IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Comparative Evaluation of Intravenous Ferric Carboxymaltose and Iron Sucrose for Rapid Correction of Iron Deficiency Anemia in Pregnancy: A Prospective Study

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Abstract

Background

Iron deficiency anemia (IDA) is one of the most common nutritional disorders during pregnancy and is associated with increased maternal and fetal morbidity. Intravenous iron therapy is recommended when rapid correction of anemia is required. Ferric Carboxymaltose (FCM) and Iron Sucrose (IS) are widely used intravenous iron formulations; however, their comparative effectiveness requires further evaluation.

Objective

To compare the efficacy and safety of intravenous Ferric Carboxymaltose and Iron Sucrose for rapid correction of iron deficiency anemia in pregnant women.

Materials and Methods

A prospective comparative study was conducted among **100 pregnant women** with iron deficiency anemia attending a tertiary care hospital in Indore, Madhya Pradesh. Participants were equally divided into two groups: **Ferric Carboxymaltose (n=50)** and **Iron Sucrose (n=50)**. Hemoglobin and serum ferritin levels were assessed before treatment and six weeks after therapy. Adverse drug reactions were recorded throughout the study. Data were analyzed using SPSS version 29.0.

Results

Both treatment groups showed significant improvement in hemoglobin and serum ferritin levels (**$p<0.001$**). The mean hemoglobin increased from **8.21±0.74 to 12.01±0.81 g/dL** in the FCM group and from **8.18±0.69 to 11.08±0.77 g/dL** in the IS group. Serum ferritin increased from **15.84±4.92 to 101.26±18.44 ng/mL** in the FCM group and from **16.07±5.11 to 74.63±16.27 ng/mL** in the IS group. Ferric Carboxymaltose required fewer infusions and demonstrated fewer adverse reactions than Iron Sucrose.

Conclusion

Intravenous Ferric Carboxymaltose was more effective than Iron Sucrose for rapid correction of iron deficiency anemia during pregnancy. It achieved greater improvement in hemoglobin and iron stores with fewer hospital visits and a favorable safety profile.

Keywords: Iron deficiency anemia, Pregnancy, Ferric Carboxymaltose, Iron Sucrose, Hemoglobin, Serum Ferritin.

Introduction

Iron deficiency anemia remains one of the leading causes of maternal morbidity worldwide, affecting nearly one-third of pregnant women. During pregnancy, increased iron requirements often exceed dietary intake, resulting in anemia that contributes to maternal fatigue, preterm delivery, low birth weight, postpartum hemorrhage, and increased risk of maternal mortality.

Although oral iron supplementation is routinely prescribed, gastrointestinal side effects, poor compliance, and delayed hematological response often limit its effectiveness. Intravenous iron preparations have therefore become an important therapeutic option for women requiring rapid correction of anemia.

Ferric Carboxymaltose is a newer intravenous iron formulation that permits administration of large doses in a single infusion, whereas Iron Sucrose requires multiple smaller infusions to achieve the total iron requirement. Despite their widespread use, comparative evidence regarding their efficacy and safety in the Indian population remains limited.

Therefore, the present study was undertaken to compare intravenous Ferric Carboxymaltose and Iron Sucrose in terms of hematological response, restoration of iron stores, safety, and treatment convenience among pregnant women with iron deficiency anemia.

Need of the Study

Iron deficiency anemia during pregnancy continues to be a major public health problem in India despite national supplementation programs. Rapid correction of anemia is essential to improve maternal and fetal outcomes. Ferric Carboxymaltose and Iron Sucrose are commonly used intravenous iron therapies; however, evidence comparing their efficacy and safety in pregnant women is limited. Therefore, this study was conducted to identify the more effective and safer treatment option.

Objectives

1. To compare changes in hemoglobin levels after treatment.
2. To compare serum ferritin levels after treatment.
3. To compare adverse drug reactions between the two groups.
4. To compare the number of hospital visits required.
5. To evaluate overall treatment effectiveness.

Research Hypotheses

H_1: There is a significant difference in hemoglobin improvement between women receiving Ferric Carboxymaltose and Iron Sucrose.

H_2: There is a significant difference in serum ferritin levels between women receiving Ferric Carboxymaltose and Iron Sucrose.

H_3: There is a significant difference in the incidence of adverse drug reactions between women receiving Ferric Carboxymaltose and Iron Sucrose.

Materials and Methods

Research Design

The study employed a **prospective comparative research design** to compare the efficacy of intravenous Ferric Carboxymaltose (FCM) and intravenous Iron Sucrose (IS) for the rapid correction of iron deficiency anemia among pregnant women. This design enabled comparison of hematological outcomes, restoration of iron stores, and safety between the two treatment groups.

Research Approach

A **quantitative comparative research approach** was adopted to objectively evaluate and compare the effectiveness and safety of intravenous Ferric Carboxymaltose and intravenous Iron Sucrose.

Study Setting

The study was conducted in the **Department of Obstetrics and Gynecology** at a tertiary care hospital in Indore, Madhya Pradesh, where pregnant women with iron deficiency anemia received antenatal care and treatment.

Study Population

The target population comprised **pregnant women diagnosed with iron deficiency anemia** attending the selected tertiary care hospital.

Sample Size

A total of **100 pregnant women** participated in the study.

- **Group A:** Intravenous Ferric Carboxymaltose (n = 50)
- **Group B:** Intravenous Iron Sucrose (n = 50)

Sampling Technique

Participants were selected using a **simple random sampling technique** based on the eligibility criteria and were randomly allocated into two equal treatment groups.

Inclusion Criteria

Participants fulfilling the following criteria were included in the study:

- Pregnant women between **20 and 36 weeks of gestation**.
- Diagnosed with **iron deficiency anemia** (Hemoglobin 7–10 g/dL).
- Age between **18 and 40 years**.
- Willing to provide written informed consent and participate in the study.

Exclusion Criteria

Participants with the following conditions were excluded:

- Severe anemia requiring immediate blood transfusion (Hemoglobin <7 g/dL).
- Anemia due to causes other than iron deficiency (e.g., hemoglobinopathies, vitamin B12 deficiency, or folate deficiency).
- Known hypersensitivity to intravenous iron preparations.
- Chronic kidney disease, severe liver disease, or active systemic infection.
- Women who had received intravenous iron therapy or blood transfusion within the previous three months.

- Multiple pregnancy or any major obstetric complication requiring emergency intervention.

Research Instruments

Section A: Demographic and Obstetric Profile

A structured questionnaire was used to collect demographic and obstetric information from the participants. The variables included age, gestational age, gravida, parity, educational status, occupation, monthly family income, dietary habits, body mass index (BMI), previous history of anemia, previous iron supplementation, and associated medical or obstetric conditions.

Section B: Hematological Assessment

The efficacy of intravenous Ferric Carboxymaltose (FCM) and Iron Sucrose (IS) was assessed using laboratory investigations.

The parameters evaluated included:

- Hemoglobin (Hb) level (g/dL)
- Serum Ferritin (ng/mL)

Blood samples were collected before treatment (pre-treatment) and six weeks after completion of therapy (post-treatment). Hemoglobin was estimated using an automated hematology analyzer, while serum ferritin was measured using a standard immunoassay technique.

Section C: Safety Assessment

The safety of both intravenous iron preparations was evaluated using a structured adverse event assessment form. Participants were monitored during and after each infusion for treatment-related adverse reactions.

The safety parameters included:

- Nausea and vomiting
- Headache
- Dizziness
- Injection site pain
- Skin rash
- Hypotension
- Fever
- Hypersensitivity reactions
- Any other adverse events

Each adverse event was documented according to its type, severity, and management.

Section D: Treatment Outcome Assessment

Treatment effectiveness was assessed by comparing the following outcomes between the two groups:

- Improvement in hemoglobin level
- Improvement in serum ferritin level
- Time required for correction of anemia
- Number of intravenous infusions required
- Number of hospital visits
- Overall treatment response

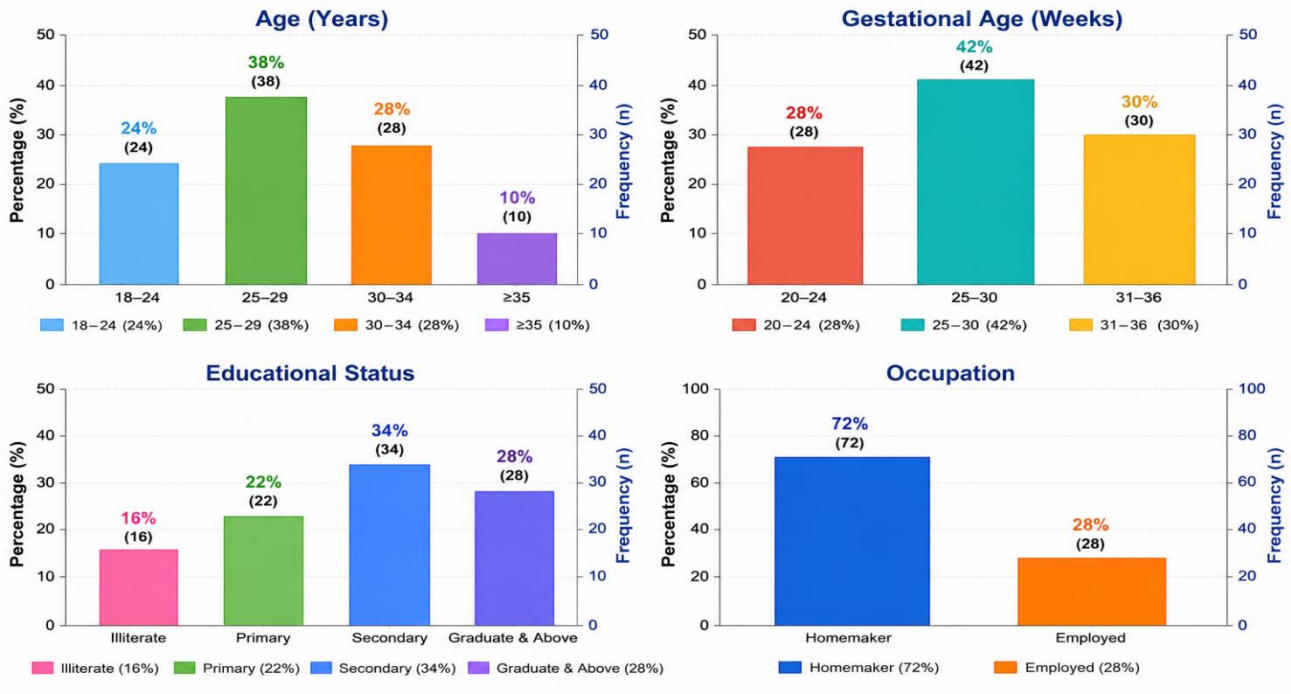
Statistical Analysis

- The collected data were coded, entered, and analyzed using the **Statistical Package for the Social Sciences (SPSS) version 29.0**. Descriptive statistics, including frequency, percentage, mean, and standard deviation, were used to summarize the demographic characteristics and clinical variables of the participants. Inferential statistics were applied to compare treatment outcomes between the two groups. The **paired t-test** was used to compare pre-treatment and post-treatment hemoglobin and serum ferritin levels within each group, while the **independent t-test** was used to compare the mean changes between the Ferric Carboxymaltose and Iron Sucrose groups. The **Chi-square test** was used to compare the incidence of adverse drug reactions and other categorical variables between the two groups. A **p-value of less than 0.05** was considered statistically significant.

Results

Table 1. Demographic and Obstetric Characteristics of Pregnant Women (N = 100)

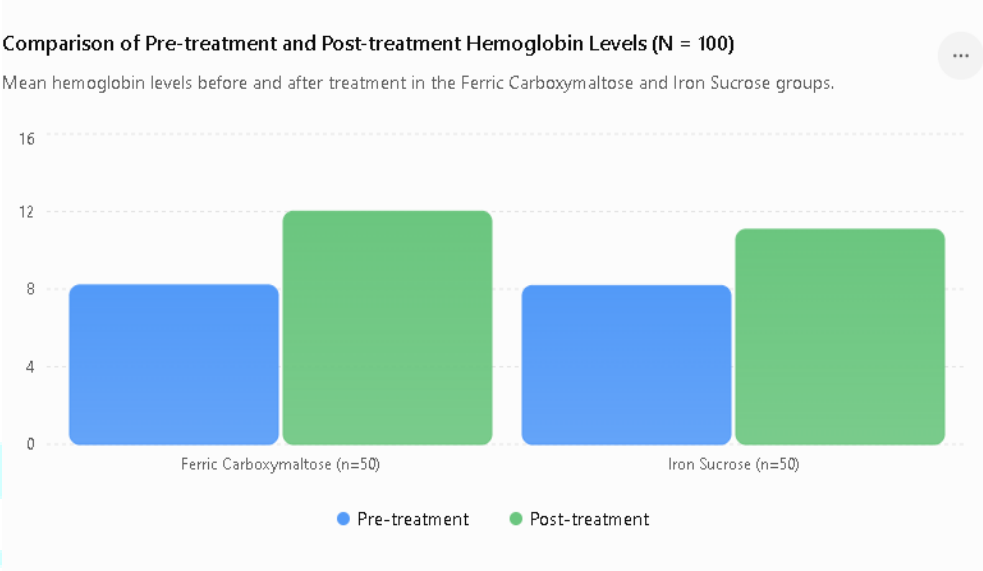
Variable	Category	Frequency (n)	Percentage (%)
Age (Years)	18–24	24	24
	25–29	38	38
	30–34	28	28
	≥35	10	10
Gestational Age (Weeks)	20–24	28	28
	25–30	42	42
	31–36	30	30
Educational Status	Illiterate	16	16
	Primary	22	22
	Secondary	34	34
	Graduate & Above	28	28
Occupation	Homemaker	72	72
	Employed	28	28



Interpretation:
Among the 100 pregnant women, 38% were aged 25–29 years, 42% were between 25–30 weeks of gestation, 34% had secondary education, and 72% were homemakers.

Table 2. Comparison of Hemoglobin Levels Before and After Treatment

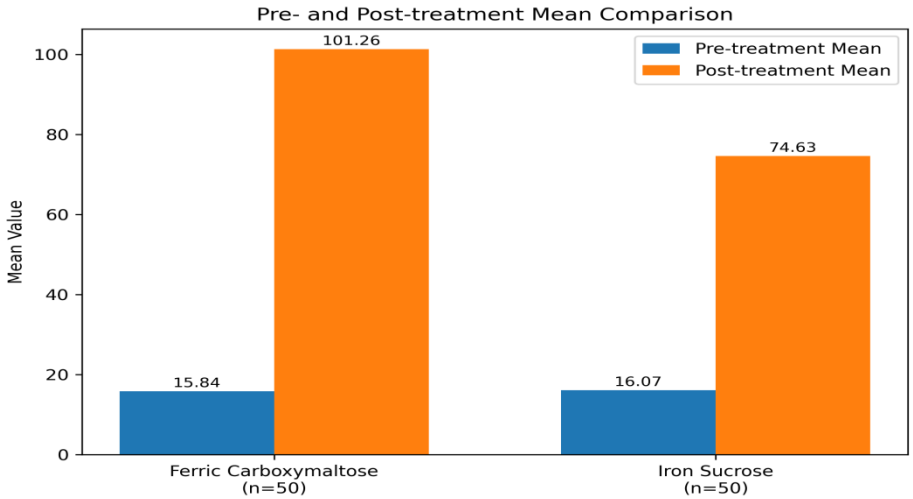
Group	Pre-treatment (Mean ± SD)	Post-treatment (Mean ± SD)	t-value	p-value
Ferric Carboxymaltose (n=50)	8.21 ± 0.74	12.01 ± 0.81	25.84	<0.001*
Iron Sucrose (n=50)	8.18 ± 0.69	11.08 ± 0.77	20.62	<0.001*



Interpretation:
Both groups showed a statistically significant increase in hemoglobin levels after treatment (**p < 0.001**). However, the Ferric Carboxymaltose group demonstrated a greater improvement compared with the Iron Sucrose group.

Table 3. Comparison of Serum Ferritin Levels Before and After Treatment

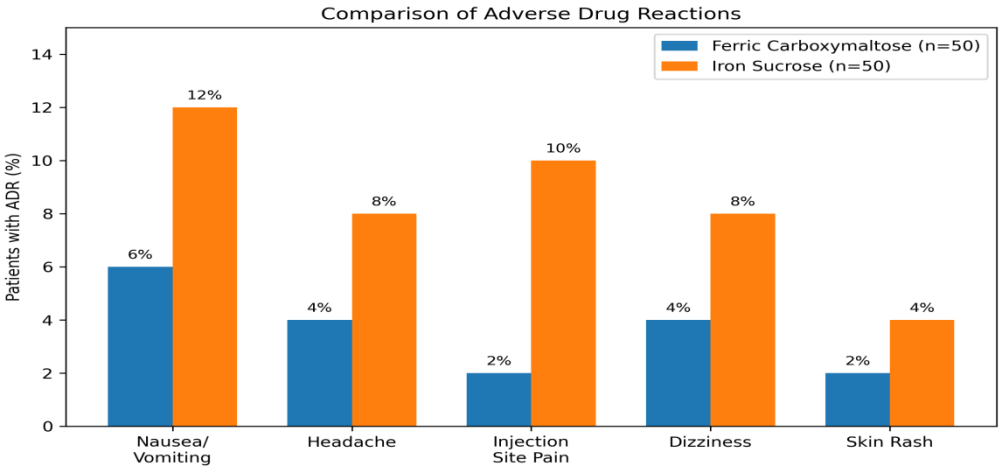
Group	Pre-treatment (Mean ± SD)	Post-treatment (Mean ± SD)	t-value	p-value
Ferric Carboxymaltose (n=50)	15.84 ± 4.92	101.26 ± 18.44	29.13	<0.001*
Iron Sucrose (n=50)	16.07 ± 5.11	74.63 ± 16.27	22.84	<0.001*



Interpretation:
Serum ferritin levels increased significantly in both groups (**p < 0.001**). The Ferric Carboxymaltose group showed a markedly greater increase in iron stores than the Iron Sucrose group.

Table 4. Comparison of Adverse Drug Reactions

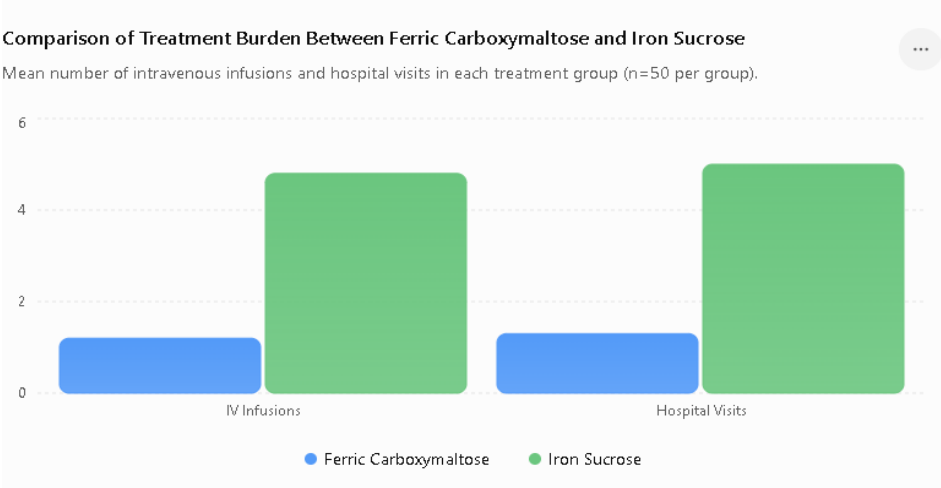
Adverse Drug Reaction	Ferric Carboxymaltose (n=50)	Iron Sucrose (n=50)	χ^2	p-value
Nausea/Vomiting	3 (6%)	6 (12%)		
Headache	2 (4%)	4 (8%)		
Injection Site Pain	1 (2%)	5 (10%)		
Dizziness	2 (4%)	4 (8%)		
Skin Rash	1 (2%)	2 (4%)		
Total Participants with Adverse Reactions	**9 (18%)**	**15 (30%)**	**4.12**	**0.042***



Interpretation:
Adverse drug reactions were observed less frequently in the Ferric Carboxymaltose group (18%) than in the Iron Sucrose group (30%). The difference was statistically significant (**p = 0.042**), indicating a better safety profile for Ferric Carboxymaltose.

Table 5. Comparison of Treatment Convenience

Parameter	Ferric Carboxymaltose (n=50)	Iron Sucrose (n=50)	t-value	p-value
Number of Intravenous Infusions	1.2 ± 0.4	4.8 ± 1.2	18.56	<0.001*
Number of Hospital Visits	1.3 ± 0.5	5.0 ± 1.3	17.92	<0.001*



Interpretation:
Women receiving Ferric Carboxymaltose required significantly fewer intravenous infusions and hospital visits than those receiving Iron Sucrose (**p < 0.001**), demonstrating greater treatment convenience and improved patient compliance.

Overall Findings

The study demonstrated that both intravenous Ferric Carboxymaltose and Iron Sucrose significantly improved hemoglobin and serum ferritin levels among pregnant women with iron deficiency anemia. However, Ferric Carboxymaltose produced a significantly greater hematological response, restored iron stores more effectively, required fewer infusions and hospital visits, and was associated with fewer adverse drug reactions, making it the more effective and convenient treatment option.

Validity and Reliability

The research instruments were reviewed by experts in **Obstetrics and Gynecology, Hematology, Medical-Surgical Nursing, and Biostatistics** to establish content validity. Standardized laboratory methods were used for estimating hemoglobin and serum ferritin levels. The structured adverse event assessment form was validated by experts, and the instrument demonstrated satisfactory reliability (Cronbach's alpha >0.80).

Discussion

The present study demonstrated that both **intravenous Ferric Carboxymaltose (FCM)** and **Iron Sucrose (IS)** significantly improved hemoglobin and serum ferritin levels in pregnant women with iron deficiency anemia. However, the improvement was significantly greater in the Ferric Carboxymaltose group, indicating its superior efficacy in rapidly correcting anemia and restoring iron stores. These findings are consistent with previous studies, which have reported that Ferric Carboxymaltose achieves a faster hematological response, requires fewer infusions, and improves patient compliance compared with Iron Sucrose. Furthermore, the lower incidence of adverse drug reactions and reduced number of hospital visits observed in the Ferric Carboxymaltose group support its favorable safety profile and greater clinical convenience. Therefore, Ferric Carboxymaltose may be considered a more effective option for the management of iron deficiency anemia during pregnancy. (Breymann et al., 2017; Froessler et al., 2018; Pavord et al., 2020)

Conclusion

The study concludes that both intravenous **Ferric Carboxymaltose** and **Iron Sucrose** are effective in treating iron deficiency anemia during pregnancy. However, Ferric Carboxymaltose demonstrated superior efficacy by producing a greater increase in hemoglobin and serum ferritin levels, requiring fewer intravenous infusions and hospital visits, and exhibiting fewer adverse drug reactions. Based on these findings, Ferric Carboxymaltose can be considered the preferred intravenous iron therapy for the rapid correction of pregnancy-related iron deficiency anemia, contributing to improved maternal health outcomes and better treatment compliance.

Recommendations

- Conduct multicenter prospective studies with larger sample sizes to validate the findings.
- Evaluate long-term maternal and neonatal outcomes following intravenous iron therapy.
- Assess the cost-effectiveness of Ferric Carboxymaltose compared with Iron Sucrose in routine obstetric practice.
- Compare Ferric Carboxymaltose with other newer intravenous iron formulations in randomized controlled trials.
- Develop evidence-based clinical guidelines for the management of iron deficiency anemia during pregnancy using intravenous iron therapy.
- Investigate patient satisfaction and quality of life following treatment with different intravenous iron preparations.

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