Section: Miscellaneous

Original Research Article

# EFFICACY, SAFETY, AND PATIENT SATISFACTION OF FERRIC CARBOXYMALTOSE VERSUS IRON SUCROSE IN THE MANAGEMENT OF ANTENATAL IRON-DEFICIENCY ANEMIA

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ABSTRACT

**Background:** Iron-deficiency anemia (IDA) is the most common medical disorder of pregnancy and a major contributor to maternal and neonatal morbidity. Oral iron often fails due to intolerance or poor compliance, making intravenous (IV) iron therapy essential. Among available formulations, iron sucrose (IS) requires multiple infusions, whereas ferric carboxymaltose (FCM) allows higher single doses, potentially improving treatment efficiency and compliance. This study was designed to compare the efficacy, safety, and treatment convenience of IV FCM versus IS in antenatal women with moderate IDA.

**Materials and Methods:** A prospective randomized study was conducted on 120 antenatal women with moderate anemia (Hb 7–9.9 g/dL) attending a tertiary care hospital. Participants were randomized into two groups: Group IS (n=60) received 200 mg iron sucrose on alternate days until the calculated dose was completed, while Group FC (n=60) received up to 1000 mg ferric carboxymaltose in a single infusion, repeated after one week if needed. Hematologic parameters, ferritin levels, adverse events, treatment burden, and patient satisfaction were assessed at baseline, 2 weeks, and 4 weeks.

**Results:** Both groups showed significant improvement in Hb and ferritin at 4 weeks; however, FCM demonstrated superior outcomes. Mean Hb rise was +2.64 g/dL in FCM versus +1.70 g/dL in IS ($p < 0.001$). Mean ferritin increased to 96.4 ng/mL with FCM compared to 46.4 ng/mL with IS ($p < 0.001$). FCM required fewer visits (1.3 vs 5.8), less infusion time (1.0 vs 6.2 hours), and was associated with higher patient satisfaction. Both treatments were safe with only minor, self-limiting adverse events.

**Conclusion:** FCM is more effective, convenient, and equally safe compared with IS for treating moderate anemia in pregnancy, making it a preferable option for rapid correction.

**Keywords:** Ferric Carboxymaltose, Iron Sucrose, Iron-Deficiency Anemia.

## INTRODUCTION

Anemia in pregnancy is a global health challenge, affecting nearly 40% of pregnant women worldwide, with the highest prevalence in low- and middle-income countries.[1] Iron-deficiency anemia (IDA) accounts for more than 90% of these cases and is associated with increased risks of maternal morbidity, preterm delivery, intrauterine growth restriction, and low birth weight.[2,3] In India, where dietary insufficiency and high parity contribute significantly, the prevalence of anemia in pregnancy remains over 50%, making it a major public health concern.[4]

Physiological changes during pregnancy, including plasma volume expansion, elevate iron requirements, making pregnant women particularly vulnerable to IDA.[5] Oral iron supplementation remains the first-line therapy; however, gastrointestinal side effects, poor absorption, and non-compliance often limit its effectiveness.[6] Furthermore, in women with moderate anemia, oral iron may be insufficient for rapid correction before delivery.[7] In such cases, intravenous (IV) iron therapy provides a more effective and timely approach.[8]

Among IV formulations, iron sucrose (IS) has been widely used in pregnancy owing to its safety profile and good tolerability.[9] However, IS can only be administered in relatively small doses (≤200 mg per infusion), necessitating multiple hospital visits to achieve the total iron requirement, which is often between 1000–1500 mg in moderate anemia.[10] This increases treatment burden and may compromise adherence.

Ferric carboxymaltose (FCM), a newer IV iron complex, offers a significant advantage by allowing administration of up to 1000 mg in a single short infusion.[11] This enables rapid replenishment of iron stores with fewer visits and greater convenience. Several studies have demonstrated that FCM results in faster hemoglobin correction and improved ferritin levels compared to IS, with similar safety outcomes.[12,13] However, there is limited randomized evidence in Indian antenatal populations, where compliance and access to repeated hospital visits pose major challenges. Given the high prevalence of anemia in pregnancy in India and the need for practical, effective treatment strategies, this study was designed to compare the efficacy, safety, and patient convenience of IV iron sucrose and ferric carboxymaltose in antenatal women with moderate anemia.

## MATERIALS AND METHODS

This prospective randomized study was conducted in the Department of Obstetrics and Gynaecology, Pratima Institute of Medical Sciences, Nagunoor, Telangana between January 2024 and June 2025. A total of 120 antenatal women was calculated assuming a difference of 1 g/dL in mean Hb improvement between groups, with 80% power and 5% significance level, allowing for 10% attrition.

Inclusion criteria: Pregnant women aged 18-40 years, gestational age 14-34 weeks, Hb 7.0-9.9 g/dL, Serum ferritin <30 ng/mL or transferrin saturation <20%, intolerant or non-responsive to oral iron and willing to participate were included.

Exclusion criteria: Pregnant women with severe anemia (Hb <7 g/dL), non-iron deficiency anemia, Multiple gestation, previous history of IV iron therapy in current pregnancy, hypersensitivity to IV iron, renal complications, hepatic diseases and cardiac complications and not willing to participate were excluded.

The study Participants were randomly allocated to two groups. Group IS (n=60) medicated with 200 mg IV iron sucrose in 100 mL normal saline infused over 30–45 minutes on alternate days until calculated total dose completed. Group FC (n=60) was medicated Up to 1000 mg IV FCM in 100 mL normal saline infused over 15–30 minutes in a single sitting, repeated after 7 days if additional dose required. The total iron requirement was calculated using modified Ganzoni's formula.[14]

The baseline information of complete blood count, serum ferritin, transferrin saturation, serum phosphate, vital signs were collected. The similar parameters were assessed in the treatment follow up at two weeks ad 4 weeks. The parameters like infusion time, number of visits, patient satisfaction assessed by using five-point Likert scale and details about adverse events were recorded at every follow-up.

The collected data was analysed by using SPSS v.26.0. Continuous variables were expressed as mean and standard deviation, categorical variables as frequency and percentages. Comparisons between groups was assessed by independent t-test and for categorical variables by Chi-square test. $p<0.05$ was considered statistically significant outcome.

## RESULTS

The mean age was 25.8 ± 3.6 years in the Iron Sucrose (IS) group and 26.1 ± 3.8 years in the Ferric Carboxymaltose (FC) group ($p = 0.64$). The mean gestational age was similar (25.2 ± 4.1 vs 25.5 ± 4.3 weeks, $p = 0.72$). Mean BMI did not differ significantly (23.4 ± 2.5 vs 23.6 ± 2.7 kg/m², $p = 0.55$). Distribution of parity showed no significant difference (Nulliparous: 38.3% vs 40%). Baseline Hb (8.62 ± 0.5 vs 8.56 ± 0.4 g/dL) and ferritin (18.3 ± 6.1 vs 19.1 ± 5.8 ng/mL) levels were comparable ($p > 0.05$), indicating successful randomization. [Table 1]

**Table 1: Demographic characteristics of study participants (n=120)**

| Characteristic | Group IS (n=60) | Group FC (n=60) | p-value |
|---|---|---|---|
| Age (In years) | 25.8 ± 3.6 | 26.1 ± 3.8 | 0.64 |
| Gestational age (weeks) | 25.2 ± 4.1 | 25.5 ± 4.3 | 0.72 |
| BMI (kg/m²) | 23.4 ± 2.5 | 23.6 ± 2.7 | 0.55 |
| **Parity** | | | |
| Nulliparous | 23 (38.3%) | 24 (40%) | 0.81 |
| Multiparous | 37 (61.67%) | 36 (60%) | |
| Baseline Hb (g/dL) | 8.62 ± 0.5 | 8.56 ± 0.4 | 0.47 |
| Ferritin (ng/mL) | 18.3 ± 6.1 | 19.1 ± 5.8 | 0.52 |

At baseline, mean Hb levels were comparable between IS (8.62 ± 0.5 g/dL) and FC (8.56 ± 0.4 g/dL). At 2 weeks, the FC group achieved a significantly higher mean Hb (10.36 ± 0.6 g/dL) compared to IS (9.46 ± 0.6 g/dL, p < 0.001). By 4 weeks, the difference widened further, with FC reaching 11.20 ± 0.5 g/dL compared to 10.32 ± 0.6 g/dL in IS (p < 0.001). The mean Hb rise was almost double in FC at both 2 weeks (+1.80 vs +0.84 g/dL) and 4 weeks (+2.64 vs +1.70 g/dL). Importantly, a higher proportion of women in the FC group achieved the target Hb ≥11 g/dL (70% vs 42.7%, p < 0.001). [Table 2]

**Table 2: Hematologic outcomes during follow-up**

| Parameter | Group IS | Group FC | p-value |
|---|---|---|---|
| **Haemoglobin (g/dl)** | | | |
| At baseline | 8.62 ± 0.5 | 8.56 ± 0.4 | 0.47 |
| At 2 weeks | 9.46 ± 0.6 | 10.36 ± 0.6 | <0.001 |
| At 4 weeks | 10.32 ± 0.6 | 11.20 ± 0.5 | <0.001 |
| **Raise of mean Haemoglobin (g/dl)** | | | |
| At 2 weeks | +0.84 ± 0.3 | +1.80 ± 0.5 | <0.001 |
| At 4 weeks | +1.70 ± 0.5 | +2.64 ± 0.6 | <0.001 |
| Women achieving Hb ≥11 g/dL | 25 (42.67%) | 42 (70%) | <0.001 |

Baseline ferritin values were similar (18.3 ± 6.1 ng/mL vs 19.1 ± 5.8 ng/mL, p = 0.52). At 2 weeks, the FC group demonstrated a marked improvement (68.2 ± 9.2 ng/mL) versus IS (32.6 ± 7.4 ng/mL, p < 0.001). This superiority persisted at 4 weeks (96.4 ± 10.5 ng/mL vs 46.4 ± 8.2 ng/mL, p < 0.001). Notably, 88.3% of women in the FC group achieved ferritin ≥50 ng/mL compared to 48.3% in the IS group (p < 0.001), highlighting more effective replenishment of iron stores with FC. [Table 3]

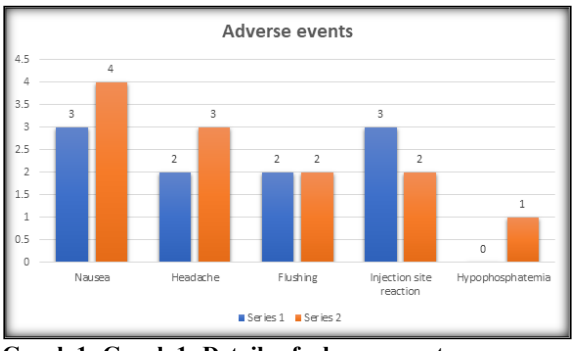
**Table 3: Serum Ferritin outcome during follow-up**

| Serum Ferritin (ng/mL) | Group IS | Group FC | p-value |
|---|---|---|---|
| At baseline | 18.3 ± 6.1 | 19.1 ± 5.8 | 0.52 |
| At 2 weeks | 32.6 ± 7.4 | 68.2 ± 9.2 | <0.001 |
| At 4 weeks | 46.4 ± 8.2 | 96.4 ± 10.5 | <0.001 |
| Women achieving ≥50 ng/mL | 29 (48.3%) | 53 (88.3%) | <0.001 |

**Table 4: Details of treatment burden and patient-reported satisfaction**

| Parameter | Group IS | Group FC | p-value |
|---|---|---|---|
| Number of visits (mean ± SD) | 5.8 ± 1.2 | 1.3 ± 0.5 | <0.001 |
| Total infusion time (In hours) | 6.2 ± 0.8 | 1.0 ± 0.2 | <0.001 |
| High satisfaction (Likert 4-5) % | 55% | 82% | 0.02 |
| Willing to repeat same treatment | 58% | 90% | <0.001 |

The IS group required significantly more hospital visits (5.8 ± 1.2 vs 1.3 ± 0.5, p < 0.001) and infusion time (6.2 ± 0.8 vs 1.0 ± 0.2 hours, p < 0.001) compared to FC. Patient-reported outcomes favoured FC, with 82% reporting high satisfaction versus 55% in the IS group (p = 0.02). Additionally, 90% of FC recipients expressed willingness to repeat the same treatment compared to 58% in IS (p < 0.001). [Table 4]




**Graph 1: Graph 1: Details of adverse events**

The overall incidence of minor adverse events was low and comparable between groups. Nausea, headache, flushing, and mild injection site reactions were the most commonly reported, occurring in 16.7% of IS and 20% of FC participants, with no statistically significant difference (p > 0.05). No serious adverse events, including anaphylaxis or hemodynamic instability, were observed. One asymptomatic case of mild hypophosphatemia was recorded in the FC group and managed conservatively. [Graph 1]

## DISCUSSION

The present study compared the efficacy, safety, and patient acceptability of intravenous (IV) ferric carboxymaltose (FCM) and iron sucrose (IS) in antenatal women with moderate iron-deficiency anemia (IDA). The findings demonstrate that both treatments effectively improved haemoglobin (Hb) and ferritin levels, but FCM provided significantly greater hematologic responses, faster correction of anemia, higher replenishment of iron stores, and superior patient satisfaction, with a comparable safety profile.

The rise in Hb was significantly greater in the FCM group than the IS group at both 2 and 4 weeks. By

week 4, the mean Hb increase in the FCM group (+2.64 g/dL) was almost one gram higher than in the IS group (+1.70 g/dL). Furthermore, a greater proportion of women in the FCM arm achieved the target Hb ≥11 g/dL (70% vs 42.7%). These results are consistent with earlier studies. Breymann et al,[12] reported that FCM achieved faster and greater improvements in Hb compared with IS in pregnant women. Similarly, Van Wyck et al. observed superior Hb gains with FCM in postpartum women.[15] A systematic review and meta-analysis by Qassim et al. confirmed that FCM is superior to IS in terms of Hb rise and faster anemia correction.[16]

The higher efficacy of FCM is attributable to its ability to deliver larger doses (up to 1000 mg) in a single sitting, enabling rapid replenishment of iron deficit, whereas IS requires multiple small infusions limited to 200 mg each.[17] This pharmacologic advantage makes FCM particularly useful in antenatal women who need quick correction of anemia to reduce perinatal risks.

The improvement in ferritin levels was significantly higher in the FCM group. At 4 weeks, mean ferritin was more than double in the FCM arm (96.4 ng/mL vs 46.4 ng/mL). Nearly 88% of FCM patients achieved ferritin ≥50 ng/mL compared with only 48% of those receiving IS. This finding is supported by Muñoz et al,[18] who highlighted that FCM replenishes iron stores more effectively due to its stable structure and controlled release of bioavailable iron. Restoration of ferritin is crucial in pregnancy to ensure adequate reserves for maternal health, fetal development, and prevention of postpartum anemia.[19]

One of the most important findings of this study is the reduction in treatment burden with FCM. The IS group required an average of 5-6 hospital visits compared to 1–2 visits for FCM, with total infusion times of over 6 hours for IS versus 1 hour for FCM. This reduction in visits and chair time translates to improved patient convenience, reduced healthcare resource utilization, and increased compliance. In our study, 82% of women in the FCM group reported high satisfaction, and 90% expressed willingness to repeat the treatment, significantly higher than IS. Similar findings were reported by Khalafallah et al,[5] who observed that women preferred IV regimens that required fewer visits. In the Indian context, where many women face challenges in accessing healthcare facilities due to distance, cost, and competing responsibilities, FCM offers a major practical advantage.

Both treatments were well tolerated in this study. Minor adverse events such as nausea, headache, and flushing occurred with similar frequency in both groups. Importantly, no serious adverse events, including anaphylaxis, hypotension, or life-threatening reactions, were observed. One case of asymptomatic hypophosphatemia was noted in the FCM group, which is a recognized but usually transient effect of this formulation.[19]

Previous studies have confirmed the safety of both FCM and IS in pregnancy. Breymann et al,[12] and Muñoz et al,[18] found that FCM is equally well tolerated. The current results therefore reinforce the evidence base that both preparations can be safely administered during pregnancy.

The results of this study have important clinical implications for the management of IDA in pregnancy. Anemia remains highly prevalent in India and is a major contributor to maternal mortality and morbidity.[4] The need for rapid, safe, and effective correction of anemia is particularly important in women presenting in the second or third trimester. The superior efficacy and convenience of FCM make it a strong candidate for routine use in moderate anemia. However, its relatively higher cost compared with IS may limit widespread adoption in low-resource settings unless weighed against the savings in reduced hospital visits and improved compliance.

This study has some limitations in terms of single centric with a modest sample size, which may limit generalizability. The follow-up was limited to 4 weeks, so long-term outcomes such as postpartum anemia and neonatal status were not evaluated.

## CONCLUSION

This study demonstrates that ferric carboxymaltose is superior to iron sucrose in correcting moderate IDA in pregnancy, with greater improvements in Hb and ferritin, fewer treatment visits, and higher patient satisfaction, while maintaining similar safety. These findings support the consideration of FCM as a preferable option in antenatal anemia management, especially where rapid correction and improved compliance are required.

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