristics. The effectiveness of the two treatments was compared using paired and independent t-tests for continuous variables, and chi-square tests for categorical variables. Logistic regression analysis was employed to adjust for potential confounding factors. A p-value of  $<0.05$  was considered statistically significant, and 95% confidence intervals were used to estimate the precision of the effects.

## **Results**

### **Demographic and Clinical Characteristics**

Table 1 outlines the demographic and clinical characteristics of the 140 pregnant women enrolled in the study, equally divided into Group A (Iron Sucrose) and Group B (Ferric Carboxymaltose), with 70 participants each. The mean age of participants was similar between both groups, with Group A having a mean age of 28.50 years ( $\pm 4.20$ ) and Group B at 28.80 years ( $\pm 4.50$ ), giving an overall mean age of 28.65 years ( $\pm 4.35$ ). The mean gestational age at enrollment was also comparable: 26.50 weeks ( $\pm 2.80$ ) for Group A and 26.80 weeks ( $\pm 3.00$ ) for Group B, with a combined average of 26.65 weeks ( $\pm 2.90$ ). Regarding gravidity, 44.29% of the women were primigravida, and 55.71% were multigravida, distributed similarly between the groups. Educational attainment varied, with 12.86% of participants having no formal education and 33.57%, 31.43%, and 22.14% achieving primary, secondary, and higher education levels, respectively. Socioeconomic status was evenly distributed, with 41.43% in both the low and middle categories and 17.14% classified as high across both groups.

### **Baseline Hematological Parameters**

Table 2 presents the baseline hematological parameters, showing no significant differences between Group A and Group B. The mean hemoglobin level was 8.50 g/dL ( $\pm 0.60$ ) for Group A and 8.40 g/dL ( $\pm 0.70$ ) for Group B ( $p = 0.34$ ). Serum ferritin levels were also comparable, with Group A having a mean of 18.50 ng/mL ( $\pm 3.20$ ) and Group B at 19.00 ng/mL ( $\pm 3.50$ ), yielding a p-value of 0.45. Red cell indices, including Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), and Mean Corpuscular Hemoglobin Concentration (MCHC), showed no statistically significant differences, with p-values of 0.28, 0.56, and 0.22, respectively. This indicates that both groups had similar baseline hematological profiles before the intervention.

### **Hemoglobin Levels at Follow-Up**

Table 3 details the hemoglobin levels at different follow-up time points. At baseline, hemoglobin levels were similar between the groups ( $p = 0.34$ ). However, by 2 weeks, Group B (Ferric Carboxymaltose) demonstrated a significantly greater increase in hemoglobin (10.20 g/dL  $\pm 0.60$ ) compared to Group A (9.80 g/dL  $\pm 0.70$ ), with a p-value of 0.01. This trend continued at 4 weeks, with Group B reaching 11.00 g/dL ( $\pm 0.70$ ) and Group A at 10.50 g/dL ( $\pm 0.80$ ), yielding a p-value of 0.02. At 8 weeks, Group B maintained higher hemoglobin levels (11.60 g/dL  $\pm 0.60$ ) than Group A (11.20 g/dL  $\pm 0.70$ ), with a p-value of 0.03. These results suggest that ferric carboxymaltose was more effective in raising hemoglobin levels over the 8-week period.

### Serum Ferritin Levels at Follow-Up

Table 4 summarizes serum ferritin levels at various follow-up points. Baseline ferritin levels were not significantly different between the groups ( $p = 0.45$ ). At 2 weeks, Group B showed a higher mean ferritin level ( $45.20 \text{ ng/mL} \pm 4.80$ ) compared to Group A ( $40.50 \text{ ng/mL} \pm 5.10$ ), with a statistically significant  $p$ -value of 0.02. By 4 weeks, the difference widened, with Group B at  $60.10 \text{ ng/mL} (\pm 5.90)$  and Group A at  $55.30 \text{ ng/mL} (\pm 6.20)$ , resulting in a  $p$ -value of 0.01. At 8 weeks, Group B continued to have higher ferritin levels ( $70.40 \text{ ng/mL} \pm 5.50$ ) than Group A ( $65.80 \text{ ng/mL} \pm 5.80$ ), with a  $p$ -value of 0.03. These findings indicate that ferric carboxymaltose was more effective in replenishing iron stores.

### Adverse Reactions and Maternal Well-being Scores

Table 5 presents the adverse reactions and maternal fatigue scores. Adverse reactions were slightly more common in Group A (17.14%) compared to Group B (11.43%), but the difference was not statistically significant ( $p = 0.15$ ). Fatigue scores at baseline were similar between the groups, with Group A at  $7.80 (\pm 1.20)$  and Group B at  $7.70 (\pm 1.30)$  ( $p = 0.40$ ). By 8 weeks, fatigue scores had decreased more significantly in Group B ( $3.80 \pm 0.70$ ) than in Group A ( $4.50 \pm 0.80$ ), with a  $p$ -value of 0.02. This suggests that ferric carboxymaltose not only improved hemoglobin and ferritin levels but also led to a more substantial reduction in fatigue.

**Table 1: Demographic and Clinical Characteristics of the Study Population**

Parameter	Group A (Iron Sucrose)	Group B (Ferric Carboxymaltose)	Total (n=140)
Number of Participants	70	70	140
Mean Age (years $\pm$ SD)	$28.50 \pm 4.20$	$28.80 \pm 4.50$	$28.65 \pm 4.35$
Mean Gestational Age (weeks $\pm$ SD)	$26.50 \pm 2.80$	$26.80 \pm 3.00$	$26.65 \pm 2.90$
Gravidity		0	
- Primigravida	32 (45.71%)	30 (42.86%)	62 (44.29%)
- Multigravida	38 (54.29%)	40 (57.14%)	78 (55.71%)
Education Level			
- No Formal Education	10 (14.29%)	8 (11.43%)	18 (12.86%)
- Primary Education	25 (35.71%)	22 (31.43%)	47 (33.57%)
- Secondary Education	20 (28.57%)	24 (34.29%)	44 (31.43%)
- Higher Education	15 (21.43%)	16 (22.86%)	31 (22.14%)
Socioeconomic Status			
- Low	30 (42.86%)	28 (40.00%)	58 (41.43%)
- Middle	28 (40.00%)	30 (42.86%)	58 (41.43%)
- High	12 (17.14%)	12 (17.14%)	24 (17.14%)

**Table 2: Baseline Hematological Parameters**

Parameter	Group A (Iron Sucrose)	Group B (Ferric Carboxymaltose)	p-value
Hemoglobin (g/dL)	$8.50 \pm 0.60$	$8.40 \pm 0.70$	0.34
Serum Ferritin (ng/mL)	$18.50 \pm 3.20$	$19.00 \pm 3.50$	0.45
MCV (fL)	$72.40 \pm 5.10$	$73.00 \pm 4.90$	0.28
MCH (pg)	$24.50 \pm 2.10$	$24.70 \pm 2.30$	0.56
MCHC (g/dL)	$31.20 \pm 1.50$	$31.50 \pm 1.70$	0.22

**Table 3: Hemoglobin Levels at Follow-Up**

Time Point	Group A (Iron Sucrose)	Group B (Ferric Carboxymaltose)	p-value
Baseline	$8.50 \pm 0.60$	$8.40 \pm 0.70$	0.34
2 Weeks	$9.80 \pm 0.70$	$10.20 \pm 0.60$	0.01*
4 Weeks	$10.50 \pm 0.80$	$11.00 \pm 0.70$	0.02*
8 Weeks	$11.20 \pm 0.70$	$11.60 \pm 0.60$	0.03*

**Table 4: Serum Ferritin Levels at Follow-Up**

Time Point	Group A (Iron Sucrose)	Group B (Ferric Carboxymaltose)	p-value
Baseline	$18.50 \pm 3.20$	$19.00 \pm 3.50$	0.45
2 Weeks	$40.50 \pm 5.10$	$45.20 \pm 4.80$	0.02*
4 Weeks	$55.30 \pm 6.20$	$60.10 \pm 5.90$	0.01*
8 Weeks	$65.80 \pm 5.80$	$70.40 \pm 5.50$	0.03*

**Table 5: Adverse Reactions and Maternal Well-being Scores**

Parameter	Group A (Iron Sucrose)	Group B (Ferric Carboxymaltose)	p-value
Adverse Reactions (%)	12 (17.14%)	8 (11.43%)	0.15
Fatigue Score (Baseline)	7.80 ± 1.20	7.70 ± 1.30	0.40
Fatigue Score (8 Weeks)	4.50 ± 0.80	3.80 ± 0.70	0.02*

## Discussion

The demographic and clinical characteristics in this study revealed a well-balanced distribution between the two groups, Iron Sucrose (Group A) and Ferric Carboxymaltose (Group B), each comprising 70 participants. The mean age of 28.65 years and the mean gestational age of 26.65 weeks are representative of a typical cohort of pregnant women with iron deficiency anemia (IDA). This demographic profile aligns with Sharma et al. (2018), who reported a mean age of 27.8 years in their study of IDA in pregnancy, with a comparable distribution of gravidity, where multigravidas made up around 54% of their sample.<sup>7</sup> Similarly, Gupta et al. (2019) emphasized the importance of socioeconomic and educational diversity in studies of maternal health, and the current study's even distribution across these parameters reduces the risk of confounding variables impacting outcomes.<sup>8</sup>

At baseline, both groups had comparable hematological profiles, with no statistically significant differences in hemoglobin levels, serum ferritin, or red cell indices. Group A had a mean hemoglobin level of 8.50 g/dL, while Group B's mean level was 8.40 g/dL. This is consistent with the findings of Khalafallah et al. (2020), who observed a mean hemoglobin of 8.45 g/dL in a similar population before treatment.<sup>9</sup> The baseline serum ferritin levels were also comparable, averaging 18.50 ng/mL for Group A and 19.00 ng/mL for Group B. This initial homogeneity ensures that any observed treatment effects are likely due to the interventions rather than pre-existing differences, similar to results reported by Avni et al. (2018), who highlighted the importance of matching baseline characteristics in anemia studies.<sup>10</sup> The follow-up results clearly demonstrate the superior efficacy of ferric carboxymaltose over iron sucrose in increasing hemoglobin levels. By 2 weeks, Group B exhibited a significantly greater increase in hemoglobin (10.20 g/dL) compared to Group A (9.80 g/dL,  $p = 0.01$ ). At 4 weeks, the trend continued, with Group B reaching 11.00 g/dL versus 10.50 g/dL in Group A ( $p = 0.02$ ), and at 8 weeks, Group B maintained higher hemoglobin levels (11.60 g/dL) compared to Group A (11.20 g/dL,  $p = 0.03$ ). These results are consistent with Qassim et al. (2021), who found that ferric carboxymaltose led to a more rapid and sustained increase in hemoglobin compared to iron sucrose.<sup>11</sup> A meta-analysis by Abeysuriya et al. (2019) also supports this, demonstrating that ferric carboxymaltose provides faster

hematological recovery, making it a preferred option in pregnancy-associated IDA.<sup>12</sup>

Serum ferritin, an indicator of iron storage, was significantly higher in Group B at all follow-up points, emphasizing the superior iron replenishment provided by ferric carboxymaltose. At 2 weeks, Group B's mean ferritin level was 45.20 ng/mL, significantly higher than Group A's 40.50 ng/mL ( $p = 0.02$ ). This difference became more pronounced at 4 weeks (60.10 ng/mL for Group B vs. 55.30 ng/mL for Group A,  $p = 0.01$ ) and persisted at 8 weeks (70.40 ng/mL for Group B vs. 65.80 ng/mL for Group A,  $p = 0.03$ ). Breyman et al. (2018) similarly reported that ferric carboxymaltose more effectively replenishes iron stores compared to iron sucrose, due to its enhanced bioavailability and efficient iron utilization.<sup>13</sup> Geisser et al. (2022) also highlighted the better iron storage mechanism of ferric carboxymaltose, corroborating the findings of the present study.<sup>14</sup>

Adverse reactions were slightly higher in Group A (17.14%) compared to Group B (11.43%), though the difference was not statistically significant ( $p = 0.15$ ). This is consistent with Froessler et al. (2018), who found that both treatments are well-tolerated, with a slightly lower incidence of adverse effects for ferric carboxymaltose.<sup>15</sup> Fatigue scores, an indicator of maternal well-being, showed a more significant reduction in Group B by 8 weeks, with scores decreasing from 7.70 to 3.80 compared to a reduction from 7.80 to 4.50 in Group A ( $p = 0.02$ ). Bhandal and Russell (2021) observed similar improvements in fatigue with ferric carboxymaltose, attributing it to more effective iron replenishment and a faster increase in hemoglobin levels.<sup>16</sup> This reduction in fatigue underscores the clinical benefits of ferric carboxymaltose, not only in hematological improvement but also in enhancing the overall quality of life for pregnant women with IDA.

## Conclusion

In conclusion, this study demonstrates that ferric carboxymaltose is more effective than iron sucrose in rapidly increasing hemoglobin levels and replenishing iron stores in pregnant women with iron deficiency anemia. Ferric carboxymaltose also leads to greater improvements in maternal well-being with fewer infusions, enhancing treatment convenience. While both treatments are generally safe, ferric carboxymaltose offers a more efficient and patient-friendly option, though considerations of cost and accessibility remain important in clinical decision-making.

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