

A Prospective Comparative Study of Safety and Efficacy of Intravenous Ferric Carboxymaltose and Iron Sucrose in the Treatment of Postpartum Iron Deficiency Anaemia in Rajendra Institute of Medical Sciences, Ranchi

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Received: 25-09-2024 / Revised: 23-10-2024 / Accepted: 05-11-2024

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Conflict of interest: Nil

Abstract:

Introduction: This prospective comparative study evaluates the safety and efficacy of intravenous ferric carboxymaltose (FCM) versus iron sucrose in treating postpartum iron deficiency anemia (IDA) at Rajendra Institute of Medical Sciences, Ranchi, from April 2021 to September 2022.

Methods: A total of 100 postpartum women with hemoglobin levels below 10 g/dL were enrolled and divided into two treatment groups: 40 received a single 500 mg dose of FCM, while 60 received iron sucrose at 100 mg doses on alternate days for ten days. Hemoglobin and serum ferritin levels were assessed pre-and post-treatment, alongside monitoring adverse reactions.

Results: Study showed that FCM significantly increased hemoglobin (mean increase of 3.42 g/dL vs. 1.77 g/dL in iron sucrose) and ferritin levels (mean increase of 120.03 µg/L vs. 50.87 µg/L), indicating superior efficacy. Furthermore, FCM had a markedly lower incidence of adverse reactions (5% vs. 30%), suggesting better patient tolerance.

Conclusion: This study concludes that FCM is a more effective and safer option than iron sucrose for managing postpartum IDA, advocating its use as a first-line treatment, especially in resource-limited settings where quick recovery is essential.

Keywords: Ferric Carboxymaltose, Iron Sucrose, Postpartum Anemia, Safety and Efficacy.

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Introduction

Globally, postpartum iron deficiency anaemia (IDA) is a major and pervasive health problem that primarily affects maternal health [1]. IDA, which is characterised by decreased haemoglobin or red blood cell counts, is a significant cause of postpartum women's increased morbidity and can result in symptoms including exhaustion, cognitive decline, as well as postpartum depression. The most common causes of the illness include inadequate iron intake during pregnancy, severe blood loss following birth, and nutritional inadequacies. Haemoglobin levels fall below 8 g/dL in about 10% of severe cases of postpartum anaemia, which affects about 27% of women. These numbers highlight the need for safe, affordable, and efficient treatments to lessen the negative effects on new moms' health [2,3].

About one-third of the world's population suffers from IDA, with iron deficiency accounting for about half of these instances. Because iron is vital for energy metabolism, cellular function, and oxygen transport, treating IDA is particularly important [4]. The body's capacity to make haemoglobin and sufficiently oxygenate tissues is hampered by insufficient iron, which has an impact on both mental and physical health [5]. Since poor maternal health can affect mother-baby bonding and infant development, the symptoms—which include weakness, poor concentration, and delayed recovery after childbirth—significantly impair the wellbeing of both mother and child [6]. Effective management of postpartum iron deficiency anaemia necessitates a dependable iron supplementation strategy, with options ranging

from intravenous (IV) iron therapy to oral iron supplements. Even though oral iron supplements are the conventional first line of treatment, they frequently have drawbacks such as gastrointestinal side effects and low absorption rates [7]. Because IV iron therapy provides a quicker response, these difficulties have caused the focus to shift toward them in patients with severe IDA. Iron sucrose and ferric carboxymaltose (FCM) are two of the most notable IV alternatives. Despite differences in safety, administration methods, and patient tolerance, each has been proven to be successful [8].

Ferric carboxymaltose (FCM) is particularly advantageous due to its neutral pH, physiological

osmolality, and ability to deliver higher single doses over shorter periods, reducing the number of hospital visits needed [9]. FCM's composition also reduces the risk of severe adverse reactions, making it a promising choice for postpartum women [10]. On the other hand, iron sucrose, though effective, typically requires multiple doses administered over an extended period and has a relatively higher rate of mild side effects. Research comparing these two treatments indicates that FCM not only leads to a quicker rise in hemoglobin and ferritin levels but is also associated with higher patient satisfaction and fewer adverse reactions [11].

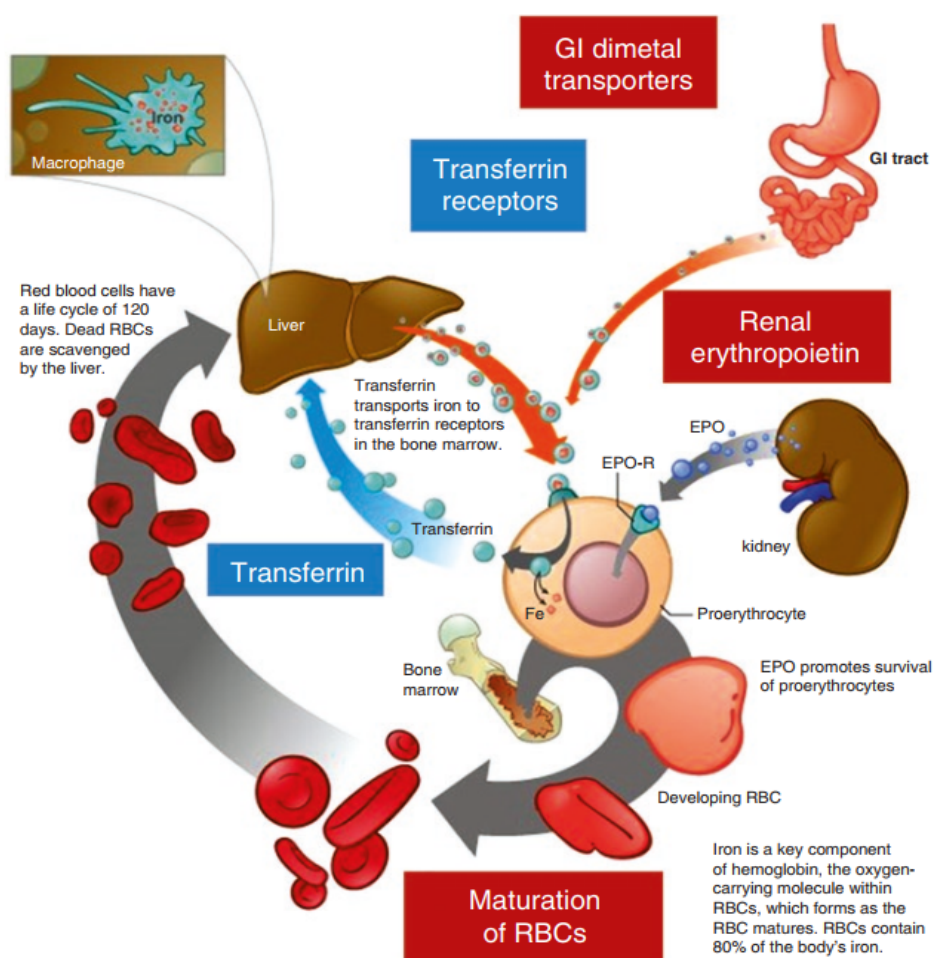


Figure 1: Mechanisms of erythropoiesis and iron homeostasis

This study aims to investigate and compare the efficacy, safety, and overall patient experience between FCM and iron sucrose in managing postpartum IDA. By evaluating these treatments within a clinical setting, this research seeks to provide insights into the best approaches for restoring iron levels in postpartum women, ultimately enhancing both maternal and child health.

Materials and Methods

Study Design and Setting: This observational, prospective study was conducted at the Department of Obstetrics and Gynecology at the Rajendra Institute of Medical Sciences, Ranchi. The study spanned from April 2021 to September 2022.

Study Population and Sample Size: A total of 100 postpartum women diagnosed with iron

deficiency anemia (IDA) were enrolled. Eligible participants were identified as those with hemoglobin (Hb) levels below 10 g/dL, admitted to the hospital post-delivery.

Inclusion Criteria

1. Postpartum women aged 18–45 years.
2. Confirmed diagnosis of postpartum anemia due to nutritional deficiency or postpartum blood loss.
3. Hemoglobin level <10 g/dL.
4. Participants who consented to inpatient monitoring for the treatment period.

Exclusion Criteria

1. Women with anemia due to sickle cell disease, thalassemia, bone marrow diseases, renal or liver disease.
2. History of hepatitis.

Study Groups: The 100 participants were divided into two treatment groups based on their assigned iron supplementation method:

- **Group FCM (n=40):** Received a single dose of 500 mg ferric carboxymaltose (FCM) intravenously.
- **Group Iron Sucrose (n=60):** Received 100 mg iron sucrose intravenously on alternate days for a total of 5 doses within 10 days postpartum.

Treatment Administration

- **Ferric carboxymaltose (FCM):** A single 500 mg dose of FCM was diluted in 100 ml of 0.9% normal saline and administered over 15 minutes. No follow-up dose was needed.
- **Iron Sucrose:** Iron sucrose was administered in 100 mg doses, diluted in 100 ml of 0.9% normal saline, and infused over 30 minutes. This dose was repeated every alternate day for a total of five doses.

Follow-Up and Monitoring

Patients in both groups underwent baseline and follow-up assessments:

1. **Baseline Assessment:** Hemoglobin (Hb) levels and serum ferritin were measured before the initial dose.
2. **Post-Treatment Follow-Up:** Hb and serum ferritin levels were measured again 14 days after completing the treatment.

Statistical Analysis: Microsoft Excel was used to enter the data, and SPSS software version 21.0 was used for analysis. While averages and standard deviations were used to describe quantitative data, frequencies and percentages were used to show qualitative data. Relations between categorical variables were evaluated using a chi-square test; a p-value of less than 0.05 was deemed statistically significant.

Results

This study examined the effectiveness and safety of treating postpartum iron deficiency anaemia (IDA) in 100 postpartum women using ferric carboxymaltose (FCM) and iron sucrose. Serum ferritin, haemoglobin (Hb) levels, mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentration (MCHC), and the frequency of adverse events were among the important evaluation criteria. The results below show each treatment's overall efficacy and patient tolerability.

Demographic Distribution and Clinical Characteristics: The study population showed some demographic similarities and variations between the treatment groups, as summarized below:

Parameter	Group FCM (n=40)	Group Iron Sucrose (n=60)	p-value	Description
Age Distribution	55% aged 21-25	38.3% aged 18-20	Not significant	Majority of Group FCM were aged 21-25, whereas Group Iron Sucrose had a majority aged 18-20.
Socioeconomic Status	77.5% lower income	71.7% lower income	Not significant	Most participants in both groups came from lower socioeconomic backgrounds.
Region	62.5% rural	65% rural	Not significant	Both groups had a high percentage of participants from rural areas, reflecting higher IDA prevalence.
Parity	82.5% multigravida	58.3% multigravida	0.011 (significant)	Group FCM had a higher proportion of multigravida participants than Group Iron Sucrose.

Mode of Delivery	60% cesarean section	22% cesarean section	0.000 (significant)	Cesarean deliveries were more common in Group FCM, while vaginal deliveries were higher in Group Iron Sucrose.
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Most participants came from lower socioeconomic backgrounds and rural regions, which are factors commonly associated with higher IDA prevalence. Significant differences in parity and delivery mode were observed, with more multigravida participants and cesarean deliveries in the FCM group, indicating potential influencing factors on IDA severity and treatment outcomes.

Hematological Outcomes: Changes in Hb and serum ferritin levels were assessed pre-and post-treatment, showing significant improvement in both groups. However, Group FCM exhibited a greater and faster increase in both Hb and ferritin levels.

Parameter	Group FCM (Mean \pm SD)	Group Iron Sucrose (Mean \pm SD)	p-value	Description
Hemoglobin (Hb) (g/dL)	Pre: 6.20 \pm 0.82 Post: 9.62 \pm 0.45	Pre: 6.74 \pm 0.73 Post: 8.51 \pm 0.49	0.000 (significant)	Group FCM showed a greater increase in Hb levels post-treatment compared to Group Iron Sucrose.
Serum Ferritin (μ g/L)	Pre: 29.58 \pm 11.47 Post: 149.61 \pm 24.58	Pre: 37.47 \pm 10.41 Post: 88.34 \pm 25.36	0.000 (significant)	Group FCM showed a significantly higher increase in serum ferritin levels post-treatment.

Group FCM showed a statistically significant increase in Hb (3.42 g/dL) and ferritin levels, surpassing the increases observed in Group Iron Sucrose. The results indicate that FCM is more effective at rapidly restoring Hb and iron stores, making it potentially more suitable for postpartum

IDA management where quicker recovery is beneficial.

Adverse Reactions: The incidence and severity of adverse reactions were monitored in both groups. Group FCM experienced significantly fewer adverse reactions compared to Group Iron Sucrose.

Parameter	Group FCM (n=40)	Group Iron Sucrose (n=60)	p-value	Description
Adverse Reactions	5% (mild reactions)	30% (varied reactions)	0.002 (significant)	Group FCM had a significantly lower incidence of adverse reactions, indicating better patient tolerance.

Group FCM had a notably lower incidence of adverse reactions (5%) than Group Iron Sucrose (30%), with responses in FCM being mild and self-limiting (e.g., mild shortness of breath, tingling sensation). In contrast, Iron Sucrose patients reported varied symptoms, including giddiness, nausea, and chest pain. This finding indicates that FCM may offer a safer profile, especially suitable for postpartum patients needing better treatment tolerance.

The findings show that ferric carboxymaltose is superior than iron sucrose in raising Hb and ferritin levels and is linked to fewer and milder side effects. Given the notable haematological gains and decreased frequency of side effects in the FCM group, FCM might be a better option for treating postpartum IDA, especially when quick iron level restoration and few side effects are needed. The necessity for focused interventions in lower

socioeconomic and rural groups, where IDA prevalence is high, is further supported by the demographic data.

Discussion

Because postpartum iron deficiency anaemia (IDA) has a major influence on the health and quality of life of mothers, it must be managed. To treat IDA in postpartum women, this study compared the safety and effectiveness of two intravenous iron therapies: iron sucrose and ferric carboxymaltose (FCM) [12]. According to the results, FCM is better than iron sucrose for both haematological improvement and patient tolerance, which suggests that it would be a preferable option for managing postpartum IDA. The substantial rise in haemoglobin (Hb) and serum ferritin levels in both groups was one of the study's main findings [13]. Hb increased by an average of 3.42 g/dL in the FCM group, but only 1.77 g/dL in the iron sucrose

group, indicating a larger improvement. Furthermore, the FCM group experienced a greater increase in serum ferritin levels, a measure of iron storage, from 29.58 to 149.61 µg/L, compared to the iron sucrose group, which saw an increase from 37.47 to 88.34 µg/L. For people who are caring for newborns, this difference is clinically significant since faster and bigger gains in ferritin and haemoglobin can result in a speedier resolution of anaemia symptoms and a quicker recovery for postpartum mothers [14].

FCM's pharmacokinetic characteristics, which permits larger single dosages and more effective iron absorption, may be the reason for its quicker effectiveness. FCM is preferred for postpartum patients who need to recuperate right away because of its neutral pH and physiological osmolarity, which allow for the administration of a single high dose (up to 1000 mg in 15 minutes) with little side effects [15]. On the other hand, because iron sucrose has a reduced single-dose capacity, it needs to be taken in several doses, which causes iron reserves to rise more gradually. Additionally, the study demonstrated that FCM was less likely than iron sucrose to cause negative effects [16]. While 30% of individuals in the iron sucrose group experienced more varied and severe side effects, including headaches, nausea, giddiness, and chest pain, only 5% of people in the FCM group reported mild side effects, such as tingling and shortness of breath. These results are consistent with other studies that found that because FCM does not contain dextran, it generally has a superior safety profile than iron sucrose, lowering the risk of hypersensitivity and anaphylaxis [17].

Clinical practice is significantly impacted by the disparity in safety profiles. FCM can decrease hospital visits, enhance patient compliance, and facilitate quicker discharge because of its higher tolerance and lower frequency of adverse responses. This is especially important in environments with high patient turnover or limited healthcare resources [18]. Both groups shared a similar proportion of lower socioeconomic levels and rural areas, which are typically linked to greater IDA rates because of restricted access to wholesome food and medical treatment. Because chronic iron loss increases the risk of anemia in women with multiple pregnancies, the majority of participants were also multigravida. Nonetheless, the FCM group had a greater percentage of cesarean sections, which would have affected the severity of the anaemia because surgical deliveries frequently cause more blood loss than vaginal ones. To make sure that delivery type does not affect the severity of anaemia in different groups, future research could account for this variable [19].

Larger investigations are advised to validate these findings across more diverse demographics and

healthcare settings, even if the sample size of 100 was suitable for preliminary comparisons. To evaluate the long-term impacts of these treatments on iron storage and any delayed adverse reactions, lengthier follow-ups would also be beneficial. According to the study's findings, FCM is a safer and more efficient way to treat postpartum IDA than iron sucrose. FCM helps postpartum women recover more quickly by facilitating a stronger and faster rise in haemoglobin and iron levels, which is crucial for their health and ability to provide care. Its usage is further supported by the low frequency of adverse responses, which may enhance patient satisfaction and treatment compliance [20]. The single-dose regimen of FCM can be especially helpful in situations where outpatient follow-up may be difficult because it eliminates the need for frequent hospital visits. Compared to iron sucrose, FCM has some advantages when it comes to treating postpartum IDA. Its combination of excellent safety and quick efficacy makes it a significant therapy option, particularly in areas with low resources where quick recovery and few hospital stays are crucial. The evidence for FCM's use as a first-line treatment for postpartum IDA would be strengthened by additional studies including bigger and more varied populations.

Conclusion

This study demonstrates that ferric carboxymaltose (FCM) is a superior option compared to iron sucrose for the treatment of postpartum iron deficiency anemia (IDA), offering both enhanced efficacy and improved safety. FCM led to a more substantial and rapid increase in hemoglobin and serum ferritin levels, allowing for quicker recovery, which is particularly beneficial for postpartum women. Additionally, FCM's single-dose administration and lower incidence of adverse reactions improve patient compliance and comfort, making it a more practical choice in clinical settings. These findings support the adoption of FCM as a preferred treatment for postpartum IDA, especially in scenarios where quick recovery and minimal side effects are essential.

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