

**Retrospective Study on the Effectiveness and Outpatient Safety of Intravenous Ferric Carboxymaltose in Antenatal Anemia**Smriti Kumari<sup>1</sup>, Chanchal<sup>2</sup>, Poonam Kumari<sup>3</sup><sup>1</sup>Senior Resident, Department of Obstetrics and Gynaecology, Jannayak Karpoori Thakur Medical College and Hospital (JNKTMCH) Madhepura, Bihar, India.<sup>2</sup>Assistant Professor, Department of Obstetrics and Gynaecology, Jannayak Karpoori Thakur Medical College and Hospital (JNKTMCH) Madhepura, Bihar, India.<sup>3</sup>Associate Professor and HOD, Department of Obstetrics and Gynaecology, Jannayak Karpoori Thakur Medical College and Hospital (JNKTMCH) Madhepura, Bihar, India.

Received: 15-09-2025 / Revised: 08-10-2025 / Accepted: 24-10-2025

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Conflict of interest: Nil

**Abstract:****Background:** Iron deficiency anemia (IDA) is highly prevalent in pregnancy and is associated with adverse maternal and perinatal outcomes. Oral iron therapy is often limited by poor tolerance and inadequate response, especially in late gestation, prompting the use of intravenous preparations such as ferric carboxymaltose (FCM).**Aim:** To retrospectively evaluate the effectiveness and outpatient safety of intravenous ferric carboxymaltose in the management of antenatal iron deficiency anemia.**Methodology:** This retrospective observational case-control study included 90 pregnant women with IDA at Department of Obstetrics and Gynaecology in Jannayak Karpoori Thakur Medical College and Hospital (JNKTMCH) Madhepura, Bihar, India. Seventy-two women received intravenous FCM (case group), while 18 eligible women managed with oral iron served as controls. Hematological parameters, obstetric outcomes, and adverse events were compared between groups.**Results:** Baseline characteristics were comparable. The FCM group showed a significantly higher mean hemoglobin at delivery ( $10.7 \pm 0.9$  vs  $9.0 \pm 0.8$  g/dL;  $p < 0.001$ ), greater hemoglobin rise ( $+2.1 \pm 0.8$  vs  $+0.4 \pm 0.6$  g/dL), and a higher proportion achieving Hb  $\geq 10$  g/dL (72.2% vs 27.8%). Adverse effects were minimal (2.8%), with no serious reactions or hospital admissions.**Conclusion:** Intravenous ferric carboxymaltose is an effective and safe outpatient treatment for antenatal IDA, providing superior hematological improvement without adverse obstetric or neonatal outcomes.**Keywords:** Antenatal anemia; Iron deficiency anemia; Ferric carboxymaltose; Intravenous iron; Pregnancy; Outpatient safety.

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**Introduction**

Anemia in pregnancy remains one of the most common and refractory public health problems worldwide, particularly in low- and middle-income countries. It is associated with significant maternal and fetal morbidity and mortality and continues to pose a substantial burden on healthcare systems. The Royal College of Obstetricians and Gynaecologists (RCOG), in agreement with the British Committee for Standards in Haematology (BCSH), has defined anemia in pregnancy as hemoglobin (Hb) levels less than 11.0 g/dL in the first trimester, less than 10.5 g/dL in the second and third trimesters, and less than 10.0 g/dL in the postpartum period [1]. The most commonly encountered form is microcytic, hypochromic anemia, predominantly resulting from iron deficiency compounded by the physiological hemodilution of pregnancy. Additional contributing factors include poor dietary intake, reduced

absorption, increased iron requirements, and non-compliance with prescribed therapy. However, alternative etiologies such as hemoglobinopathies, chronic blood loss due to parasitic infections, malaria, blood dyscrasias, and other nutritional deficiencies must also be systematically excluded to ensure appropriate management.

IDA is the most common cause of anemia among pregnant women, complicating close to 50% of pregnancies worldwide [2]. It affects over 56 million women from all over the world, with the greatest burden being in Asia [3]. The increased demands for iron during pregnancy due to expanded maternal red cell mass, placental development, and fetal growth usually surpass dietary iron intake, especially in resource-limited settings. Iron deficiency during pregnancy has been consistently associated with adverse

maternal and perinatal outcomes, such as preterm birth, fetal growth restriction, low birth weight, and postpartum infections [4]. These outcomes underscore the critical importance of timely diagnosis and effective treatment of anemia during pregnancy.

From the maternal perspective, iron deficiency anemia is associated with increased fatigue, reduced physical capacity, and diminished quality of life. Furthermore, it has been associated with higher rates of obstetric complications such as preterm labor and delivery [5], preeclampsia [6], placental abruption [7], and an increased susceptibility to postpartum hemorrhage. Severe anemia significantly raises the risk of maternal mortality through increased vulnerability to cardiac failure, especially in late pregnancy and during the peripartum period. For the fetus and the newborn, iron deficiency more than doubles the infant mortality rate [8]. Iron is an essential micronutrient critical for oxygen transport, cellular respiration, and enzymatic activity, with the role of iron being highly critical during rapid cellular turnover like fetal brain development. Maternal iron deficiency has been associated with long-term neurodevelopmental consequences in offspring, including impairments in recognition, memory, and information processing during infancy. These deficits may contribute to poor mother–infant bonding and have been implicated in neurodevelopmental disorders such as autism spectrum disorders and schizophrenia later in life [9].

Early detection and correction of iron deficiency anemia in pregnancy are thus crucial, especially in women from high-risk groups. These include those at the extremes of reproductive age, those from low socioeconomic backgrounds, women with low BMI, high parity, and those who start antenatal care late in pregnancy [10]. A diagnosis is primarily made based on laboratory investigations, including an FBC and peripheral smear, along with an iron profile. Serum ferritin is considered the most sensitive and specific indicator regarding iron stores. According to the World Health Organization, iron deficiency in pregnant women is defined as serum ferritin less than 15  $\mu\text{g/L}$ . However, the BCSH guidelines recommend starting treatment when ferritin levels fall below 30  $\mu\text{g/L}$ , as this reflects an early iron depletion that will gradually worsen if left untreated [11]. Other investigations, such as hemoglobin electrophoresis to exclude thalassemia and also evaluation of vitamin B12 and folate levels, become necessary to accurately diagnose and appropriately treat the patient.”

Iron supplementation is the cornerstone of treatment for iron deficiency anemia in pregnancy and may be given orally or parenterally, depending on the severity of the anemia, gestational age, tolerance, and urgency of correction. Oral iron remains the first-line treatment for mild anemia; however, its efficiency is often compromised by gastrointestinal side effects, poor compliance, and impaired absorption.

Parenteral iron therapy has gained increasing utilization in cases of moderate to severe anemia, intolerance or nonresponse to oral iron, or when correction is urgent due to advanced gestational age. The mainstay of treatment has been to improve maternal hemoglobin levels, optimize perinatal outcomes, and avoid blood transfusion, which is usually indicated in severe anemia ( $\text{Hb} < 5 \text{ g/dL}$  before 36 weeks or  $< 6 \text{ g/dL}$  after 36 weeks) without decompensation, sickle cell disease, severe malaria, serious bacterial infection, or pre-existing cardiac disease.

Intravenous iron formulations have undergone significant development over the past decades, with improved safety and efficacy profiles. Ferric carboxymaltose represents a newer intravenous iron preparation that is dextran free and hence does not possess the allergenic potential of the older dextran-based preparations. This compound allows high-dose iron administration—up to 1,000 mg per single 20 mL infusion—over a relatively short duration. Ferric carboxymaltose has demonstrated high bioavailability and has been effectively used in patients with malabsorptive gastrointestinal disorders [12] and chronic cardiac failure [13] to improve hemoglobin levels. Of note, this compound has also been demonstrated to be a safe and effective treatment modality for iron deficiency anemia in pregnancy [14].

The ability to administer ferric carboxymaltose as a single or limited number of outpatient infusions offers significant practical advantages, particularly for pregnant women presenting in later gestation where time for oral iron therapy is limited. Its use has been increasing in obstetric practice because of its rapid efficacy, favorable safety profile, and potential to reduce the need for hospital admission and blood transfusion. However, despite its growing use, data on its effectiveness, impact on delivery outcomes, and safety when administered in an outpatient setting remain limited, particularly in real-world clinical practice.

The present study also sought to review the effectiveness of intravenous ferric carboxymaltose retrospectively in pregnant women diagnosed with iron deficiency anemia; assess maternal and delivery outcomes following treatment; and evaluate the safety of administering ferric carboxymaltose as an outpatient procedure. In addressing these objectives, this study joins a wealth of evidence in support of the use of intravenous ferric carboxymaltose within antenatal care and offers some useful reflection to inform clinical decisions in the management of iron deficiency anemia during pregnancy.

## Methodology

**Study Design:** This study was a retrospective observational case–control study conducted to evaluate the effectiveness and outpatient safety of intravenous ferric carboxymaltose (FCM) in the management of antenatal iron deficiency anemia. The study

compared maternal hematological and obstetric outcomes between pregnant women who received intravenous ferric carboxymaltose (case group) and those who met the criteria for intravenous therapy but did not receive it (control group).

**Study Area:** The study was conducted in the Department of Obstetrics and Gynaecology, Jannayak Karpoori Thakur Medical College and Hospital (JNKTMCH), Madhepura, Bihar, India

**Study Duration:** The study was carried out over a period of 6 months from March 2025 to August 2025, during which retrospective data were collected from hospital medical records of antenatal patients.

**Sample Size:** A total of 90 antenatal women diagnosed with iron deficiency anemia and referred for intravenous ferric carboxymaltose therapy during the study period were included. As this was a retrospective study, all eligible cases available during the study period were considered, and no formal sample size calculation was performed.

**Study Population:** The study population consisted of pregnant women diagnosed with iron deficiency anemia who attended the antenatal outpatient or day-care services of the Department of Obstetrics and Gynaecology at JNKTMCH.

- **Case group:** Antenatal women who received intravenous ferric carboxymaltose
- **Control group:** Antenatal women who fulfilled the criteria for intravenous ferric carboxymaltose but defaulted on or declined treatment and were managed with oral iron therapy alone

Both groups had comparable baseline characteristics and met the institutional criteria for referral for intravenous iron therapy.

**Data Collection:** Data for the present study were collected retrospectively from hospital records maintained in the Department of Obstetrics and Gynaecology at Jannayak Karpoori Thakur Medical College and Hospital, Madhepura. Medical case files, antenatal records, laboratory investigation reports, outpatient day-care registers, and delivery records were reviewed for all eligible patients during the study period. Information related to demographic characteristics, gestational age at the time of referral, baseline hemoglobin levels, details of intravenous ferric carboxymaltose administration, and follow-up hemoglobin values were extracted. Obstetric outcomes, including mode of delivery and maternal outcomes, as well as any documented adverse events following intravenous iron administration, were also recorded. Patients were categorized into case and control groups based on whether they received intravenous ferric carboxymaltose or defaulted on treatment despite meeting referral criteria. All collected data were anonymized and entered into

a structured data collection format to ensure consistency and confidentiality.

#### Inclusion Criteria

- Pregnant women diagnosed with iron deficiency anemia
- Antenatal women referred for intravenous ferric carboxymaltose therapy
- Availability of complete medical and laboratory records
- Patients managed on an outpatient basis

#### Exclusion Criteria

- Pregnant women with anemia due to causes other than iron deficiency (e.g., hemoglobinopathies, anemia of chronic disease)
- Patients with incomplete or missing medical records
- Women with known hypersensitivity to intravenous iron preparations
- Patients who received blood transfusions during pregnancy

**Procedure:** Eligible patient records were identified from departmental registers and hospital databases. Patients were categorized into case and control groups based on whether they received intravenous ferric carboxymaltose. Hematological parameters and pregnancy outcomes at delivery were compared between the two groups to assess the effectiveness and safety of intravenous ferric carboxymaltose in antenatal anemia.

**Statistical Analysis:** The collected data were compiled and analyzed using Statistical Product and Service Solutions (SPSS) software, version 23 (IBM SPSS Statistics for Windows, Armonk, NY, USA). Continuous variables were summarized using mean and standard deviation, while categorical variables were expressed as frequencies and percentages. The effectiveness of intravenous ferric carboxymaltose was assessed by comparing hematological parameters between baseline and follow-up values, as well as between the case and control groups. A paired t-test was used to evaluate changes in hemoglobin levels within groups. Statistical significance was considered at a p value of less than 0.05. The results were interpreted to determine the effectiveness and outpatient safety of intravenous ferric carboxymaltose in the management of antenatal anemia”.

#### Result

Table 1 presents the baseline demographic and hematological characteristics of the study participants (N = 90), showing that the case group (FCM, n = 72) and control group (n = 18) were comparable at baseline. The mean age was similar between groups ( $26.8 \pm 4.5$  vs  $27.4 \pm 4.9$  years), with nearly equal proportions of primigravida (43.1% vs 44.4%) and multigravida women (56.9% vs 55.6%). Gestational age at booking was comparable ( $11.9 \pm 2.6$  vs  $12.3$

$\pm 2.9$  weeks). Baseline hemoglobin levels at booking were similar ( $10.5 \pm 0.7$  g/dL in the FCM group vs  $10.6 \pm 0.8$  g/dL in controls), as were MCV values ( $76.4 \pm 5.2$  vs  $77.1 \pm 5.5$  fL). During the second/third trimester, both groups showed comparable degrees of anemia, with mean hemoglobin levels of  $8.8 \pm 0.6$  g/dL and  $9.0 \pm 0.7$  g/dL, and similar MCV values

( $75.9 \pm 4.8$  vs  $76.6 \pm 5.0$  fL). Serum ferritin levels were low and comparable in both groups ( $8.2 \pm 3.1$  vs  $9.0 \pm 3.4$   $\mu$ g/L), confirming iron deficiency. In the case group, FCM was administered at a mean gestational age of  $32.8 \pm 2.1$  weeks, and treatment-related adverse effects were minimal, occurring in only 2.8% of patients, indicating good tolerability.

Characteristics*	Case Group (FCM) (n = 72)	Control Group (No FCM) (n = 18)
Age (years)	26.8 $\pm$ 4.5	27.4 $\pm$ 4.9
Primigravida, n (%)	31 (43.1)	8 (44.4)
Multigravida, n (%)	41 (56.9)	10 (55.6)
Gestational age at booking (weeks)	11.9 $\pm$ 2.6	12.3 $\pm$ 2.9
Hemoglobin at booking (g/dL)	10.5 $\pm$ 0.7	10.6 $\pm$ 0.8
MCV at booking (fL)	76.4 $\pm$ 5.2	77.1 $\pm$ 5.5
Hemoglobin in 2nd/3rd trimester (g/dL)	8.8 $\pm$ 0.6	9.0 $\pm$ 0.7
MCV in 2nd/3rd trimester (fL)	75.9 $\pm$ 4.8	76.6 $\pm$ 5.0
Serum ferritin ( $\mu$ g/L)	8.2 $\pm$ 3.1	9.0 $\pm$ 3.4
Gestational age at FCM administration (weeks)	32.8 $\pm$ 2.1	–
Treatment-related adverse effects, n (%)	2 (2.8)	–

Table 2 compares maternal and obstetric outcomes at delivery between the case group receiving ferric carboxymaltose (FCM) (n = 72) and the control group (n = 18). While the gestational age at delivery was comparable between the groups ( $38.5 \pm 1.2$  vs  $38.3 \pm 1.4$  weeks;  $p = 0.52$ ), the hemoglobin status at delivery was significantly better in the FCM group, with a higher mean hemoglobin level ( $10.7 \pm 0.9$  g/dL vs  $9.0 \pm 0.8$  g/dL;  $p < 0.001$ ) and a greater proportion achieving Hb  $\geq 10$  g/dL (72.2% vs 27.8%;  $p < 0.001$ ). The mean rise in hemoglobin from pre-treatment to delivery was also markedly higher in

the FCM group ( $+2.1 \pm 0.8$  g/dL vs  $+0.4 \pm 0.6$  g/dL;  $p < 0.001$ ), along with a significantly higher MCV at delivery ( $82.1 \pm 4.6$  vs  $76.8 \pm 5.1$  fL;  $p < 0.01$ ). Mode of delivery (spontaneous vaginal, assisted vaginal, and cesarean section), mean birth weight ( $3020 \pm 410$  g vs  $2940 \pm 450$  g;  $p = 0.47$ ), and need for antenatal blood transfusion did not differ significantly between groups ( $p > 0.05$ ). Importantly, no hospital admissions due to FCM-related reactions were reported, indicating good safety and superior hematological outcomes with FCM therapy.

Outcome*	Case Group (FCM) (n = 72)	Control Group (n = 18)	P value
Gestational age at delivery (weeks)	38.5 $\pm$ 1.2	38.3 $\pm$ 1.4	0.52
Hemoglobin at delivery (g/dL)	10.7 $\pm$ 0.9	9.0 $\pm$ 0.8	<0.001
Hemoglobin $\geq 10$ g/dL at delivery, n (%)	52 (72.2)	5 (27.8)	<0.001
Change in Hb from pre-treatment to delivery (g/dL)	+2.1 $\pm$ 0.8	+0.4 $\pm$ 0.6	<0.001
MCV at delivery (fL)	82.1 $\pm$ 4.6	76.8 $\pm$ 5.1	<0.01
Spontaneous vaginal delivery, n (%)	41 (56.9)	10 (55.6)	0.91
Assisted vaginal delivery, n (%)	6 (8.3)	2 (11.1)	0.68
Cesarean section, n (%)	25 (34.8)	6 (33.3)	0.88
Mean birth weight (g)	3020 $\pm$ 410	2940 $\pm$ 450	0.47
Antenatal blood transfusion, n (%)	5 (6.9)	1 (5.6)	0.84
Hospital admission due to FCM reaction	0	–	–

## Discussion

The present retrospective study further supports the increasing body of evidence regarding the efficacy and outpatient safety of intravenous ferric carboxymaltose for treating antenatal iron deficiency anemia. In our cohort, women who were treated with FCM achieved a clinically and statistically

significant increase in Hb by delivery compared to those who did not receive intravenous iron, despite similar baseline characteristics and comparative degrees of anemia during the second and third trimesters. The mean increase in Hb of  $2.1 \pm 0.8$  g/dL seen in this treated group is quite consistent with previously published data, further supporting the

consistency of hematological response to FCM in pregnancy.”

Corresponding results have been described in the literature by Pels and Ganzevoort, who documented an average Hb increase of 2.3 g/dL after FCM administration later in pregnancy, with values increasing from 8.4 g/dL to 10.7 g/dL at term, equivalent to the delivery Hb achieved in our treated group ( $10.7 \pm 0.9$  g/dL) (Pels & Ganzevoort, 2015) [15]. Similarly, Myers et al. have illustrated a progressive Hb increase following the administration of FCM, with an earlier hematological response compared with iron dextran, and no adverse events, supporting the efficacy and safety profile observed in our outpatient setting (Myers et al., 2012) [16]. This would suggest that FCM repeatedly yields rapid iron repletion even when administered in the third trimester, during a period in which time to delivery is limited.

Our findings also resonate with the broader comparative literature that evaluates intravenous versus oral iron therapy. Qassim et al., in a systematic review and meta-analysis, concluded that intravenous iron during pregnancy resulted in a greater rise in Hb at delivery compared with oral iron, particularly in women with moderate to severe anemia (Qassim et al., 2019) [17]. In our study, despite oral iron supplementation, both groups experienced a decline in Hb from booking to the second/third trimester, and minimal improvement, thereafter, highlighting the limited effectiveness of oral iron in this population and underlining the role of intravenous FCM as a rescue therapy.

Data from randomized controlled trials further supports our observations. Pasricha et al. reported lower rates of anemia across subsequent gestational ages among women receiving FCM compared with oral iron, without significant differences in neonatal birth weight, consistent with the comparable neonatal outcomes seen in our cohort (Pasricha et al., 2023) [18]. Similarly, in the postpartum period, superior correction of iron deficiency was seen with FCM compared to oral iron by Vanobberghen et al., indicating that intravenous iron may exert more long-lasting beneficial effects on iron stores and hemoglobin recovery beyond delivery (Vanobberghen et al. 2021) [19]. While our study did not measure ferritin at delivery, significantly higher Hb and improved red cell indices in the treated group indirectly mirrored effective replenishment of iron stores.

Safety remains a significant concern with intravenous therapies in pregnancy. In our study, treatment-related adverse effects were low (2.8%) and mild, and no hospital admissions were required. Such a good safety profile is consistent with the literature to date. Moore et al., in their meta-analysis of randomised clinical trials, demonstrated low rates of serious adverse events associated with FCM, supporting its tolerability (Moore et al., 2011) [20]. Furthermore,

observational studies comparing intravenous and oral iron showed lower rates of gastrointestinal side effects such as constipation, nausea, and vomiting with FCM, which could increase treatment acceptance and adherence (Das et al., 2020) [21].

Importantly, our study showed that improvement in maternal hematological parameters did not result in significant differences in obstetric or neonatal outcomes such as gestational age at delivery, mode of delivery, birth weight. This corroborates previous studies suggesting that improvement in anemia improves maternal reserves and reduces transfusion risk but does not always yield measurable differences in short-term perinatal outcomes, especially in cohorts with predominantly moderate anemia (Beckert et al., 2019; Sifakis & Pharmakides, 2000) [22,23,24]. However, the higher percentage of women who delivered with Hb  $\geq 10$  g/dL in the treated group is of clinical significance as this may decrease vulnerability to postpartum hemorrhage and the need for postnatal blood transfusion.

The outpatient administration of FCM seen in our study further supports its feasibility in real-world clinical practice. High attendance and acceptance rates combined with minimal adverse events echo findings from prior studies highlighting that intravenous FCM can safely be delivered outside an inpatient setting when appropriate monitoring and trained personnel are available (Pels & Ganzevoort, 2015; Myers et al., 2012) [15,16]. This has important implications for resource-limited settings, where reducing hospital admissions and transfusion requirements can substantially decrease healthcare burden.

Generally, our findings agree with 10–12 key studies that show intravenous ferric carboxymaltose is an effective, well-tolerated, and practical option for the treatment of antenatal iron deficiency anemia. Whereas our retrospective design and lack of ferritin follow-up data are limitations to our study, the apparent hematological benefits along with reassuring safety outcomes support FCM as an important therapeutic option among pregnant women who have failed to respond or could not tolerate oral iron therapy.

## Conclusion

This is a retrospective study showing that intravenous ferric carboxymaltose is effective and safe for the management of antenatal anemia in the outpatient setting. Women who received ferric carboxymaltose demonstrated a significantly better improvement in hematological parameters at the time of delivery, with more subjects in this group attaining adequate hemoglobin levels and improved red cell indices. Maternal and obstetric outcomes were similar between groups regarding gestational age at delivery, mode of delivery, and neonatal birth weight, which suggests that treatment did not adversely affect pregnancy outcomes. The low

incidence of mild treatment-related adverse effects and absence of serious reactions or hospital admissions further support its safety profile. Overall, intravenous ferric carboxymaltose seems to be well-tolerated and hence an effective therapeutic option for correcting iron deficiency anemia during pregnancy, thereby minimizing the chances of blood transfusion and improving hematological status at delivery.

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