Original Article

Ferric carboxymaltose: A game changer in the management of iron deficiency anaemia in pregnancy

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Abstract

Anaemia is a well-known global health concern in the South Asian countries, and it is estimated that India has the utmost prevalence of anaemia and maternal deaths due to iron deficiency anaemia. This study aims to assess the efficacy and safety of intravenous ferric carboxymaltose (FCM) in antenatal women with anaemia in the second and third trimesters of pregnancy. **Methods:** A single-arm prospective cohort (before–after) study among 60 antenatal women with moderate to severe anaemia in the second and third trimesters was conducted from December 2020 to December 2022, and the eligible women were given 1000 mg of intravenous FCM injection. Efficacy was assessed by rate of improvement in haemoglobin and ferritin at 2 weeks post infusion. Safety analysis was done by assessing adverse drug reactions and foetal heart monitoring during the infusion. **Results:** A total 60 antenatal women with a median gestational age of 32.5 weeks at presentation received 1000 mg of intravenous FCM. There was a rise in mean haemoglobin from 8.05 gm% pre-infusion to 10.93 gm% 2 weeks post infusion, showing a mean rise of 2.88 gm%. Similar improvement was noted in mean serum ferritin levels from 25.92 pre-infusion to 253.96 post FCM infusion. There were no reports of drug-related major adverse effects in the mother or the foetus. **Conclusions:** FCM is found to be safe and effective treatment with rapid replenishment of haemoglobin and ferritin levels in a single dose, which makes it suitable and compels consideration as the first choice for treatment of iron-deficiency anaemia.

Keywords: Antenatal, ferric carboxymaltose, ferritin, haemoglobin, iron deficiency anaemia

Introduction

Anaemia is a well-known global health concern with a prevalence of 33–89% and an incidence of 42% [World Health Organisation (WHO), 2015].[1,2] About 1.62 billion people are affected by anaemia globally, which constitutes 24.8% of the total population, with pregnant women being the greatest number of individuals affected (41.8%).[3] Worldwide, about 32.4 million pregnant women suffer from anaemia, of which 0.8% are severely anaemic.[1] In addition, an estimate by WHO attributes about 591,000 perinatal deaths and 115,000 maternal deaths globally to iron deficiency anaemia (IDA) directly or indirectly.[2,4]

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Anaemia is the most common haematological disorder in pregnancy, especially in the low-income countries. Among the South Asian countries, it is projected that India has the utmost prevalence of anaemia (57–96.2%)[5-7] with estimated maternal deaths of approximately 326,000 and an estimated disability-adjusted life years (DALYs) of 12,497,000 due to IDA.[4] Furthermore, anaemia during pregnancy in India contributes as a cause to 20% maternal death directly and 50% for associated causation.[2] Analysis of data from the National Family Health Survey 5 (NFHS5) in India observed anaemia in 52.2% of pregnant and 57.2% of non-pregnant women.[7] Given such a significant prevalence of anaemia in Indian women, the majority of them are expected to enter pregnancy in an anaemic state.

It has been well established that more than 50% cases of anaemia are attributed to iron deficiency.[1] Anaemia gets all the more aggravated in pregnancy due to pregnancy-related physiological changes and increased demand of the growing foetus.[8] During pregnancy, the need for absorbed iron increases from 0.8 mg/day in the first trimester to 7.5 mg/day in the third trimester.[9] An increase in dietary iron intake alone cannot compensate for this humongous increased iron demand.

To combat this global burden caused by anaemia, several preventive and therapeutic measures have been adopted in the form of both oral and intravenous preparations of iron supplements. Blood transfusion is stored as the last resort for more severe cases of anaemia with decompensation. Although oral iron supplementation raises the haemoglobin to a fairly satisfactory level, its major drawback is its poor compliance owing to its poor tolerability and side effects like nausea, constipation, and gastritis, which is reported in nearly 70% of women with oral iron.[10] Intravenous iron preparations used for treating IDA have shown promising results by providing greater and more rapid repletion of iron stores, making it possible to avoid blood transfusion and side effects of oral iron preparation.[11]

The most commonly used intravenous iron preparation is iron sucrose (IS). However, multiple dosing is required for IS, which decreases the compliance and popularity. Ferric carboxymaltose (FCM) is a new type of iron III complex, dextran-free, which makes it possible to be administered without a test dose for hypersensitivity. It has a neutral PH (5.0–7.0) and physiological osmolality, allowing a dose as high as 1000 mg to be administered in as little time as 15–20 min, thereby offering the greatest advantage of administering large doses in a short period of time with very less side effects overcoming the limitations of the existing intravenous iron agents. In addition, it has been already proven in an *in vitro* dual perfusion model that FCM does not cross the placental barrier and its use is approved in the second and third trimesters of pregnancy.[12]

Several studies have been reported to demonstrate the efficacy and side effects of intravenous iron preparations, but there is paucity of data using FCM as the intravenous iron preparation, especially in antenatal cases. This is the first prospective study for FCM in North East India among pregnant women presenting with IDA. Our study not only demonstrates the efficacy of FCM in rapid replenishment of haemoglobin levels but also emphasises the need of making FCM as the first choice of intravenous iron preparation in the treatment of IDA in the antenatal period considering its promising results and safety profile.

Methodology

This was a single-arm prospective cohort (before–after) study conducted among 60 pregnant women visiting the Department of Obstetrics and Gynaecology at North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS), Meghalaya, India, from December 2020 to December 2022. Ethical clearance was taken from the Institutional Committee [NEIGR/IEC/M14/F15/2021].

Pregnant women in the second and third trimesters with documented IDA defined as Hb <11 gm%[13] with S.ferritin levels <30 ug/dL and peripheral blood showing microcytic hypochromic picture were included in this study irrespective of the obstetric score. A written consent was obtained from patients fulfilling the selection criteria, and detailed demographic and clinical data were obtained from the subjects. Exclusion criteria included women with anaphylaxis to iron substitutes; uncontrolled hypertension; any cardiac, renal, or hepatic disease; and anaemia due to chronic disease.

Patients included in our study were administered intravenous FCM. The maximal dose per sitting was 1000 mg, which was diluted in 250 ml 0.9% normal saline and administered as an IV infusion over 15–30 min.

Blood samples were collected to measure haemoglobin and ferritin levels 2 weeks post-infusion to record the rise in haemoglobin and ferritin values. We observed women during and post infusion to see for any side effects like flushing, nausea, dizziness, pain/irritation/staining at the injection site, tachycardia, and hypotension/raised blood pressure. In addition to maternal monitoring, post-transfusion NST was done in third trimester patients to assess foetal well-being.

Statistical analysis

Data were analysed using SPSS 21.0 version statistical software. Variables were presented as frequency and percentage. Continuous variables like gestational age and parity were presented as mean (SD)/median (IQR), depending on the type of distribution. Student's paired *t*-test was used to determine the effect of FCM on the haemoglobin and ferritin before and post FCM administration. Difference in difference (DID) analysis was used to determine the association between parity and mean changes in Hb and ferritin levels following intervention. A P value of < 0.005 was considered statistically significant.

Results

The mean gestational age of the study population was 32.5 weeks at the time of presentation. The gravida median was 3 (2–4), and the parity median was 2 (1–3) [Table 1]. Our study showed that anaemia was higher in the multigravidas (93.3%) in comparison to the primigravidas (6.6%).

The mean haemoglobin in the study group before FCM infusion was 8.05 gm/dL. Two weeks post FCM infusion, the mean haemoglobin became 10.93 gm/dL. All participants reported improvement in the haemoglobin level after infusion, showing a mean haemoglobin rise of 2.88 gm/dL, which was found to be statistically significant. Similar improvement was noted in the S.ferritin levels after FCM infusion. The mean ferritin level before infusion was 25.92, which increased to a mean ferritin level of 253.96 post FCM infusion, which was found to be statistically significant [Table 2].

Table 2 shows that there was a significant change in the mean haemoglobin status ($P < 0.001$) and ferritin levels ($P = 0.004$) following the infusion of FCM.

Further analysis was made to determine association of other factors such as parity on the mean changes in haemoglobin and ferritin levels following intervention with FCM. Although a rise in mean haemoglobin (3.1 vs 2.86) and ferritin levels (250.2 vs 226.4) was found greater in primigravidas compared to multigravidas, the rise was only numerical and not found to be statistically significant [Table 3].

Table 3 shows that there was no significant association between the gravida status of the study participants and the change in the blood parameters following the infusion of FCM ($P > 0.05$).

No major anaphylactic reactions were noted in any of the participants. Minor side effects such as tingling at the infusion site were reported in two cases, which was transient in nature, did not require any intervention, and resolved spontaneously. No evidence of foetal distress was noted due to FCM injection.

Discussion

This single-arm prospective cohort (before–after) study investigated the efficacy and safety of FCM in IDA during the antenatal period. Our study successfully demonstrated that just one intravenous injection of FCM improved the studied blood parameters in a significant consideration in anaemic pregnant women.

The mean gestational age at the time of presentation was 32.5 weeks [Table 1]. Anaemia was higher in the multigravidas (93.3%) in comparison to the primigravidas (6.6%). This can be attributed to lack of spacing, increasing parity, inadequate replenishment of iron, ignorance and lack of motivation, and misconceptions on the benefits of haematinics.

Table 1: Obstetric characteristics among the study participants ($N = 60$)

Characteristics	Values
Gestational age in weeks Mean (SD)	32.6 (4.8)
Gravida Median (IQR)	3 (2-4)
Parity Median (IQR)	2 (1-3)

Table 2: Changes in the blood parameters among the study participants ($N = 60$)

Parameter	Mean	SD	Mean Difference (Pre-Post)	*P**
Hemoglobin (gm%)				
Pre-infusion	8.05	0.88	-2.89	<0.001
Post infusion	10.94	0.82		
Ferritin (mcg/l)				
Pre-infusion	25.92	23.27	-228.04	0.004
Post infusion	253.97	45.75		

*Paired t test

Table 3: Association of gravida with the change in the blood parameters among the study participants ($N = 60$)

	Gravida		*P**
	Primi Mean (SD)	Multi Mean (SD)	
Haemoglobin (gm%)	3.15 (0.29)	2.87 (0.61)	0.257
Ferritin (mcg/l)	250.20 (60.20)	226.46 (41.86)	0.481

*DID analysis

Our study demonstrated a substantial elevation in haemoglobin and ferritin levels post FCM infusion, which was found to be statistically significant [Table 2]. Charmila *et al.*[14] reported similar results following intravenous administration of FCM. Froessler *et al.*[15] also reported significant increased haemoglobin levels and improved iron store following use of FCM in the second and third trimesters of pregnancy. Another study by Khalafallah *et al.*[16] also demonstrated that the mean Hb and ferritin level differences between the baseline intervention time point and 4 weeks thereafter were significantly higher in the FCM versus the oral group by 4.35 g/L (95% CI: 1.64–7.05; $P = 0.0006$) and 166 μg/L (95% CI: 138–194; $P < 0.0001$), respectively. In the REGAIN study conducted by Wani *et al.*,[17] a direct proportional relationship was noted between increasing IV FCM dose and the increase of ≥2 g/dL in blood haemoglobin. A change of ≥2 g/dL was achieved by 27.5%, 39.2%, and 63.9% of women administered a dose of 500 mg, 1000 mg, and 1500 mg of IV FCM, respectively. Sharma *et al.*[18,19] in their studies showed that use of FCM in the treatment of anaemia in the postpartum period and anaemia due to gynaecological causes resulted in significant improvement of both haemoglobin and ferritin levels, thereby expanding the use of FCM in the treatment of anaemia besides antepartum use. Similarly, several studies showed a higher increase in serum ferritin levels with FCM than with iron sucrose or oral iron.[20-26] Thus, it is safe to conclude that compared to oral iron or IV iron sucrose, FCM is a better choice of iron supplementation for IDA in pregnancy.

The goal of iron therapy should not be limited to treatment alone, but more importantly, it should aim to avoid progression beyond low iron stores to impaired haemoglobin or frank IDA. Moreover, anaemia in the early duration of pregnancy is known to result in poor maternal and foetal outcomes. With this consideration, we believe the ideal time of FCM administration for best results is in the late second or early third trimester. In the third trimester, it should be administered at least 2 weeks before the expected date of delivery. Improving haemoglobin, even at a late stage of the third trimester, shields mothers from the risks of an allogeneic transfusion, which is not only an expensive affair but also short in supply and has its share of well-defined risks and adverse effects.

The present study also documented safety of FCM in pregnant women. Compared to other studies,[3,27-29] no major side effects were noted besides a few minor reactions like tingling sensation and discoloration at the injection site in two women which resolved without intervention. In a study by Wani *et al*.,[17] a total of 7 (0.7%) women reported mild, non-serious adverse events during the study. Although extremely rare, serious anaphylactic reaction following FCM infusion is possible as is reported by Sharma *et al*.[30] in a patient who received FCM for moderate anaemia post suction and evacuation for incomplete abortion. The patient was managed symptomatically, recovered fully, and was discharged well. This warrants careful monitoring of patients and judicious use of the preparation. However, there are some clinical pieces of evidence supporting the effective and safe use of IV FCM for correcting anaemia and replenishing iron stores during pregnancy.[31-35]

The latest NFHS-5[7] (2019–2020) data showed that anaemia is prevalent in more than half (52.2%) of all Indian pregnant women and IDA accounts for 75% of antenatal anaemia.[36] Moreover, the incidence of anaemia in under-5 children (from 58 to 67%), women (53.1 to 57%), and even men (22 to 25%) has worsened in all states of India.[7] Clearly, despite all the various programs and schemes launched by the Government of India, anaemia continues to be a significant health concern in India. One of the levels of inefficiency seems to lie in failure of participation or lack of compliance by the beneficiaries. This can be overcome by ensuring adequate delivery of services to the beneficiaries. One such initiative could be by substituting all iron requirements by FCM administration, particularly in those at high risk such as reproductive aged and pregnant women.

Another major problem encountered in India is the late presentation of women for their first antenatal visit.[37] Thus, anaemia is diagnosed late, necessitating quick correction of anaemia to prevent adverse maternal and neonatal outcomes. This need can be adequately fulfilled with parenteral iron therapy with an agent which causes rapid replenishment, does not cross the placenta, and is safe in pregnancy. FCM meets all these properties, making it the ideal parenteral iron preparation and therefore the first choice for correction of anaemia during pregnancy.

Such rapid and single-dose administration not only improves patient satisfaction but more importantly saves hospital resources. These properties also allow drug administration in an outpatient basis. Its easy administration and safety profile allow its use in limited resource settings by primary health care providers, who are the ones that come first in contact with the majority of the patients, including antenatal women. Availability of care at the primary centre decreases loss to follow-up by referral to a higher centre, increasing treatment of the condition and decreasing the overall disease burden. Compared to iron sucrose, FCM offers savings of 30–44% per patient per treatment cycle.[38] Thus, the higher cost of FCM is well balanced by single-dose administration, less hospital stay, convenience to the patients, and less burden on health providers, which is the need of the hour.

In the PROMISE study,[14] which is a retrospective, observational, and real-world study to assess the efficacy and safety of FCM in adolescents and adults with IDA, it was found that FCM efficiently, safely, and rapidly corrects moderate-to-severe anaemia in a short span of 4 weeks. Also, safety of FCM was rated very good to good in 97.2% subjects. Physicians' positive clinical impression of efficacy and safety supports clinical usage of FCM in the real-world scenario. Real-world evidence (RWE) is important because it substantiates the clinical trial evidence in real-world scenarios.[39]

Conclusion

Our study showed FCM was highly effective in improving haemoglobin and ferritin levels, thereby reflecting its efficacy in optimum and early replenishment of iron stores in antepartum anaemia. Its single and rapid administration further improves patient satisfaction as well as saves hospital resources. The wide use of FCM in the second and third trimesters as well as in the postpartum period demands a need for a unified consensus on the optimum use of FCM in the management of IDA in pregnancy and postpartum anaemia in routine clinical practice. Through this paper, we attempt to provide evidence on the superior efficacy of FCM and recommending FCM as the first choice of treatment of IDA in pregnancy.

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Conflicts of interest

There are no conflicts of interest.

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