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Efficacy and Safety of Single-Dose Intravenous Ferric Carboxymaltose 1 g at 24 ± 1 Weeks of Gestation in Pregnant Women with Iron Deficiency Anaemia: A Prospective Interventional Study

Running Title: Ferric Carboxymaltose in Pregnancy-Associated Iron Deficiency Anaemia

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Abstract: ***Background*: Iron deficiency anaemia (IDA) during pregnancy remains a major contributor to maternal fatigue, poor pregnancy tolerance, low birth weight and perinatal morbidity. Oral iron is useful in mild disease but is limited by poor gastrointestinal tolerance, slow haemoglobin response and inadequate compliance. Ferric carboxymaltose (FCM) permits administration of a high iron dose in a single sitting and may support rapid correction during the second trimester. *Aim*: To evaluate the efficacy, safety and maternal-neonatal outcomes of single-dose intravenous ferric carboxymaltose 1 g administered at 24 ± 1 weeks of gestation in pregnant women with iron deficiency anaemia. *Materials and Methods*: This prospective, single-centre, hospital-based interventional study included 200 pregnant women aged 18-45 years at 24 ± 1 weeks of gestation with Hb 7.0 to <10.0 g/dL and laboratory evidence of iron deficiency. Participants received FCM 1 g diluted in 250 mL normal saline over 15-30 minutes. Haemoglobin, serum ferritin and mean corpuscular volume were assessed at baseline, 4 weeks and 8 weeks. Maternal, neonatal and adverse-event outcomes were recorded. *Results*: Mean haemoglobin increased from 8.2 ± 0.6 g/dL at baseline to 10.3 ± 0.5 g/dL at 4 weeks and 11.2 ± 0.6 g/dL at 8 weeks, with a mean rise of 3.0 g/dL (p<0.001). Serum ferritin increased from 14.9 ± 6.3 ng/mL to 101.3 ± 6.4 ng/mL, while MCV improved from 77.3 ± 4.6 fL to 88.2 ± 1.3 fL (p<0.001). Overall, 93% achieved target Hb >=10 g/dL. FTND occurred in 55%, LSCS in 26%, and no severe postpartum haemorrhage or blood transfusion was recorded. Neonatal outcomes were favourable, with 72% normal birth weight, 97% APGAR >=7 at 5 minutes and 12% NICU admission. No adverse event occurred in 78%; reported reactions were mild and self-limiting, with no anaphylaxis or therapy discontinuation. *Conclusion*: Single-dose intravenous ferric carboxymaltose 1 g at 24 ± 1 weeks is an effective, safe and operationally feasible treatment for moderate iron deficiency anaemia in pregnancy.***

Keywords: Ferric carboxymaltose, iron deficiency anaemia, pregnancy, haemoglobin, serum ferritin, intravenous iron, neonatal outcome

1. Introduction

Iron deficiency anaemia (IDA) in pregnancy remains one of the most common nutritional and haematological challenges in obstetric practice. Pregnancy imposes increased iron demand because of expansion of maternal red cell mass, fetal and placental growth, and expected blood loss at delivery. When maternal iron stores are inadequate, progressive depletion of iron reserves results in microcytic hypochromic anaemia, reduced oxygen-carrying capacity, fatigue and poor pregnancy tolerance.[1]

The clinical relevance of IDA extends beyond laboratory correction. Maternal anaemia is associated with reduced functional capacity, increased susceptibility to infection, postpartum morbidity, and a higher likelihood of transfusion in the peripartum period. Fetal and neonatal consequences include low birth weight, prematurity, intrauterine growth restriction, poor neonatal iron stores and increased need for neonatal intensive care.[2,3]

Oral iron remains the conventional first-line therapy for mild anaemia. However, its real-world impact is frequently constrained by nausea, vomiting, constipation, epigastric discomfort, poor adherence and slow haematological recovery. These limitations are especially important during mid and late pregnancy, where timely correction of anaemia is required before delivery.[4]

Ferric carboxymaltose (FCM) is a stable, non-dextran intravenous iron complex that allows administration of large iron doses in a short infusion time. Its controlled release profile enables rapid replenishment of iron stores with a favourable tolerability profile and fewer hospital visits compared with conventional multi-dose parenteral regimens.[5,6]

Administration of FCM at 24 ± 1 weeks of gestation provides a clinically strategic window for correction of moderate IDA before the high iron-demand third trimester and before labour. The present study was conducted to evaluate the efficacy and safety of single-dose intravenous FCM 1 g in pregnant women with IDA, with additional assessment of maternal, fetal and neonatal outcomes.

2. Materials and Methods

This prospective, hospital-based, single-centre interventional study was conducted in the Department of Obstetrics and Gynaecology at a tertiary care teaching hospital from January 2024 to January 2026. Institutional Ethics Committee approval was obtained before recruitment, and written informed consent was taken from all participants.

The study population comprised pregnant women aged 18-45 years attending the antenatal clinic at 24 ± 1 weeks of gestation. A total of 200 women fulfilling the selection criteria were enrolled.

Inclusion criteria were willingness to participate, gestational age of 24 ± 1 weeks confirmed by last menstrual period or ultrasonography, Hb between 7.0 and <10.0 g/dL, serum ferritin <30 µg/L or ferritin <50 µg/L with transferrin saturation <20%, and eligibility for intravenous iron therapy.

Exclusion criteria included refusal to participate, gestational age <23 weeks or >25 weeks, anaemia due to causes other than iron deficiency, evidence of iron overload, known hypersensitivity to intravenous iron, active liver disease, HBV or HCV infection, chronic kidney disease, HIV/AIDS, asthma, rheumatoid arthritis or malignancy.

Baseline demographic details, obstetric history, residence, socioeconomic status, antenatal registration, medical co-morbidities and clinical findings were recorded in a structured case record form. Baseline investigations included complete blood count, serum ferritin, transferrin saturation, peripheral smear and relevant screening tests to exclude non-iron-deficiency causes of anaemia.

The intervention consisted of Inj. ferric carboxymaltose 1 g diluted in 250 mL normal saline and administered intravenously over 15-30 minutes under aseptic precautions. Maternal pulse, blood pressure and respiratory status were monitored during infusion and for at least 30 minutes after infusion. No other parenteral iron was administered during the study period. Standard antenatal supplementation and care were continued as per institutional protocol.

Participants were followed up at 4 weeks and 8 weeks after infusion. Haemoglobin, serum ferritin and MCV were reassessed, and any immediate or delayed adverse events were documented. Maternal outcomes recorded at delivery included mode of delivery, preterm birth, postpartum haemorrhage and blood transfusion requirement. Neonatal outcomes included birth weight, APGAR score at 5 minutes and NICU admission.

Quantitative variables were expressed as mean ± standard deviation. Categorical variables were expressed as frequency and percentage. Paired comparisons of haematological parameters were analysed using appropriate statistical tests, and categorical variables were compared using chi-square or Fisher's exact test as applicable. A p-value <0.05 was considered statistically significant.

3. Results

A total of 200 pregnant women with iron deficiency anaemia at 24 ± 1 weeks of gestation were included in the final analysis. The key study findings are presented below.

The majority of participants belonged to the 21-25 years age group (38%), followed by 26-30 years (28%). Multigravida women formed 70% of the cohort, with gravida 2 being the largest subgroup (40%). Rural participants accounted for 55%, while 45% were urban. Most women belonged to lower socioeconomic strata, with upper lower and lower classes together contributing 66%. Registered antenatal cases constituted 82% of the study population.

Table 1: Baseline demographic and obstetric profile (N=200)

Parameter	Category	n	%
Age group (years)	18-20	24	12
	21-25	76	38
	26-30	56	28
	31-35	30	15
	36-40	14	7
Gravida	Primigravida	60	30
	Gravida 2	80	40
	Gravida 3	40	20
	Gravida 4 and above	20	10
Residence	Rural	110	55
	Urban	90	45
ANC registration	Registered	164	82
	Unregistered	36	18

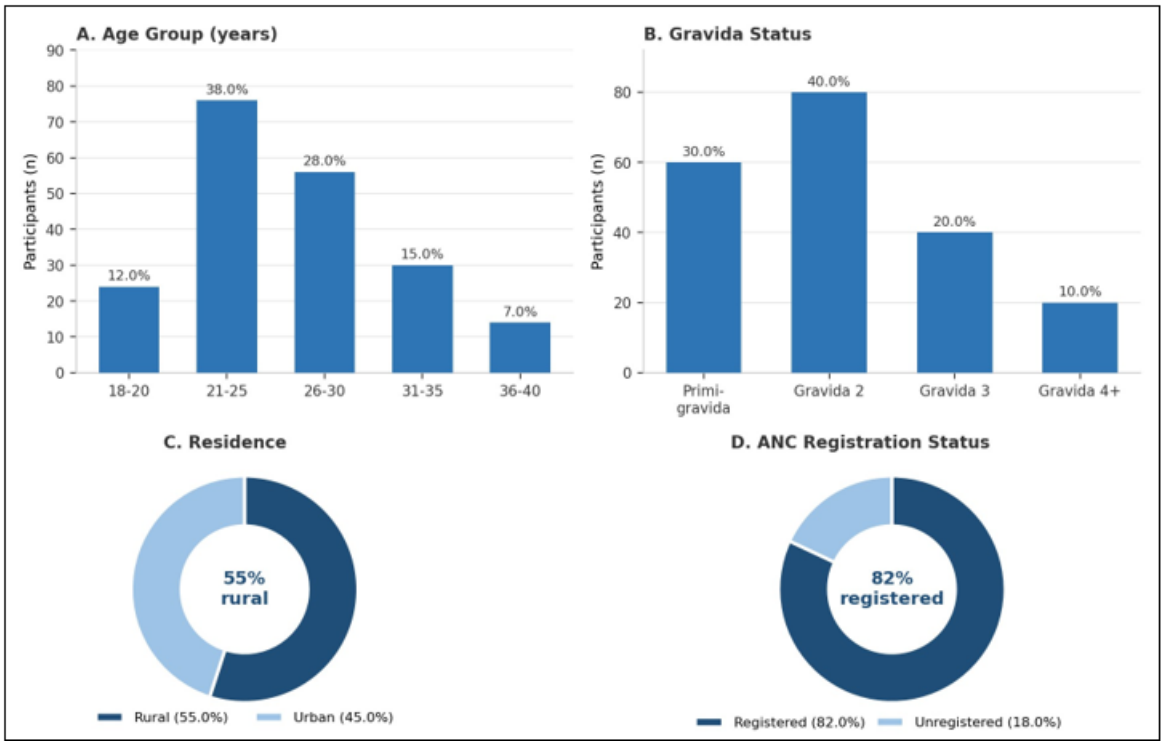


Figure 1: Baseline Demographic and Obstetric Profile (N= 200)

Baseline Hb distribution showed that 25% had Hb 7.0-7.9 g/dL, 39% had Hb 8.0-8.9 g/dL and 36% had Hb 9.0-9.9 g/dL. The mean baseline Hb was 8.2 ± 0.6 g/dL, consistent with moderate iron deficiency anaemia. Most women (72%) had no associated co-morbidity. PIH/gestational hypertension was the most common co-morbidity (10%), followed by hypothyroidism (6%) and gestational diabetes mellitus (5%).

Table 2: Socioeconomic status, baseline haemoglobin and co-morbidities (N=200)

Parameter	Category	n	%
Socioeconomic class	Upper	4	2
	Upper middle	20	10
	Lower middle	44	22
	Upper lower	96	48
	Lower	36	18
Baseline Hb (g/dL)	7.0-7.9	50	25
	8.0-8.9	78	39
	9.0-9.9	72	36
Co-morbidity	No co-morbidity	144	72
	PIH / Gestational hypertension	20	10
	Hypothyroidism	12	6
	Gestational diabetes mellitus	10	5
	UTI	6	3
	Twin pregnancy	4	2
	Heart disease	2	1

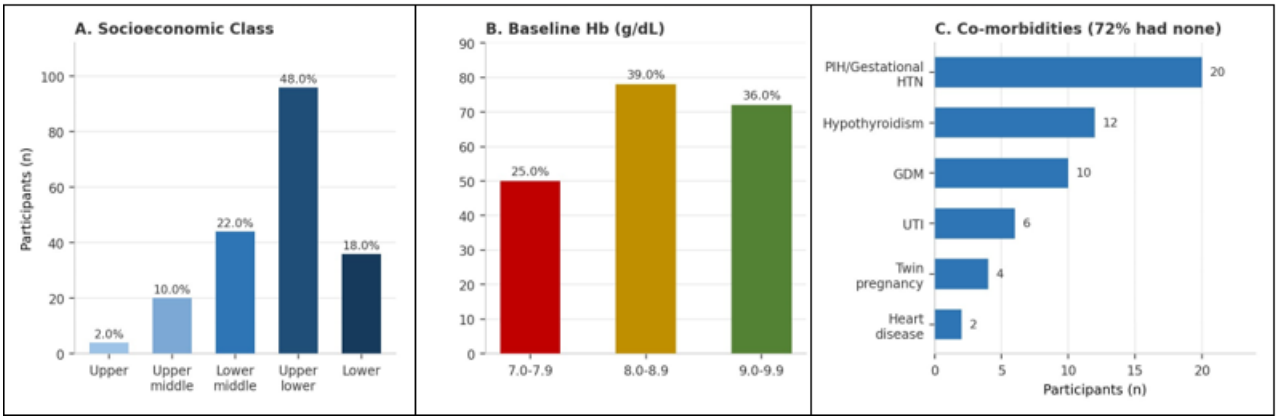


Figure 2: Socio- Economic Status, Baseline Anaemia Severity and Co- Morbidities (N= 200)

A highly significant haematological response was observed after FCM therapy. Mean Hb increased from 8.2 ± 0.6 g/dL at baseline to 10.3 ± 0.5 g/dL at 4 weeks and 11.2 ± 0.6 g/dL at 8 weeks ($p<0.001$). Serum ferritin increased from 14.9 ± 6.3 ng/mL to 81.1 ± 10.2 ng/mL at 4 weeks and 101.3 ± 6.4 ng/mL at 8 weeks ($p<0.001$). MCV improved from 77.3 ± 4.6 fL to

88.2 ± 1.3 fL by 8 weeks, confirming correction of microcytosis.

Table 3: Haematological response after ferric carboxymaltose therapy

Parameter	Baseline	4 weeks	8 weeks	p-value
Haemoglobin (g/dL)	8.2 ± 0.6	10.3 ± 0.5	11.2 ± 0.6	<0.001
Rise in Hb from baseline	-	+2.1 g/dL	+3.0 g/dL	<0.001
Serum ferritin (ng/mL)	14.9 ± 6.3	81.1 ± 10.2	101.3 ± 6.4	<0.001
Rise in ferritin from baseline	-	+66.2 ng/mL	+86.4 ng/mL	<0.001
MCV (fL)	77.3 ± 4.6	85.5 ± 2.2	88.2 ± 1.3	<0.001
Change in MCV from baseline	-	+8.2 fL	+10.9 fL	<0.001

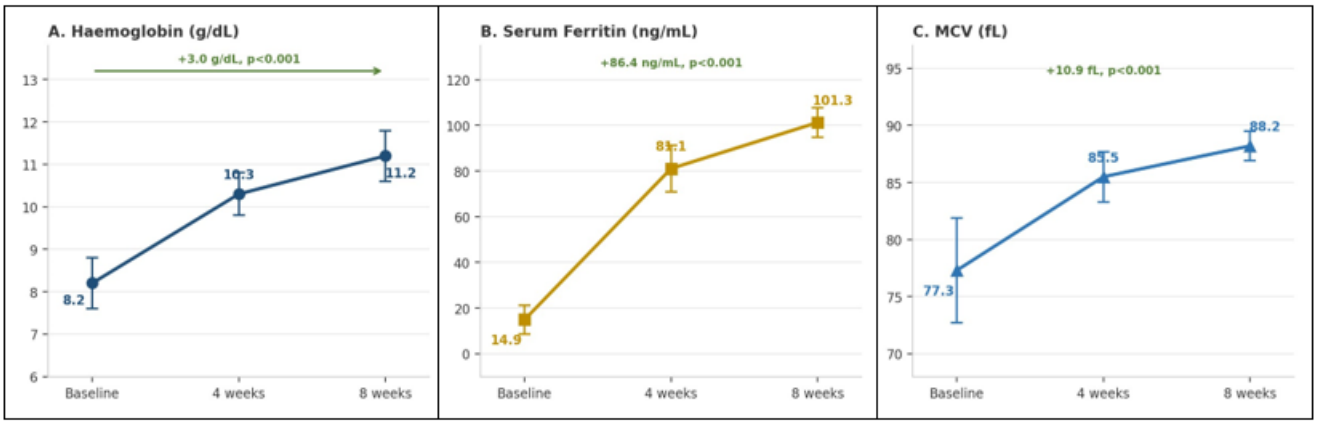
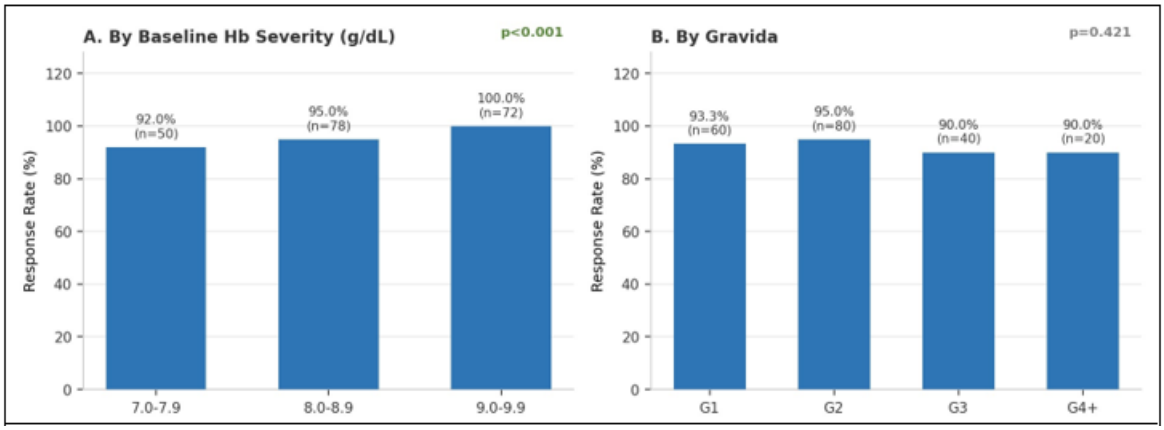


Figure 3: Haematological Response after FCM Therapy (Mean ± SD)

Overall, 93% of participants achieved target Hb >=10 g/dL. Response was robust across all baseline severity groups: 92% among women with initial Hb 7.0-7.9 g/dL, 95% among those with Hb 8.0-8.9 g/dL and 100% among those with Hb 9.0-9.9 g/dL.

Table 4: Haemoglobin response by initial severity and selected subgroups

Variable	Subgroup	Total	Responders	Response rate (%)	p-value
Initial Hb	7.0-7.9 g/dL	50	46	92	<0.001
	8.0-8.9 g/dL	78	74	95	
	9.0-9.9 g/dL	72	72	100	
Gravida	G1	60	56	93.3	0.421
	G2	80	76	95	
	G3	40	36	90	
	G4 and above	20	18	90	
Residence	Urban	90	86	95.6	0.538
	Rural	110	102	92.7	
ANC registration	Registered	164	152	92.7	0.004
	Unregistered	36	24	66.7	



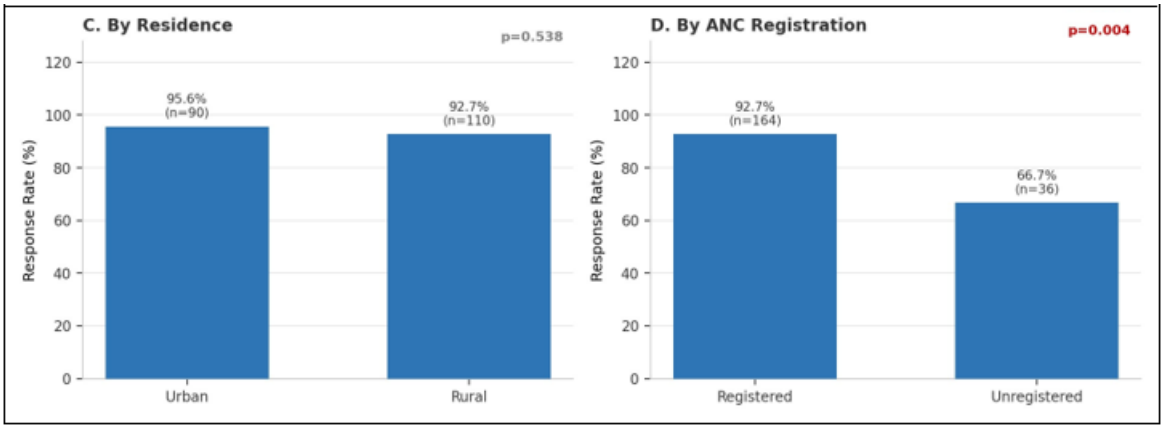


Figure 4: Haemoglobin Response Rate (Hb≥ 10 g/dl) by Subgroup

Maternal outcomes were favourable. Full-term normal vaginal delivery was achieved in 55%, LSCS was required in 26%, preterm vaginal delivery occurred in 14%, and instrumental delivery in 5%. No participant required blood transfusion, and no severe postpartum haemorrhage requiring surgical intervention was recorded.

Neonatal outcomes also demonstrated a positive trend. Normal birth weight (2.5-3.5 kg) was observed in 72% of neonates, low birth weight in 14%, very low birth weight in 4%, and birth weight >3.5 kg in 10%. APGAR score at 5 minutes was normal (7-10) in 97% of newborns. NICU admission was required in 12%, mainly for prematurity or low birth weight. No stillbirth or early neonatal death was recorded in the study cohort.

Table 5: Maternal and neonatal outcomes (N=200)

Outcome	Category	n	%
Mode of delivery	Full-term normal delivery	110	55
	Preterm vaginal delivery	28	14
	LSCS	52	26
	Instrumental delivery	10	5
Birth weight	<1.5 kg	8	4
	1.5-2.49 kg	28	14
	2.5-3.5 kg	144	72
	>3.5 kg	20	10
5-minute APGAR	0-3	0	0
	04-6	6	3
	07-10	194	97
NICU admission	Admitted	24	12
	Not admitted	176	88

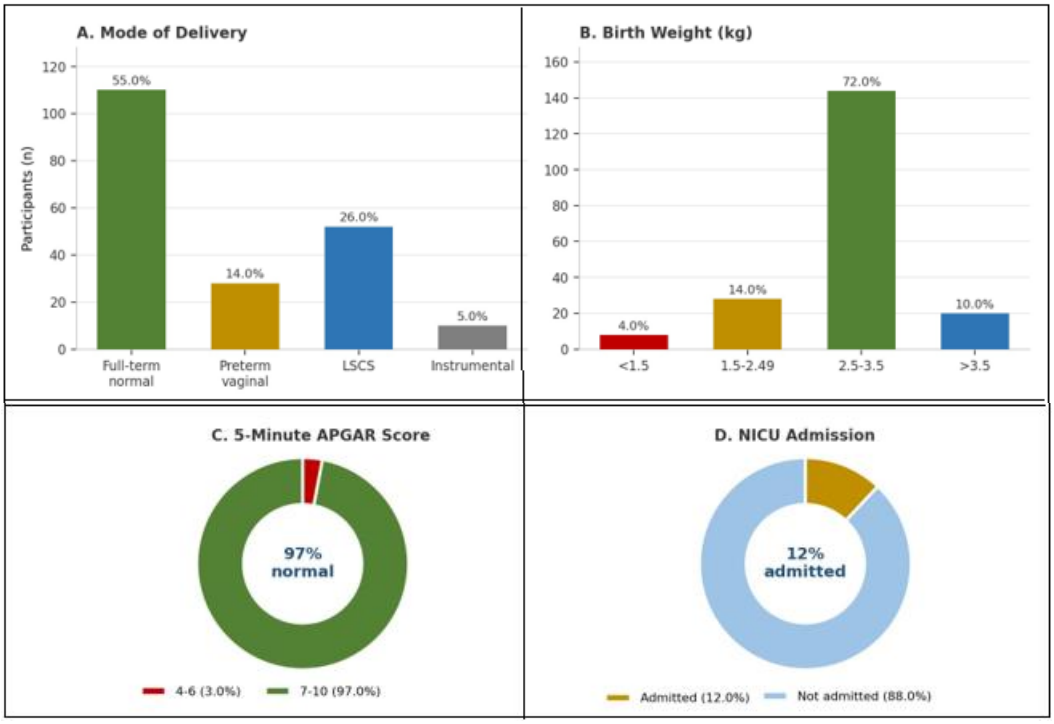


Figure 5: Maternal and Neonatal Outcomes (N= 200)

FCM was well tolerated. No adverse event was observed in 78% of women. Mild nausea (4%), dizziness (3%), injection-site pain (3%), vomiting (2%), fever (2%), myalgia (2%), rigors (2%), breathlessness (1%) and constipation (1%) were recorded. All adverse effects were self-limiting and managed conservatively. No anaphylaxis, severe hypersensitivity, emergency intervention or therapy discontinuation occurred.

Table 6: Adverse events following ferric carboxymaltose therapy (N=200)

Adverse event	n	%
No adverse event	156	78
Nausea	8	4
Dizziness	6	3
Injection-site pain	6	3
Vomiting	4	2
Fever	4	2
Myalgia	4	2
Rigors	4	2
Breathlessness	2	1
Constipation	2	1

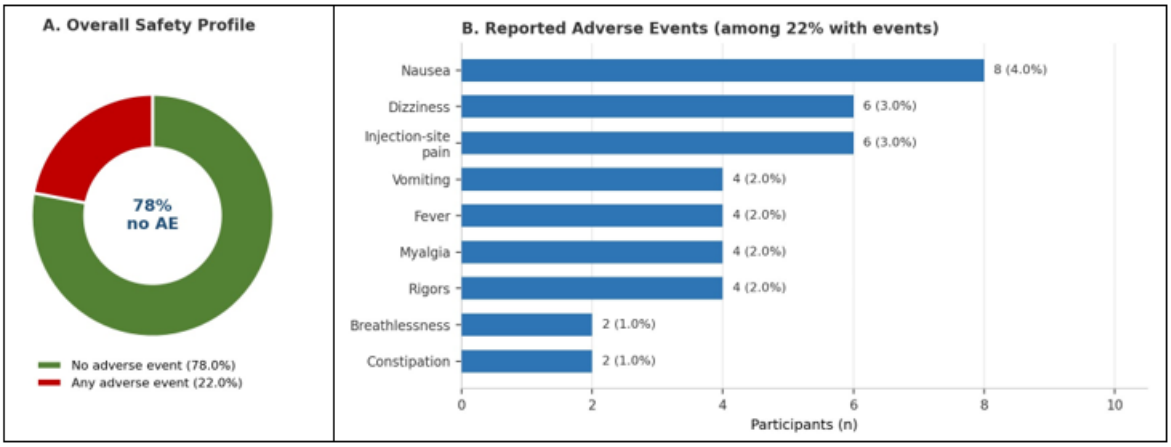


Figure 6: Adverse Effects following FCM Therapy (N= 200)

4. Discussion

The present study demonstrates that single-dose intravenous ferric carboxymaltose 1 g administered at 24 ± 1 weeks of gestation produces rapid and sustained correction of moderate iron deficiency anaemia in pregnancy. The mean Hb rise of 2.1 g/dL at 4 weeks and 3.0 g/dL at 8 weeks indicates a clinically meaningful response within a short treatment window. This is aligned with the pharmacological advantage of FCM, which permits high-dose iron delivery and rapid utilisation for erythropoiesis. [5, 7]

The improvement in serum ferritin is particularly important because correction of haemoglobin alone does not necessarily confirm restoration of iron reserves. In this cohort, ferritin increased more than sixfold from 14.9 ng/mL at baseline to 101.3 ng/mL at 8 weeks, indicating durable iron-store repletion.

Similar improvement in iron stores has been reported in earlier studies evaluating FCM in antenatal IDA. [8, 9]

The improvement in MCV from 77.3 fL to 88.2 fL further supports cellular-level correction of iron deficiency. Recovery of red cell indices in addition to haemoglobin and ferritin suggests that FCM produced comprehensive haematological improvement rather than transient symptomatic correction. These findings are consistent with comparative evidence showing superior or faster haematological response with FCM compared with oral iron or conventional intravenous iron sucrose regimens.[10, 11]

The response was maintained across baseline severity groups. Women with lower baseline Hb showed a larger absolute rise, while women closer to the therapeutic threshold achieved target Hb more consistently. This has practical value for obstetric practice because a single 1 g dose may substantially improve moderate anaemia within the second trimester and reduce the need for repeated hospital visits.

Subgroup analysis showed that socioeconomic status and antenatal registration influenced treatment response. Women from higher socioeconomic strata and registered ANC groups demonstrated better response rates. This suggests that parenteral iron therapy should be integrated with nutrition counselling, follow-up compliance, screening for concurrent deficiencies and structured antenatal care to optimise outcomes.

Maternal outcomes in the present study were reassuring. The majority achieved full-term normal vaginal delivery, and no severe postpartum haemorrhage or blood transfusion requirement was observed. Timely antenatal correction of IDA may improve maternal reserve before labour and improve tolerance to physiological blood loss at delivery.[12]

Neonatal findings were also favourable, with 72% normal birth weight, 97% normal 5-minute APGAR scores and 12% NICU admission. Although this single-arm design cannot prove causality, correction of maternal anaemia during mid-pregnancy may support placental oxygen delivery, fetal growth and neonatal adaptation. [13, 14]

Safety is a core consideration for any intravenous therapy in pregnancy. In this cohort, 78% had no adverse event, and all reported reactions were mild and self-limiting. Importantly, no anaphylaxis, severe hypersensitivity or treatment discontinuation was observed. This supports existing

evidence that FCM has a favourable safety profile in pregnancy when administered with appropriate monitoring. [6, 15]

The study's clinical value lies in its operational relevance. A single, short-duration infusion provides rapid Hb improvement, replenishes iron stores, minimizes repeated hospital visits and may improve adherence among women who are intolerant or non-compliant with oral iron. In high-volume antenatal settings, this could streamline anaemia management pathways and create measurable improvement in maternal preparedness for delivery.

5. Conclusion

The present study concludes that **single-dose intravenous ferric carboxymaltose 1 g is a safe, effective, and well-tolerated treatment for moderate iron deficiency anaemia during pregnancy**. Administration of ferric carboxymaltose at **24 ± 1 weeks of gestation** resulted in significant improvement in haemoglobin concentration, serum ferritin levels, and red cell indices within a short duration.

Ferric carboxymaltose produced a clinically meaningful rise in haemoglobin from **8.2 ± 0.6 g/dL** at baseline to **11.2 ± 0.6 g/dL** at 8 weeks, with an overall mean rise of **3.0 g/dL**. It also effectively replenished iron stores, as shown by the rise in serum ferritin from **14.9 ng/mL** to **101.3 ng/mL**, and improved MCV from **77.3 fL** to **88.2 fL**. These findings confirm that ferric carboxymaltose corrects both anaemia and underlying iron deficiency.

The study also showed favourable maternal and neonatal outcomes. The majority of women achieved full-term normal delivery, and no severe postpartum haemorrhage or blood transfusion requirement was observed. Neonatal outcomes were satisfactory, with most newborns having normal birth weight, good APGAR scores, and low NICU admission rates. No stillbirths or early neonatal deaths were reported.

Ferric carboxymaltose was well tolerated by most women. The adverse effects observed were mild, self-limiting, and managed conservatively. No serious hypersensitivity reaction, anaphylaxis, or discontinuation of therapy occurred. Therefore, ferric carboxymaltose can be considered a practical and patient-friendly option for pregnant women with moderate iron deficiency anaemia, particularly when rapid correction is required, oral iron is poorly tolerated, or compliance with oral therapy is inadequate.

6.

Declarations

Conflict of Interest Statement: The authors declare no conflicts of interest.

Funding Statement: This research received no external funding.

Ethics Approval: This study was approved by the Institutional Ethics Committee of Government Medical College and Hospital, Chhatrapati Sambhajinagar and written informed consent was obtained from all participants.

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