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Original Research Article

Safety and Efficacy of Ferric Carboxymaltose in Management of Iron Deficiency Anemia in Pregnant and Peripartum Women

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Conflict of interest: Nil

Abstract:

Background: Iron deficiency anemia is a common complication during pregnancy, particularly in developing regions like West Gujarat.

Aim: To evaluate the safety and efficacy of intravenous ferric carboxymaltose (FCM) in managing anemia among pregnant women.

Material and Methods: A prospective observational study was conducted on 100 pregnant and postpartum women receiving FCM at a tertiary care hospital in Gujarat. Hemoglobin levels were measured before and after infusion to assess response.

Results: A significant rise in hemoglobin levels was observed in the majority of participants, with minimal adverse effects.

Conclusion: Intravenous FCM is a safe and effective treatment option for anemia in pregnancy, especially in moderate to severe cases.

Keywords: Anemia, Ferric Carboxymaltose, Peripartum Women, Pregnancy.

Introduction

Anemia in pregnancy remains a major public health concern worldwide, especially in developing countries like India, where it significantly contributes to maternal and perinatal morbidity and mortality. According to the World Health Organization (WHO), anemia affects approximately 41.8% of pregnant women globally, with iron deficiency being the most common cause [1]. In India, the prevalence of anemia among pregnant women is alarmingly high, ranging from 50% to 70% depending on the region and population studied [2,3].

Iron deficiency anemia (IDA) during pregnancy can lead to several adverse outcomes such as preterm delivery, low birth weight, intrauterine growth restriction, and increased risk of maternal infections [4]. Timely and effective correction of iron deficiency is crucial to ensure favorable maternal and neonatal outcomes. Traditionally, oral iron supplementation has been the first-line treatment due to its cost-effectiveness and ease of administration. However, it is often associated with poor gastrointestinal tolerance, noncompliance, and inadequate response in moderate to severe cases [5].

In recent years, intravenous (IV) iron therapy has emerged as a valuable alternative, especially in cases where rapid correction of anemia is desired or where oral iron is ineffective or poorly tolerated. Among the various IV iron formulations, ferric carboxymaltose (FCM) has gained considerable attention due to its unique pharmacological profile. It allows for administration of high doses in a single sitting with a minimal risk of serious adverse reactions, making it particularly suitable for pregnant women requiring urgent replenishment of iron stores [6].

Several studies have highlighted the efficacy of FCM in increasing hemoglobin levels and replenishing iron stores in pregnant women, often demonstrating superior outcomes compared to oral iron and other IV formulations [7]. Furthermore, FCM has been shown to improve fatigue, quality of life, and maternal well-being, which are often compromised in anemic pregnancies [8]. Safety is a critical consideration in pregnancy, and current evidence suggests that FCM has a favorable safety profile with minimal risks to both the mother and fetus [9,10].

Regional variations in dietary patterns, healthcare access, and socio-economic status may influence treatment outcomes and acceptance. Therefore, this study aims to evaluate the safety and efficacy of intravenous ferric carboxymaltose in managing

anemia among pregnant women attending a tertiary care hospital in West Gujarat. The findings of this study may contribute to formulating localized clinical guidelines and optimizing anemia management strategies in this region.

Material and Methods

This was a prospective, observational study conducted to evaluate the safety and efficacy of intravenous ferric carboxymaltose (FCM) in the management of anemia among pregnant women. The study was conducted at the Department of Obstetrics and Gynecology of a tertiary care hospital in West Gujarat over a period of one year, from January 2023 to December 2023. The study included 100 pregnant women diagnosed with iron deficiency anemia attending the antenatal clinic or admitted to the obstetric ward during the study period. Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study. Written informed consent was obtained from all participants after explaining the study protocol in their local language.

Inclusion Criteria

- Pregnant women between 14 and 34 weeks of gestation
- Hemoglobin levels between 7.0 and 10.9 g/dL (moderate anemia)
- Confirmed diagnosis of iron deficiency anemia (based on serum ferritin <30 ng/mL)
- Willing to provide informed written consent

Exclusion Criteria

- Anemia due to causes other than iron deficiency (e.g., thalassemia, hemolytic anemia, vitamin B12/folate deficiency)
- Hypersensitivity to intravenous iron preparations
- History of chronic infections, liver or kidney disorders
- Multiple pregnancy or high-risk obstetric conditions
- Women who received blood transfusion or IV iron within the previous 4 weeks

Intervention: Eligible participants received intravenous ferric carboxymaltose (FCM) infusion as per standard dosing guidelines, calculated using the Ganzoni formula or a simplified weight-based protocol. A maximum of 1000 mg was administered per sitting over 15–30 minutes, under medical supervision. Repeat doses were given if required after a week, based on clinical and laboratory assessment.

Data Collection: Baseline data including demographic details, obstetric history, hemoglobin levels, serum ferritin, and vital signs were recorded. Hemoglobin and serum ferritin were reassessed at 2 and 4 weeks post-infusion. Adverse events, if any, were documented during and after the infusion.

Statistical Analysis: Data were analyzed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation (SD) and compared using paired t-tests. Categorical variables were presented as frequencies and percentages. A p-value of <0.05 was considered statistically significant.

Results

Table 1 shows the age distribution of the study participants. The majority of the women were between 18 and 25 years of age (60%), followed by 32% in the 26–34 years age group. A smaller proportion (8%) were above 34 years. Table 2 shows the obstetric history of the study participants. The largest group comprised women who were fourth gravida or above (33.33%), followed by third gravida (29.63%). Second gravida and primi gravida participants accounted for 22.22% and 14.81%, respectively.

Table 3 shows the association between Gravida and Anemia. Primigravidae women had a higher average hemoglobin level (9.1 g/dL) compared to multigravidae women, who had a lower average of 7.3 g/dL, indicating a greater severity of anemia among women with multiple pregnancies.

Table 4 shows the hemoglobin levels of the participants on admission. A majority of the women (58%) had hemoglobin levels ≤8 g/dL, indicating moderate to severe anemia, while 42% had levels between 8.1 and 9 g/dL. Table 5 shows the gestational age at the time of ferric carboxymaltose (FCM) infusion. The majority of participants (42%) received FCM between 32.1 and 36 weeks of gestation, followed by 28–32 weeks (22%). A smaller proportion received it after 36 weeks (12%), while 24% were given FCM in the postnatal period.

Table 6 shows the rise in hemoglobin levels following FCM infusion. The majority of participants (60%) experienced an increase between 1.1 and 2 g/dL, while 24% experienced a rise of more than 2 g/dL. A smaller proportion (16%) showed a rise of less than 1 g/dL.

Table 1: Age distribution

Age (years)	Number (n=100)	Proportion (%)
18–25	60	60%
26–34	32	32%
>34	8	8%

Table 2: Obstetric history

Gravida (antenatal)	Number (n=54)	Proportion (%)
Primi gravida	8	14.81%
Second gravida	12	22.22%
Third gravida	16	29.63%
Fourth gravida and above	18	33.33%

Table 3: Association between gravida score and anemia

Gravida	Average hemoglobin levels (gm/dl)
Primigravidae	9.1
Multigravidae	7.3

Table 4: Hemoglobin levels on admission

Hemoglobin levels on admission (gm/dl)	Number (n=100)	Proportion (%)
≤8	58	58%
8.1–9	42	42%

Table 5: Gestational age at the time of FCM infusion.

Status at the time of FCM infusion	Number (n=100)	Proportion (%)
28–32 weeks antenatal	22	22%
32.1–36 weeks antenatal	42	42%
>36 weeks antenatal	12	12%
Postnatal	24	24%

Table 6: Rise in hemoglobin levels.

Rise in hemoglobin levels (gm/dl)	Number (n=100)	Proportion (%)
<1	16	16%
1.1 – 2	60	60%
>2	24	24%

Discussion

The findings of this study demonstrate that intravenous ferric carboxymaltose (FCM) is both a safe and effective intervention for managing iron deficiency anemia in pregnant and postpartum women. A significant rise in hemoglobin levels was observed among most participants following FCM infusion, with over 80% experiencing an increase of more than 1 g/dL. These results align with existing literature, reinforcing FCM's efficacy in improving hematological parameters within a short duration.

The mean hemoglobin level among multigravida women was notably lower than that of primigravidae, indicating a possible cumulative effect of repeated pregnancies on iron reserves. This supports previous observations that multigravida women are more prone to anemia due to increased nutritional demands and shorter interpregnancy intervals [11]. Moreover, the high prevalence of anemia in women admitted during the third trimester and postnatal period underlines the need for timely screening and intervention earlier in pregnancy.

Intravenous FCM offers several advantages over conventional oral iron therapy, particularly in moderate to severe anemia where rapid correction is critical. It allows the administration of larger single doses with fewer gastrointestinal side effects, improving compliance and patient comfort [12]. In our study, no serious adverse reactions were reported, echoing findings from other studies on the favorable safety profile of FCM during pregnancy [13].

The gestational age distribution at the time of infusion in our study indicates that most patients received FCM late in the antenatal period or postnatally, possibly due to late diagnosis or referral patterns. Early identification and intervention could potentially result in better maternal and fetal outcomes, as iron therapy initiated in the second trimester has been associated with greater improvements in birth weight and reduced incidence of preterm labor [14].

Our results are consistent with prior Indian studies, where FCM has shown superior outcomes in rural and resource-limited settings due to its simplicity of administration and rapid effectiveness [15]. This is especially important in regions like West Gujarat, where anemia continues to be a leading cause of maternal morbidity.

Conclusion

Intravenous ferric carboxymaltose (FCM) is a safe, effective, and well-tolerated treatment for iron deficiency anemia in pregnancy and the postpartum

period. It leads to a significant rise in hemoglobin levels with minimal side effects, making it a valuable option, especially in moderate to severe anemia. Early identification and timely intervention with FCM can improve maternal outcomes and contribute to better perinatal care, particularly in resource-limited settings like West Gujarat.

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