



COMPARATIVE STUDY OF INTRAVENOUS FERRIC CARBOXYMALTOSE AND IRON SUCROSE FOR IRON DEFICIENCY ANAEMIA IN PREGNANCY: A PROSPECTIVE ANALYSIS AT A TERTIARY CARE CENTRE

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ABSTRACT **Background:** Iron deficiency anaemia (IDA) in pregnancy is a prevalent condition posing significant risks to maternal and fetal health. Parenteral iron therapies, particularly iron sucrose (IS) and ferric carboxymaltose (FCM), are commonly recommended for moderate to severe IDA. **Objectives:** To compare the efficacy and safety of intravenous FCM and IS in treating IDA in pregnant women. **Methods:** This prospective, comparative study was conducted at Rajshree Medical Research Institute, Bareilly, from February 2025 to February 2026, involving 200 antenatal women with IDA. Participants were divided into two groups: Group A received IV IS (n=100), and Group B received IV FCM (n=100). Changes in haemoglobin and serum ferritin levels were measured at 4 and 12 weeks post-infusion. Safety profiles and maternal outcomes were also evaluated. **Results:** FCM demonstrated significantly higher improvements in haemoglobin (mean rise: 2.95 g/dL) and serum ferritin (mean rise: 140.2 µg/L) compared to IS (1.86 g/dL and 82.1 µg/L respectively; $p<0.001$). The incidence of adverse effects was lower in the FCM group. No serious adverse events were noted. No significant differences in neonatal outcomes were observed. **Conclusion:** FCM showed superior haematological improvement and better tolerability, making it an effective alternative to IS in managing IDA in pregnancy.

KEYWORDS : Ferric Carboxymaltose, Iron Sucrose, Intravenous Iron, Iron Deficiency Anaemia, Pregnancy

INTRODUCTION

Iron deficiency anaemia (IDA) remains a major cause of maternal morbidity and poor pregnancy outcomes worldwide, affecting up to 40% of pregnant women in India. It is associated with an increased risk of preterm delivery, low birth weight, and perinatal mortality.

Although oral iron remains the first-line therapy, limited absorption and gastrointestinal side effects often limit its use. Parenteral iron formulations, such as intravenous iron sucrose (IS) and ferric carboxymaltose (FCM), have emerged as alternatives, particularly in moderate-to-severe anaemia or oral iron intolerance.

IS requires multiple small infusions to achieve the total dose, leading to patient inconvenience and increased healthcare costs. In contrast, FCM allows administration of up to 1000 mg in a single sitting, improving compliance and clinical outcomes.

Thus, this study aimed to directly compare the efficacy and safety of intravenous FCM and IS in pregnant women with moderate-to-severe IDA.

MATERIALS AND METHODS

Study Design and Setting: This was a prospective, interventional, parallel-group study conducted in the Department of Obstetrics and Gynaecology at Rajshree Medical Research Institute, Bareilly, Uttar Pradesh, from February 2025 to February 2026. The study received approval from the Institutional Ethics Committee, and written informed consent was obtained from all participants.

Participants: Inclusion criteria: singleton pregnancy in the second or third trimester, haemoglobin <9 g/dL, serum ferritin <30 µg/L, and intolerance or no response to oral iron therapy. Exclusion criteria: anaemia due to other causes (thalassaemia, B12 or folate deficiency), major hepatic, renal, or cardiovascular disease, recent blood transfusion, or known hypersensitivity to IV iron.

Sample Size and Randomization: Two hundred participants were randomized into two equal groups (n=100 each) using a computer-generated random number table.

Intervention:

- Group A (IS): 200 mg iron sucrose in 100 ml normal saline over 30 minutes on alternate days until the total calculated dose was completed.
- Group B (FCM): Up to 1000 mg ferric carboxymaltose in 250 ml normal saline over 15 minutes as a single or split dose, based on the calculated iron requirement.

The iron dose was calculated using the Ganzoni formula:
 $\text{Iron dose (mg)} = 2.4 \times \text{body weight (kg)} \times (\text{target Hb} - \text{actual Hb in g/dL}) + 500 \text{ mg (iron stores)}$

Outcome Measures: Primary endpoints: change in haemoglobin and serum ferritin at 4 and 12 weeks. Secondary endpoints: adverse drug reactions, maternal and neonatal outcomes (birth weight, APGAR score, preterm delivery).

Statistical Analysis: Data were analysed using SPSS v26. Continuous variables were compared using Student's t-test and categorical variables using the chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS

Both groups were comparable in baseline characteristics. FCM showed significantly higher rises in haemoglobin and ferritin levels at both 4 and 12 weeks. Adverse events were fewer in the FCM group.

Haemoglobin Levels: FCM (10.84 ± 0.5 g/dL at 12 weeks) vs IS (9.72 ± 0.8 g/dL), $p<0.001$.

Serum Ferritin: FCM (140.2 ± 30.4 µg/L) vs IS (82.1 ± 25.6 µg/L), $p<0.001$.

Adverse effects such as nausea and injection site pain were mild and self-limiting. No serious events were reported.

Maternal and neonatal outcomes, including mean birth weight and APGAR score, were comparable between groups.

DISCUSSION

This study confirms that ferric carboxymaltose is more effective than iron sucrose in correcting iron deficiency anaemia during pregnancy. The superior response is due to the ability of FCM to deliver a higher dose in a single administration and its superior bioavailability. These findings align with other comparative trials showing faster haematological correction and better compliance with FCM.

The improved tolerability of FCM can be attributed to fewer infusions and reduced exposure to infusion-related reactions. Although both treatments achieved comparable pregnancy outcomes, improved haematological parameters with FCM may reduce long-term maternal and fetal complications.

Further large-scale studies are warranted to assess cost-effectiveness and long-term safety outcomes of FCM use in pregnancy.

CONCLUSION

Ferric carboxymaltose is a better-tolerated and more efficacious option than iron sucrose for managing iron deficiency anaemia in pregnancy. It provides rapid haematological improvement with fewer side effects and supports its use as a first-line parenteral therapy in moderate-to-severe anaemia.

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