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Original Article

Efficacy and Safety of Intravenous Ferric Carboxymaltose in Pregnant Women with Anaemia

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ABSTRACT

Background: Iron deficiency anaemia in pregnancy is a significant global health issue, affecting over 50% of women in India. While oral iron supplements are commonly used, their effectiveness is often compromised due to poor adherence and gastrointestinal side effects. Intravenous ferric carboxymaltose offers an alternative that is well tolerated and allows rapid correction of iron deficiency. However, evidence about its safety and efficacy in pregnant women remains limited. **Materials and Methods:** A prospective observational study was conducted from November 2023 to June 2024 in Hyderabad, India. It included pregnant women aged ≥18 years, in their second or third trimester, diagnosed with mild to moderate iron deficiency anaemia (haemoglobin 7-10.9 g/dL), and receiving intravenous ferric carboxymaltose. Haemoglobin levels were measured before infusion and weekly for four weeks. Maternal safety and adverse effects were monitored throughout. Data analysis involved descriptive statistics and repeated-measures ANOVA. **Results:** Sixty-two women participated. The mean baseline haemoglobin was 8.54 g/dL, increasing to 10.85 g/dL by week four ($p<0.001$). Over 60% had moderate anaemia at baseline. No serious adverse reactions occurred. The demographic and anaemia severity patterns aligned with regional data. **Conclusion:** Intravenous ferric carboxymaltose significantly improves haemoglobin in pregnant women with iron deficiency anaemia and has a good safety profile. It's use in antenatal care could benefit women who are unresponsive to or intolerant of oral iron. Further research is needed to assess long-term maternal and neonatal outcomes.

Keywords: Iron Deficiency Anaemia, Pregnancy, Ferric Carboxymaltose, Intravenous Iron Therapy, Maternal Health Outcomes.

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INTRODUCTION

Iron deficiency anaemia remains a significant public health issue affecting women during pregnancy worldwide, with substantial implications for both maternal and neonatal health. The condition is linked to increased maternal morbidity, reduced physical functioning, and adverse perinatal outcomes such as low birth weight and preterm delivery (Safarzadeh *et al.*, 2023). In India, anaemia during pregnancy is highly prevalent and influenced by nutritional deficiencies and socioeconomic challenges, particularly in underserved regions (Let *et al.*, 2024; Pandit *et al.*, 2021). These factors contribute to a persistent burden of maternal anaemia despite ongoing public health efforts (Tandon *et al.*, 2018).

Oral iron supplementation remains the standard first-line treatment for iron deficiency anaemia in pregnancy, given its accessibility and cost-effectiveness. However, many women experience poor adherence because of gastrointestinal side effects and inadequate absorption, limiting its overall efficacy (Duarte *et al.*, 2021). To overcome these challenges, intravenous iron preparations have gained interest, particularly ferric carboxymaltose, which allows rapid restoration of iron stores and correction of anaemia with fewer administrations (Froessler *et al.*, 2014). The safety and efficacy of ferric carboxymaltose have been demonstrated in various populations, including pregnant women, with evidence suggesting a favourable safety profile and significant haemoglobin improvement (Pels and Ganzevoort, 2015).

Despite international evidence supporting intravenous ferric carboxymaltose use in pregnancy, data specific to the Indian population remain limited. Regional variation in anaemia prevalence, maternal nutritional status, and healthcare infrastructure necessitate localized studies to inform clinical guidelines (Tandon *et al.*, 2018). This study was designed to

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evaluate the effectiveness of intravenous ferric carboxymaltose in increasing haemoglobin levels and to assess maternal safety among pregnant women with iron deficiency anaemia within a Secondary care setting in India. The study hypothesizes that ferric carboxymaltose therapy leads to significant haemoglobin improvement without serious adverse effects, offering a viable alternative for managing anaemia in pregnant women who are non-compliant or intolerant to oral iron.

By addressing this evidence gap in an Indian context, the present work aims to contribute to optimizing antenatal anaemia management protocols and improving maternal and neonatal outcomes in populations at high risk. The findings will help guide clinicians in selecting appropriate iron supplementation strategies tailored to the needs of pregnant women in similar healthcare settings.

MATERIALS AND METHODS

Study Design and Setting

This observational study was conducted at the antenatal clinic of a Secondary care hospital in Hyderabad, India, over a Eight-month period. The study aimed to evaluate treatment outcomes among pregnant women with Iron Deficiency Anaemia (IDA) who were already receiving intravenous Ferric Carboxymaltose (FCM) as part of their routine antenatal management. The study protocol was approved by the Institutional Ethics Committee of Anwarul Ul Uloom College of Pharmacy, Hyderabad (Approval No: AUCP/IEC/23-24/PharmD/10/02). Written informed consent in the local language was obtained from all participants prior to their inclusion, and the confidentiality of personal data was maintained throughout all stages.

Participants

The study included pregnant women aged 18-40 years with singleton pregnancies between 16 and 39 weeks of gestation who were clinically diagnosed with IDA. The diagnosis was established based on haemoglobin levels between 7 and 10 g/dL, low serum ferritin levels (<30 ng/mL), and microcytic hypochromic indices on peripheral smear. Women were eligible if they had already been prescribed FCM infusion by the treating physician. Exclusion criteria included known hypersensitivity to parenteral iron, chronic hepatic or renal disorders, haemoglobinopathies, multiple gestation, recent blood transfusion within three months, and the presence of acute infection at the time of recruitment.

Materials and Procedures

The dosage and frequency of infusion were determined by the obstetrician based on the estimated iron deficit, generally ranging between 500 and 1000 mg per sitting. Each dose was diluted in 100 mL of normal saline and administered intravenously over approximately 15 min. Participants were routinely monitored during infusion and for 30 min thereafter to identify any infusion-related adverse effects. Data regarding total FCM dose, number of infusions, and intervals between doses were extracted from hospital records. Haemoglobin levels were obtained from medical records prior to the initiation of FCM (baseline) and immediately post-infusion, as well as at one, two, three, and four weeks following completion of therapy. Patients were counselled regarding diet, anaemia prevention, and follow-up adherence. Pharmacists maintained regular communication through weekly reminders.

Statistical Analysis

All collected data were entered into Microsoft Excel 2021 and analyzed using IBM SPSS Statistics version 26 (IBM Corp., USA). Descriptive statistics, including the mean, standard deviation, and percentages, were used to summarize baseline characteristics. The difference in haemoglobin concentration before and after FCM therapy was analyzed using a paired *t*test, with a *p*value of less than 0.05 considered statistically significant.

RESULTS

A total of 62 pregnant women diagnosed with iron deficiency anaemia received intravenous ferric carboxymaltose therapy.

Demographic Characteristics

As shown in Table 1, most participants were aged 24-29 years (54.84%), while 33.87% were aged 18-23 years. Educational levels ranged from illiterate (6.45%) to graduate (17.74%). The predominant religion was Hinduism (61.29%), followed by Islam (37.10%), and the majority of participants were housewives (95.16%).

Reproductive History

Reproductive patterns are detailed in Table 2. Almost half the women were multigravida (gravida 2; 46.77%), while 27.42% were primigravida**.** In terms of parity, 46.77% had one prior delivery, and 33.87% were nulliparous**.** A history of abortion was reported in 12.90% of cases.

Comorbidities and Anaemia Severity

As summarized in Table 3, 17.74% had pre-existing hypothyroidism, while 16.13% developed gestational hypothyroidism. The majority had moderate anaemia (62.90%), followed by mild (35.48%) and severe (1.61%) anaemia.

Haematological Response

Haemoglobin (Hb) levels demonstrated a significant and progressive increase following ferric carboxymaltose administration. The mean baseline Hb was 8.60 g/dL (95% CI: 8.30-8.90) and increased to 10.90 g/dL (95% CI: 10.50-11.30) by week four. Weekly increments averaged about 1 g/dL, as shown in Table 4 and Figure 1.

Repeated Measures ANOVA Analysis (Table 5) demonstrated a statistically significant increase in Mean Hb levels over the 4-Week Period. No serious adverse events occurred. Minor effects such as mild injection site discomfort and transient nausea were observed in a few participants and resolved spontaneously. The average defined daily dose corresponded to 0.5 g per 30 patients, consistent with standard dosing guidelines.

DISCUSSION

This study demonstrates that intravenous Ferric Carboxymaltose (FCM) produces a significant and sustained rise in haemoglobin levels among pregnant women with iron deficiency anaemia. The mean haemoglobin increase of 2.3 g/dL within four weeks is consistent with published data showing rapid correction of anaemia following FCM therapy (Froessler *et al.*, 2014).

The demographic characteristics of participants, primarily women aged 24-29 years and predominance of moderate anaemia, align with earlier findings from similar populations (Froessler *et al.*, 2014; Sharma *et al.*, 2017). The low proportion of severe anaemia (1.61%) likely reflects enhanced antenatal surveillance and early intervention, paralleling recent Indian cohort reports (Chawla *et al.*, 2022).

The observed improvement in haemoglobin mirrors outcomes from randomized controlled trials comparing FCM with oral and other intravenous iron formulations. Studies have shown greater efficacy and faster correction with FCM compared to oral ferrous sulfate, without compromising neonatal safety (Chawla *et al.*, 2022). Similarly, FCM offers practical advantages over iron sucrose, notably fewer doses, better compliance, and more rapid haemoglobin recovery (Pfenniger *et al.*, 2012; Sharma *et al.*, 2017).

Meta-analyses further confirm that intravenous iron therapies effectively correct anaemia in pregnancy, with FCM standing out for its single-dose convenience and high tolerability (Qassim *et al.*, 2018). The absence of serious adverse events in our study echoes prior evidence underscoring its excellent safety profile (Seid *et al.*, 2008; Van Wyck *et al.*, 2007; Shin *et al.*, 2021).

Table 1: Demographic Characteristics of Patients (N = 62).

Category	Subcategory	Number (N)	Percentage (%)
Age (Years)	18-23	21	33.87
	24-29	34	54.84
	30-35	7	11.29
Educational Status	Illiterate	4	6.45
	Primary	14	22.58
	Secondary	33	53.23
	Graduate	11	17.74
Religion	Hindu	38	61.29
	Muslim	23	37.10
	Christian	1	1.61
Occupation	Housewife	59	95.16
	Employed	3	4.84

Note: Data are presented as frequency (N) and percentage (%). Descriptive statistics were used for all categorical variables.

Table 2: Reproductive History of Participants (N = 62).

Category	Subcategory	Number (N)	Percentage (%)
Gravida Status	Primi (1)	17	27.42
	2	29	46.77
	≥3	16	25.81
Parity Status	0	21	33.87
	1	29	46.77
	2	8	12.90
	≥3	4	6.45
Abortion History	Yes	8	12.90
	No	54	87.10

Note: Frequencies (N) and percentages (%) reported. No inferential statistics were performed for these categorical variables.

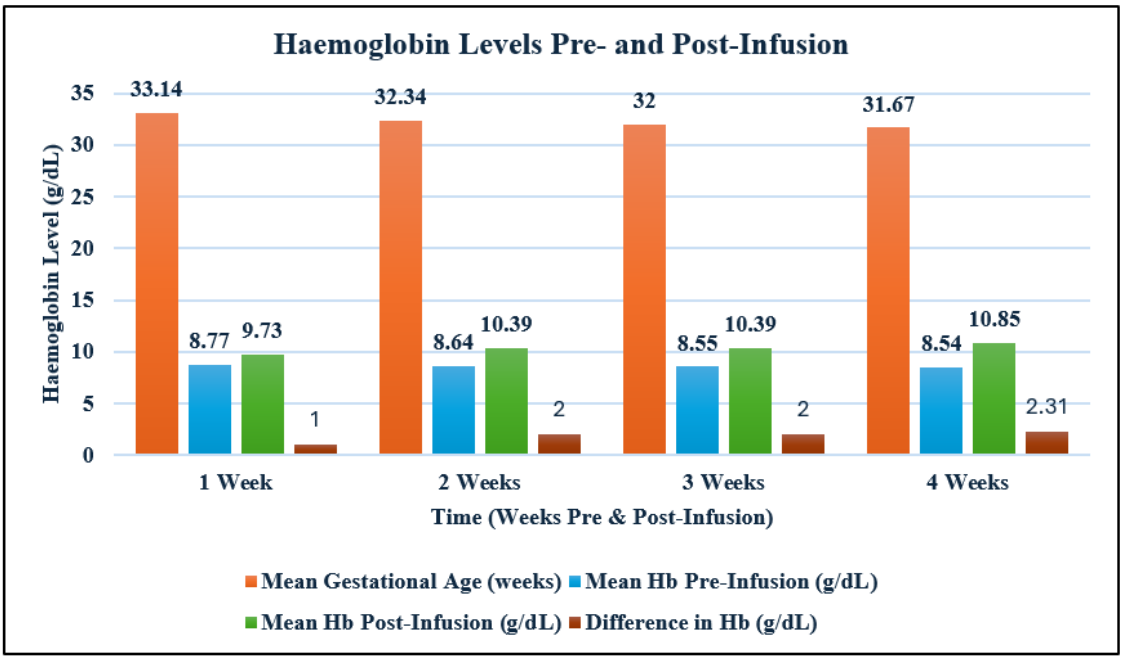

Figure 1: Mean Haemoglobin Levels Pre- and Post-Infusion Over Four Weeks in Pregnant Women Treated with Intravenous Ferric Carboxymaltose.

Table 3: Comorbidities and Severity of Anaemia Among Participants (N = 62).

Category	Subcategory	Number (N)	Percentage (%)
Comorbidities	Existing hypothyroidism	11	17.74
	Gestational hypothyroidism	10	16.13
Severity of Anaemia	Mild	22	35.48
	Moderate	39	62.90
	Severe	1	1.61

Note: Categorical data summarized as frequencies (N) and percentages (%). Anaemia severity classified according to WHO criteria.

Table 4: Change in Mean Haemoglobin Levels Over Four Weeks (N = 62).

Time Point	Mean Hb (g/dL) ± SD	95% Confidence Interval (Lower - Upper)
Baseline (Pre-Infusion)	8.60 ± 1.10	8.30 - 8.90
Week 1 Post-Infusion	9.50 ± 1.20	9.20 - 9.80
Week 2 Post-Infusion	10.20 ± 1.30	9.80 - 10.60
Week 3 Post-Infusion	10.50 ± 1.40	10.10 - 10.90
Week 4 Post-Infusion	10.90 ± 1.50	10.50 - 11.30

Note: Values are Mean±SD with 95% confidence intervals. Repeated-measures ANOVA was used to evaluate changes in haemoglobin over time.

Table 5: Repeated-Measures ANOVA Results.

Statistic	Value
F-statistic	35.42
p-value	< 0.001
Effect Size (η^2)	0.72

Note: Repeated-measures ANOVA assessed within-subject differences in haemoglobin over four time points. Effect size (η^2) calculated according to Cohen's criteria.

Strengths of this study include its prospective design, use of repeated measures for haemoglobin monitoring, and systematic safety evaluation. However, limitations include a relatively small sample size, a single-centre scope, and a lack of a control or comparative arm, which may constrain generalizability and preclude the assessment of long-term maternal or neonatal outcomes.

In conclusion, ferric carboxymaltose is an effective, safe, and well-tolerated therapy for iron deficiency anaemia in pregnancy, enabling rapid haemoglobin restoration with minimal adverse effects. Given its dosing convenience and excellent tolerability, FCM represents a valuable therapeutic alternative when oral iron is ineffective or poorly tolerated. Future research should explore larger, multicentre trials with extended follow-up to evaluate long-term clinical and perinatal outcomes.

CONCLUSION

In conclusion, this study provides compelling evidence that intravenous ferric carboxymaltose is a highly effective and safe therapeutic option for managing iron deficiency anaemia in pregnant women. The significant and sustained increase in haemoglobin levels observed over four weeks highlights its capability to rapidly restore iron levels, which is crucial during pregnancy to mitigate the risks associated with anaemia for both mother and child. The favourable safety profile, with no serious adverse events and only minor transient side effects, further supports its clinical utility, especially in cases where oral iron therapy is poorly tolerated or insufficient. Given these findings, ferric carboxymaltose should be considered a valuable addition to antenatal care protocols to improve maternal health outcomes. Nevertheless, future research involving larger, multi-centre randomized controlled trials with longer follow-up durations is essential to confirm these benefits and to evaluate the long-term maternal and neonatal outcomes associated with its use.

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ABBREVIATIONS

IDA: Iron Deficiency Anaemia; **FCM:** Ferric Carboxymaltose; **Hb:** Haemoglobin; **CI:** Confidence Interval; **mL:** Millilitre; **mg:** Milligram; **dL:** Decilitre; **ng/mL:** Nanograms per Millilitre; **IBM SPSS:** International Business Machines Statistical Package for the Social Sciences.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AI USE STATEMENT

AI-based assistance was used for improving language clarity and formatting.

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