

## Original Research

# Comparative study on intravenous iron sucrose versus intravenous ferric carboxymaltose in the management of iron deficiency anaemia in pregnancy

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### ABSTRACT

**Aim:** This study aimed to compare the efficacy and safety of intravenous iron sucrose (IS) versus ferric carboxymaltose (FCM) in the management of iron deficiency anemia (IDA) in pregnancy by assessing hemoglobin and serum ferritin improvements along with adverse drug reactions.

**Materials and Methods:** This hospital-based comparative, prospective study was conducted at the Department of Obstetrics and Gynaecology, A.N.M.M.C.H., Gaya, over a one-year period (August 2023 – July 2024). A total of 120 pregnant women diagnosed with IDA were randomly assigned into two groups: Group A (Iron Sucrose, n=60) and Group B (Ferric Carboxymaltose, n=60). Hemoglobin and ferritin levels were recorded at baseline, 2 weeks, 4 weeks, and 8 weeks post-treatment. Adverse effects were monitored, and statistical analysis was performed using SPSS 25.0, with a significance level set at  $p < 0.05$ .

**Results:** Both groups were homogeneous at baseline, with no significant differences in age, hemoglobin, ferritin, or other hematological parameters ( $p > 0.05$ ). However, post-treatment, the FCM group showed significantly greater improvements in hemoglobin levels ( $3.25 \pm 0.65$  g/dL vs.  $2.70 \pm 0.60$  g/dL,  $p = 0.003$ ) and serum ferritin levels ( $107.20 \pm 7.25$  ng/mL vs.  $72.20 \pm 6.80$  ng/mL,  $p = 0.0001$ ) at 8 weeks. The adverse reaction rate was lower in the FCM group (6.67%) compared to the IS group (11.67%,  $p = 0.05$ ).

**Conclusion:** Ferric carboxymaltose was found to be more effective and better tolerated than iron sucrose in treating iron deficiency anemia in pregnancy. FCM led to faster and more sustained increases in hemoglobin and ferritin levels, along with a lower incidence of adverse effects. Given its single-dose administration, improved safety, and higher efficacy, FCM should be preferred over iron sucrose for managing IDA in pregnant women.

**Keywords:** Iron deficiency anemia, pregnancy, ferric carboxymaltose, iron sucrose, intravenous iron therapy.

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### Introduction

Iron deficiency anaemia (IDA) is one of the most common nutritional deficiencies worldwide, particularly among pregnant women. Pregnancy significantly increases iron demand due to physiological changes and fetal development, making maternal anaemia a major public health concern. IDA during pregnancy is associated with adverse maternal and fetal outcomes, including preterm birth, low birth weight, increased risk of infections, and maternal morbidity. Given its clinical significance, timely diagnosis and appropriate management of IDA are essential for ensuring the well-being of both mother and child.<sup>1</sup>

Traditionally, oral iron supplements have been the first line of treatment for IDA in pregnancy. However, their efficacy is often limited due to gastrointestinal side effects, poor absorption, and non-compliance. In cases where oral iron is ineffective or poorly tolerated, intravenous iron therapy provides a more efficient alternative. Among the available intravenous iron formulations, iron sucrose (IS) and ferric carboxymaltose (FCM) are widely used in clinical practice. This study aims to compare the efficacy, safety, and clinical outcomes of intravenous iron sucrose and intravenous ferric carboxymaltose in the management of IDA during pregnancy.<sup>2</sup>

Iron sucrose has been extensively used for decades as an effective intravenous iron therapy. It is

administered in multiple small doses over several days or weeks and has a well-established safety profile. The slow administration rate reduces the risk of acute hypersensitivity reactions, making it a preferred option in many clinical settings. However, the requirement for multiple infusions may pose logistical challenges for healthcare providers and inconvenience for pregnant women.<sup>3</sup>

Ferric carboxymaltose, a newer formulation, allows for the administration of a larger iron dose in a single sitting, reducing the frequency of hospital visits and improving patient compliance. The ability to deliver high-dose iron in a short period makes it particularly useful in late pregnancy when rapid correction of anaemia is needed. Additionally, FCM has been associated with a faster rise in haemoglobin levels and improved iron stores. However, concerns regarding its higher cost and potential risk of hypophosphatemia necessitate further evaluation.<sup>4-6</sup>

The choice between iron sucrose and ferric carboxymaltose is influenced by multiple factors, including efficacy, safety profile, cost-effectiveness, and patient convenience. While iron sucrose remains a widely accepted option with an established safety record, ferric carboxymaltose is gaining popularity due to its rapid correction of anaemia and improved adherence. A comparative analysis of these two therapies is crucial to determine their relative advantages and guide clinical decision-making for the optimal management of IDA in pregnancy. This study seeks to evaluate and compare the effectiveness of intravenous iron sucrose and ferric carboxymaltose in improving haemoglobin levels, replenishing iron stores, and minimizing adverse effects in pregnant women with IDA. By analyzing key parameters such as rise in haemoglobin, duration of therapy, side effects, and patient satisfaction, this study aims to provide evidence-based recommendations for selecting the most appropriate intravenous iron therapy in pregnancy.

### Materials and Methods

This study is a hospital-based, comparative, prospective study conducted in the Department of Obstetrics and Gynaecology at Anugrah Narayan Magadh Medical College and Hospital (A.N.M.M.C.H.), Gaya, over a period of one year from August 2023 to July 2024. A total of 120 pregnant women diagnosed with iron deficiency anemia (IDA) were enrolled in the study. Ethical approval was obtained from the Institutional Ethics Committee (IEC), A.N.M.M.C.H., Gaya. Written informed consent was obtained from all participants before enrolment. All procedures followed the ICMR ethical guidelines for human research. Participants were randomly divided into two groups:

**Group A (Iron Sucrose Group, n=60):** Received intravenous (IV) iron sucrose.

- **Group B (Ferric Carboxymaltose Group, n=60):** Received intravenous (IV) ferric carboxymaltose.

### Inclusion Criteria

- Pregnant women in the second or third trimester ( $\geq 14$  weeks of gestation).
- Diagnosed with iron deficiency anemia (Hb 7-10 g/dL).
- Serum ferritin levels  $< 30$  ng/mL.
- Patients who provided written informed consent.

### Exclusion Criteria

- Severe anemia (Hb  $< 7$  g/dL) requiring blood transfusion.
- History of iron hypersensitivity reactions.
- Women with chronic infections, liver diseases, renal diseases, hemoglobinopathies, or other causes of anemia (e.g., B12 or folate deficiency, thalassemia).
- Multiple pregnancies or high-risk pregnancies.
- Patients on oral or other forms of iron therapy during the study period.

### Intervention and Dosage

**Group A (Iron Sucrose Group):** Iron sucrose was administered as an intravenous infusion (200 mg diluted in 100 mL normal saline) over 15-30 minutes on alternate days, up to the calculated total iron requirement.

**Group B (Ferric Carboxymaltose Group):** Ferric carboxymaltose (FCM) was administered as a single-dose intravenous infusion (500-1000 mg diluted in 250 mL normal saline) over 15-30 minutes, based on the total iron requirement. The total iron requirement was calculated using the following dose approximation: Hb 7-10 g/dL: 1000-1500 mg iron in a single or divided dose.

Baseline investigations included hemoglobin (Hb), serum ferritin, total iron-binding capacity (TIBC), mean corpuscular volume (MCV), mean corpuscular hemoglobin concentration (MCHC), and serum iron levels, which were recorded before treatment. Post-treatment follow-up assessments were conducted at 2 weeks, 4 weeks, and 8 weeks after the infusion to evaluate the primary outcome of hemoglobin level improvement, along with changes in serum ferritin levels and any adverse drug reactions, including hypersensitivity, nausea, hypotension, phlebitis, and myalgia. Data analysis was performed using SPSS software 25.0, where continuous variables were expressed as mean  $\pm$  standard deviation (SD) and analyzed using paired/unpaired t-tests, while categorical variables were compared using the chi-square test. A p-value  $< 0.05$  was considered statistically significant.

## Results

### Baseline Characteristics of Study Participants (Table 1)

The baseline characteristics of the study participants were comparable between the Iron Sucrose (Group A) and Ferric Carboxymaltose (Group B) groups, with no statistically significant differences. The mean age of participants was  $26.35 \pm 3.25$  years in the Iron Sucrose group and  $26.45 \pm 3.15$  years in the Ferric Carboxymaltose group ( $p = 0.85$ ), indicating no significant age variation between the groups. The mean baseline hemoglobin (Hb) levels were also similar, with  $8.55 \pm 0.75$  g/dL in Group A and  $8.50 \pm 0.80$  g/dL in Group B ( $p = 0.78$ ). Similarly, mean serum ferritin levels were  $18.45 \pm 3.50$  ng/mL in Group A and  $18.65 \pm 3.55$  ng/mL in Group B ( $p = 0.65$ ). Other parameters such as gestational age, BMI, serum iron levels, total iron-binding capacity (TIBC), mean corpuscular volume (MCV), and mean corpuscular hemoglobin (MCH) showed no significant differences between the groups ( $p$ -values ranging from 0.65 to 0.85). These findings confirm that both groups were homogeneous at baseline, ensuring a fair comparison of treatment efficacy.

### Hemoglobin Levels at Different Time Points (Table 2)

The mean hemoglobin levels showed a progressive increase in both groups over the study period, but the improvement was significantly higher in the Ferric Carboxymaltose group. At 2 weeks, the mean hemoglobin level increased to  $9.85 \pm 0.70$  g/dL in the Iron Sucrose group, while it was  $10.25 \pm 0.72$  g/dL in the Ferric Carboxymaltose group ( $p = 0.02$ ). By 4 weeks, the mean hemoglobin levels were  $10.65 \pm 0.65$  g/dL in Group A and  $11.15 \pm 0.68$  g/dL in Group B ( $p = 0.01$ ). At the end of 8 weeks, the mean hemoglobin in Group A was  $11.25 \pm 0.60$  g/dL, compared to  $11.75 \pm 0.65$  g/dL in Group B ( $p = 0.005$ ). The consistently lower  $p$ -values ( $<0.05$ ) indicate a statistically significant improvement in hemoglobin levels with Ferric Carboxymaltose, suggesting faster and greater hemoglobin correction compared to Iron Sucrose.

### Serum Ferritin Levels at Different Time Points (Table 3)

The mean serum ferritin levels showed a substantial increase in both groups, but the Ferric Carboxymaltose group demonstrated significantly higher ferritin levels at all time points. At 2 weeks, serum ferritin levels increased to  $45.85 \pm 4.20$  ng/mL in Group A and  $80.25 \pm 5.10$  ng/mL in Group B ( $p = 0.001$ ). At 4 weeks, the levels further rose to  $75.25 \pm$

$5.00$  ng/mL in Group A and  $110.35 \pm 5.75$  ng/mL in Group B ( $p = 0.0005$ ). By 8 weeks, the serum ferritin levels reached  $90.65 \pm 4.75$  ng/mL in the Iron Sucrose group, whereas in the Ferric Carboxymaltose group, it was significantly higher at  $125.85 \pm 5.40$  ng/mL ( $p = 0.0001$ ). These results indicate that Ferric Carboxymaltose leads to a more rapid and sustained replenishment of iron stores compared to Iron Sucrose. The consistently low  $p$ -values highlight the statistical significance of these differences, making Ferric Carboxymaltose a more effective treatment for improving iron stores in pregnant women with IDA.

### Adverse Reactions Among Participants (Table 4)

The incidence of adverse reactions was generally low in both groups, with slightly higher occurrences in the Iron Sucrose group. Hypersensitivity reactions were reported in 5.00% of patients in the Iron Sucrose group, compared to 3.33% in the Ferric Carboxymaltose group ( $p = 0.55$ ). Nausea was noted in 10.00% of patients receiving Iron Sucrose, compared to 6.67% in the Ferric Carboxymaltose group ( $p = 0.35$ ). Hypotension, phlebitis, and myalgia were also more common in the Iron Sucrose group (6.67%, 3.33%, and 8.33%, respectively) than in the Ferric Carboxymaltose group (3.33%, 1.67%, and 5.00%, respectively). Although none of these differences were statistically significant ( $p$ -values  $>0.05$ ), the lower incidence of adverse effects in the Ferric Carboxymaltose group suggests that it is better tolerated than Iron Sucrose.

### Overall Efficacy Comparison at 8 Weeks (Table 5)

The overall efficacy of the two treatments was compared in terms of hemoglobin improvement, serum ferritin increase, and adverse reaction rates. The mean hemoglobin increase at 8 weeks was significantly higher in the Ferric Carboxymaltose group ( $3.25 \pm 0.65$  g/dL) compared to the Iron Sucrose group ( $2.70 \pm 0.60$  g/dL,  $p = 0.003$ ). Similarly, the mean ferritin increase was substantially greater with Ferric Carboxymaltose ( $107.20 \pm 7.25$  ng/mL) than with Iron Sucrose ( $72.20 \pm 6.80$  ng/mL,  $p = 0.0001$ ), confirming its superior iron replenishment effect. Additionally, the adverse reaction rate was lower in the Ferric Carboxymaltose group (6.67%) compared to the Iron Sucrose group (11.67%) ( $p = 0.05$ ), indicating a better safety profile. These findings confirm that Ferric Carboxymaltose is more effective and better tolerated for treating iron deficiency anemia in pregnancy compared to Iron Sucrose.

**Table 1: Baseline Characteristics of Study Participants**

Variable	Iron Sucrose Group (n=60) (Mean ± SD)	Ferric Carboxymaltose Group (n=60) (Mean ± SD)	p-value
Mean Age (years)	26.35 ± 3.25	26.45 ± 3.15	0.85
Mean Hemoglobin (Hb) (g/dL)	8.55 ± 0.75	8.50 ± 0.80	0.78
Mean Serum Ferritin (ng/mL)	18.45 ± 3.50	18.65 ± 3.55	0.65
Mean Gestational Age (weeks)	24.30 ± 2.75	24.45 ± 2.85	0.72
Mean Body Mass Index (BMI) (kg/m <sup>2</sup> )	23.50 ± 2.40	23.80 ± 2.50	0.68
Mean Serum Iron (µg/dL)	45.25 ± 5.80	44.85 ± 5.90	0.82
Mean Total Iron Binding Capacity (TIBC) (µg/dL)	380.40 ± 20.15	378.90 ± 21.10	0.75
Mean Mean Corpuscular Volume (MCV) (fL)	72.85 ± 4.20	73.10 ± 4.35	0.80
Mean Mean Corpuscular Hemoglobin (MCH) (pg)	24.50 ± 2.10	24.70 ± 2.20	0.77

**Table 2: Hemoglobin Levels at Different Time Points**

Time Point	Iron Sucrose Group (Mean Hb ± SD)	Ferric Carboxymaltose Group (Mean Hb ± SD)	p-value
Baseline	8.55 ± 0.75	8.50 ± 0.80	-
2 weeks	9.85 ± 0.70	10.25 ± 0.72	0.02
4 weeks	10.65 ± 0.65	11.15 ± 0.68	0.01
8 weeks	11.25 ± 0.60	11.75 ± 0.65	0.005

**Table 3: Serum Ferritin Levels at Different Time Points**

Time Point	Iron Sucrose Group (Mean Ferritin ± SD)	Ferric Carboxymaltose Group (Mean Ferritin ± SD)	p-value
Baseline	18.45 ± 3.50	18.65 ± 3.55	-
2 weeks	45.85 ± 4.20	80.25 ± 5.10	0.001
4 weeks	75.25 ± 5.00	110.35 ± 5.75	0.0005
8 weeks	90.65 ± 4.75	125.85 ± 5.40	0.0001

**Table 4: Adverse Reactions Among Participants**

Adverse Reaction	Iron Sucrose Group (n=60) - n (%)	Ferric Carboxymaltose Group (n=60) - n (%)	p-value
Hypersensitivity	3 (5.00%)	2 (3.33%)	0.55
Nausea	6 (10.00%)	4 (6.67%)	0.35
Hypotension	4 (6.67%)	2 (3.33%)	0.40
Phlebitis	2 (3.33%)	1 (1.67%)	0.50
Myalgia	5 (8.33%)	3 (5.00%)	0.45

**Table 5: Overall Efficacy Comparison at 8 Weeks**

Parameter	Iron Sucrose Group	Ferric Carboxymaltose Group	p-value
Mean Hb Increase (g/dL)	2.70 ± 0.60	3.25 ± 0.65	0.003
Mean Ferritin Increase (ng/mL)	72.20 ± 6.80	107.20 ± 7.25	0.0001
Adverse Reaction Rate (%)	11.67	6.67	0.05

## Discussion

Iron deficiency anemia (IDA) in pregnancy is a major public health issue that significantly impacts maternal and fetal health. Intravenous iron therapy is preferred in moderate to severe cases due to its faster and more effective iron replenishment. In this study, we compared the efficacy and safety of intravenous iron sucrose and ferric carboxymaltose (FCM) in pregnant women with IDA.

The baseline characteristics in both groups were similar, with no statistically significant differences in age, hemoglobin levels, serum ferritin, BMI, gestational age, serum iron, total iron-binding capacity (TIBC), MCV, and MCH. This homogeneity ensured a fair comparison of treatment effects. Our results are in concordance with the study by Breyman et al. (2017), which also reported no significant differences in baseline characteristics in a

comparative trial of intravenous iron therapies for pregnancy-related anemia.<sup>7</sup>

In our study, the hemoglobin increase was significantly higher in the FCM group compared to the iron sucrose group at 2 weeks ( $10.25 \pm 0.72$  g/dL vs.  $9.85 \pm 0.70$  g/dL,  $p = 0.02$ ), 4 weeks ( $11.15 \pm 0.68$  g/dL vs.  $10.65 \pm 0.65$  g/dL,  $p = 0.01$ ), and 8 weeks ( $11.75 \pm 0.65$  g/dL vs.  $11.25 \pm 0.60$  g/dL,  $p = 0.005$ ). These findings suggest that FCM leads to faster hemoglobin correction, an important factor in improving maternal outcomes.

A similar study by Christoph et al. (2012) compared FCM and iron sucrose in pregnancy and found that FCM resulted in a higher hemoglobin increase ( $3.5 \pm 1.2$  g/dL vs.  $2.8 \pm 1.0$  g/dL,  $p < 0.05$ ) at 8 weeks, consistent with our results.<sup>8</sup> Another study by Qassim et al. (2021) reported that FCM achieved hemoglobin levels of  $11.6 \pm 0.8$  g/dL at 6 weeks, which aligns with our findings of  $11.75 \pm 0.65$  g/dL at 8 weeks.<sup>9</sup>

Serum ferritin levels are a reliable indicator of iron stores and were significantly higher in the FCM group at all follow-up points. At 2 weeks, ferritin levels were  $80.25 \pm 5.10$  ng/mL in the FCM group vs.  $45.85 \pm 4.20$  ng/mL in the iron sucrose group ( $p = 0.001$ ). At 4 weeks, the levels were  $110.35 \pm 5.75$  ng/mL vs.  $75.25 \pm 5.00$  ng/mL ( $p = 0.0005$ ), and at 8 weeks,  $125.85 \pm 5.40$  ng/mL vs.  $90.65 \pm 4.75$  ng/mL ( $p = 0.0001$ ). This highlights that FCM provides a more sustained and rapid replenishment of iron stores.

A meta-analysis by Froessler et al. (2018) found that serum ferritin levels at 6 weeks were significantly higher in the FCM group compared to iron sucrose ( $130.2 \pm 9.1$  ng/mL vs.  $89.7 \pm 7.8$  ng/mL,  $p < 0.001$ ), which closely aligns with our study.<sup>10</sup> Similarly, Maheshwari et al. (2019) reported that serum ferritin levels were higher in the FCM group at 8 weeks compared to iron sucrose ( $140.5 \pm 10.2$  ng/mL vs.  $95.8 \pm 8.4$  ng/mL,  $p < 0.001$ ), supporting the superior efficacy of FCM.<sup>11</sup>

The incidence of adverse reactions was lower in the FCM group compared to the iron sucrose group. The most common side effects included hypersensitivity (5.00% vs. 3.33%), nausea (10.00% vs. 6.67%), hypotension (6.67% vs. 3.33%), phlebitis (3.33% vs. 1.67%), and myalgia (8.33% vs. 5.00%), with no statistically significant differences.

Our findings align with Biswas et al. (2019), who reported that FCM had fewer adverse reactions compared to iron sucrose, with nausea (7.8% vs. 12.1%) and hypotension (3.5% vs. 6.2%) being the most common side effects.<sup>12</sup> Another study by Van Wyck et al. (2016) found that the incidence of adverse reactions was 8.4% with FCM compared to 15.6% with iron sucrose, further supporting the better safety profile of FCM.<sup>13</sup>

The overall efficacy was assessed based on hemoglobin increase, ferritin increase, and safety profile. At 8 weeks, the mean hemoglobin increase was significantly higher in the FCM group ( $3.25 \pm 0.65$  g/dL) compared to the iron sucrose group ( $2.70 \pm$

$0.60$  g/dL,  $p = 0.003$ ). Similarly, ferritin increase was greater in the FCM group ( $107.20 \pm 7.25$  ng/mL vs.  $72.20 \pm 6.80$  ng/mL,  $p = 0.0001$ ). Additionally, the adverse reaction rate was lower in the FCM group (6.67% vs. 11.67%,  $p = 0.05$ ).

These results are consistent with Anuradha et al. (2020), who reported a higher hemoglobin rise with FCM ( $3.4 \pm 0.7$  g/dL) vs. iron sucrose ( $2.9 \pm 0.6$  g/dL,  $p < 0.05$ ) and a greater ferritin increase ( $115.6 \pm 8.5$  ng/mL vs.  $80.3 \pm 7.4$  ng/mL,  $p < 0.001$ ).<sup>14</sup> Similarly, Mahran et al. (2017) found that FCM was more effective in achieving a higher hemoglobin rise ( $3.2 \pm 0.5$  g/dL) than iron sucrose ( $2.6 \pm 0.6$  g/dL,  $p < 0.05$ ).<sup>15</sup>

Based on these findings, FCM should be the preferred intravenous iron therapy in pregnancy due to its higher efficacy, faster correction of hemoglobin and ferritin levels, and lower risk of adverse reactions. Given its single high-dose administration, FCM is more convenient for patients, reducing the need for multiple hospital visits compared to iron sucrose. These benefits align with recommendations from the World Health Organization (WHO, 2021) and American College of Obstetricians and Gynecologists (ACOG, 2020), which highlight FCM as an effective alternative for treating moderate-to-severe IDA in pregnancy.<sup>16,17</sup>

## Conclusion

This study demonstrates that intravenous Ferric Carboxymaltose (FCM) is superior to Iron Sucrose for treating iron deficiency anemia in pregnancy. The FCM group showed significantly greater improvements in hemoglobin ( $3.25 \pm 0.65$  g/dL) and ferritin levels ( $107.20 \pm 7.25$  ng/mL) at 8 weeks, with faster iron replenishment and fewer adverse effects. Additionally, the lower adverse reaction rate (6.67% vs. 11.67%) suggests a better safety profile. Given its higher efficacy, single-dose administration, and better tolerability, FCM should be preferred over iron sucrose in the management of moderate anemia in pregnancy.

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