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Original Research Article

Efficacy and safety of ferric carboxymaltose in Indian pregnant women with iron deficiency anemia

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ABSTRACT

Background: Ferric carboxymaltose (FCM) is a third-generation intravenous dextran-free, iron formulation that can be given in a single dose over a small duration. The study assessed hematological parameters before and after FCM administration in pregnant women for whole population and according to gestational age, severity of anemia and gravida status.
Methods: This was a single centre, prospective, observational, open label, clinical study at real life scenario with 4 weeks follow up. Thirty pregnant women with IDA and visiting to the Pushpam Maternity Hospital, Ahmedabad for antenatal care were enrolled for the study. I.V. FCM was administered as a single dose of 1000 mg. Change in the haemoglobin (Hb), ferritin, other hematological parameters at baseline and after 4 weeks of completion of parenteral iron therapy was noted.
Results: A significant increase in the haemoglobin (Hb) of 2.08 gm/dl and ferritin of 92.89 ng/ml was recorded at 4 weeks. There was a significant rise in Hb, ferritin, MCV, MCH, RBC count, MCHC as compared to the baseline in patients with moderate anemia. There was significant increase in Hb, hematocrit, ferritin and MCV as compared to baseline in primi and multigravida women and also in gestational age ≤ and >28 weeks. No adverse effects were observed throughout the duration of the study.
Conclusions: FCM infusion prior to delivery significantly increased hemoglobin levels and improved ferritin levels and other haematological parameters at 4 weeks in whole population and also in moderate anemia, primi, multigravida and gestational age ≤ and >28 weeks.

Keywords: Ferric carboxymaltose, Pregnancy, Iron deficiency anemia

INTRODUCTION

Anemia is a serious worldwide health problem amongst pregnant women. Iron deficiency is the most rampant nutrient deficiency globally, estimated to affect 38.2% of pregnant women with the highest prevalence in South-East Asia (48.7%) and Africa (46.3%).[1] The NFHS-5 (2019-2020) data has stated that anemia is prevalent in more than half of all Indian pregnant women.[2]

Iron deficiency is linked with increased risk to both the mother and the developing baby. It also has substantial effects on the growth and development of offspring, both physically and neurologically.

Oral route of iron has the potential to cause direct erosion and irritation of gastrointestinal mucosa. Parenteral iron complexes have an important role in women who have an intolerance to oral iron intake due to its side effects

Newer complexes of parenteral iron developed over the recent years have higher effectiveness and safety profiles as compared to the previous formulations of iron which were responsible for severe side effects like anaphylaxis, shock, and even death.

The iron used in these newer molecules is bound to the carbohydrate core which decreases the free iron released to cells and tissues thereby decreasing the impact of damage due to peroxidation when given in bolus doses.

Treatment of Iron deficiency anemia in pregnant women with iron has undergone remarkable evolvement with the availability of parenteral iron complexes. These formulations are safe and practical for patient care reducing the repeated dose administration and side effects of iron that the patient had to undergo due to prolonged therapy.[3]

Ferric carboxymaltose (FCM) is a third-generation parenteral iron intended to overcome the short-comings of existing parenteral iron preparations. FCM is a non-dextran i.v. iron agent that has a very low immunogenic potential and hence not liable to a high risk of anaphylactic reactions. Its properties allow the administration of large doses (maximum of 1000 mg/infusion) in a single session (15-minute infusion) without the requirement of a test dose.[4]

Evidence suggests that FCM is highly effective in rapidly replenishing iron stores and correcting anemia in patients with IDA associated with a wide spectrum of anemia etiologies covering pregnancy, post-partum, gynecological causes, peri- and post-surgical, etc.[4]

However, real-world evidence (RWE) of the efficacy and safety of FCM in pregnancy is limited especially from India. The study assessed hematological parameters before and after FCM administration in pregnant women in the whole population and also according to gestational age, severity of anemia and gravida status.

METHODS

Study design

This was a single centre, prospective, open label, 4 weeks' observational study in a real-world scenario at the Pushpam Maternity Hospital and Sonography Centre, Sabarmati, Ahmedabad India. The study was conducted during January 2021 to February 2022.

Inclusion and exclusion criteria

All pregnant women visiting for the routine antenatal care, with age more than 18 years, with 16 to 36 weeks of gestation and haemoglobin levels between 6 gm/dl to <11 gm/dl, not responding to oral iron or oral iron therapy not tolerable or oral iron therapy was inappropriate based on clinical judgement of investigator were enrolled in the study after obtaining an informed consent for the study.

Subjects with anemia other than IDA, prior history of allergic reaction to i.v. iron, evidence of iron overload conditions (e.g., hemochromatosis/hemosiderosis) were excluded. Apart from that, pregnant women with malignancy, cardiovascular disease, endocrinological or metabolic disorders or any other conditions which do not justify their inclusion in the study were excluded.

Treatment characteristics

Ferric carboxymaltose (FCM) was used according to the locally approved prescribing information and institution's protocol. The cumulative dose required for haemoglobin and iron restoration was calculated by using Ganzoni's formula based on the patient's body weight and haemoglobin levels. FCM (Injection Orofer FCM 1K, Emcure Pharmaceuticals Ltd., Pune, India) was administered with a maximum dose of 1000 mg of iron per infusion for at least 15 minutes.

Outcome measures

As per the standard antenatal care the pregnant women are administered routine investigations which included haemoglobin (Hb) levels, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), serum ferritin levels and red blood cell (RBC) count were measured.

Demographic details and hematological parameters captured in the CRFs were entered in a Microsoft Excel sheet and analysed using descriptive statistical methods. Data was analysed for the entire study population and by severity of anemia, gestational age, gravida status. Any adverse events including its occurrence, nature, hospitalization and death were also recorded.

The anaemia was classified as mild, moderate, and severe as per the cut-off values recommended for the pregnant women by the World Health Organization. According to it, Hb≥11 gm/dl are non-anemia, Hb- 10-10.9 gm/dl are having mild-anemia, Hb- 7-9.9 gm/dl, moderate anemia, and <7 are severe anemia.

Ethical considerations

Ethical clearance was obtained from an independent ethics committee at Ahmedabad (Rudraksha Hospital Ethics Committee) and the trial was registered with Clinical Trial Registry of India (CTRI) CTRI/2021/01/030515.

Statistical analysis

Data were analyzed for the entire study population, and by the category of anaemia. Quantitative data were represented as mean±standard deviation (SD) or median

(min-max) as appropriate. While categorical data were presented as frequency and percentages. A paired t-test was carried out to compare the hematological parameters at baseline and four weeks after FCM treatment.

RESULTS

Total 30 pregnant women who completed the present study were enrolled after obtaining written informed consent with appropriate inclusion criteria. The mean age was 29 years (range 24 to 40 years) and mean gestational age was 28 weeks (range 24 to 32 weeks). The mean baseline Hb was 8.57 gm/dl and mean baseline serum ferritin was 44.80 ng/mL for this study group (Table 1). The mean cumulative iron dose required was 873±177.6 mg (calculated as per Ganzoni formula).

Entire population

The following hematological parameters improved significantly in the study population at 4 weeks: Hb increased by 2.08 gm/dl; serum ferritin increased by 92.89 ng/ml; similarly, there was a significant increase in RBC count, hematocrit, mean MCV, MCH and MCHC as compared to baseline (Table 2).

Table 1: Patient characteristics at baseline.

	N	Mean±SD	Median (IQR)	Range (min-max)
Age (in years)	30	29.00±4.00	29 (27,31)	24-40
Height (cm)	27	160.6±4.67	160.00 (157.48,164.5)	149.35-170.68
Weight (kg)	27	64.45±13.54	64.45 (57.30, 73.33)	40-93
Duration of pregnancy in weeks	30	28.00±2.39	28 (28, 30)	24-32
Baseline Hb (g/dl)	30	8.57±1.03	8.35 (8.03, 9.13)	6.6-10.5
Baseline hematocrit (%)	27	29.00±3.16	29 (27.2, 31.90)	23.50-36.00
Baseline serum ferritin (ng/dl)	29	44.80±53.15	21.10 (5.70, 70.70)	2.4-178.00
Baseline MCV (fl)	29	79.03±11.33	77.60 (69.40, 85.20)	64.2-111.00
Baseline MCH (pg)	29	23.25±4.16	23.00 (19.70, 25.70)	18.10-32.30
Baseline MCHC (g/dl)	29	29.33±2.19	29 (27.6, 31.4)	25.4-33.40
Baseline RBC count ($\times 10^{12}$/l)	27	3.85±0.51	3.85 (3.45, 4.09)	2.44-4.64

Table 2: Comparing hematological parameters before and after administration of ferric carboxymaltose in whole population.

	N	Baseline (mean±SD)	At 4 weeks (mean±SD)	Mean improvement ±SD
Hemoglobin (gm/dl)	30	8.57±1.03	10.65±1.48	2.08±1.69*
Hematocrit (%)	26	29.4±3.18	34.66±5.69	5.26±5.92*
Sr. ferritin (ng/dl)	29	44.8±53.15	137.69	92.89±123.8*
MCV (fl)	25	79.03±11.33	85.6±9.42	6.57±5.73*
MCH (pg)	29	23.25±4.16	28.38±11.4	5.13±10.95$
MCHC (gm/dl)	29	29.33±2.19	30.6±1.74	1.27±2.07*
RBC count ($\times 10^{12}$/l)	26	3.79±0.52	4.15±0.9	0.36±0.66$

*P value <0.001; $: p value <0.05, statistically significant difference; by paired t-test as compared to baseline

Table 3 Comparing hematological parameters before and after administration of ferric carboxymaltose by moderate anemia severity.

	N	Baseline (mean±SD)	At 4 weeks (mean±SD)	Mean improvement ±SD
Hemoglobin (gm/dl)	25	8.38±0.78	10.72±1.50	2.35±1.70*
Hematocrit (%)	21	28.93±2.76	35.31±5.86	6.38±5.85*
Serum ferritin (ng/dl)	24	46.78±52.93	132.96±93.34	86.18±108.94*
MCV (fl)	24	77.11±9.97	84.3±9.33	7.2±4.12*
MCH (pg)	24	22.53±3.8	28.38±11.4	5.63±11.92$
MCHC (gm/dl)	24	29.15±2.23	30.28±1.67	1.13±2.12$
RBC count ($\times 10^{12}$/l)	26	3.84±0.55	4.30±0.90	0.46±0.67*

*P value<0.001; $: P value <0.05 Statistically significant difference; by paired t-test as compared to baseline

Severity of anemia

Response to FCM was also analyzed according to severity of anemia. There were only 4 patients with mild anemia. There was non-significant rise in Hb and serum ferritin by 0.55 gm/dl and 146.73 ng/ml at 4 weeks respectively as compared to baseline. There was also non-significant rise in hematocrit (0.23%), MCV (0.93±4.75 fl), RBC count (0.24×10^{12}/l), MCH (1.1±1.24 pg) and MCHC (0.25±1.47 gm/dl)

In subjects with moderate IDA, Hb increased significantly by 2.35 gm/dl and serum ferritin increased significantly by 86.18 ng/ml at 4 weeks as compared to baseline; similarly, there was a significant increase in RBC count, haematocrit, MCV, MCH and MCHC (Table 3).

There was a single case of severe anemia, the Hb rise was 1.5 gm/dl and ferritin rise was 38.7 ng/ml. There was increase in haematocrit (2%), MCV (21.6 fl), MCH (9.4 pg) and MCHC (3.7 gm/dl).

Gestational age category

Response to FCM was analyzed according to gestational age ≤28 weeks, Hb increased significantly by 2.15 gm/dl and serum ferritin increased significantly by 99.1 ng/ml at 4 weeks as compared to baseline; similarly, there was a significant increase in RBC count, haematocrit, MCV and MCHC. There was a non-significant rise in MCH at 4 weeks (Table 4).

At >28 weeks, Hb increased significantly by 1.95 gm/dl and serum ferritin increased significantly by 82.3 ng/ml at 4 weeks as compared to baseline; similarly, there was a significant increase in haematocrit, MCV and MCH. There was non-significant increase in MCHC and RBC count at 4 weeks (Table 5).

Table 4: Comparing hematological parameters before and after administration of ferric carboxymaltose according to gestational age (≤28 weeks).

	N	Baseline (mean±SD)	At 4 weeks (mean±SD)	Mean improvement ±SD
Hemoglobin (gm/dl)	20	8.65±1.03	10.79±1.61	2.15±1.85*
Hematocrit (%)	17	29.78±3.27	35.22±6.37	5.44±6.64*
Sr. Ferritin (ng/dl)	20	41.18±48.06	140.27±125.32	99.1±134.56*
MCV (fl)	20	80.44±11.96	86.41±8.59	5.97±5.54*
MCH (pg)	20	23.7±4.59	29.49±13.55	5.79±13.13#
MCHC (gm/dl)	20	29.29±1.99	30.41±1.72	1.12±1.93*
RBC count ($\times10^{12}$/l)	17	3.77±0.55	4.19±1.02$	0.42±0.74*

*p<0.001; $: p<0.05; statistically significant difference; #p value>0.05, non-significant difference by paired t-test as compared to baseline

Table 5: Comparing hematological parameters before and after administration of ferric carboxymaltose according to gestational age (>28 weeks).

	N	Baseline (mean±SD)	At 4 weeks (mean±SD)	Mean improvement
Hemoglobin (gm/dl)	10	8.41±1.08	10.36±1.19	1.95±1.41$
Hematocrit (%)	9	28.68±3.07	33.6±4.24	4.92±4.61$
Sr. ferritin (ng/dl)	10	52.07±61.83	134.37±64.71	82.3±96.35$
MCV (fl)	20	75.89±9.67	83.81±11.41	7.92±6.26$
MCH (pg)	9	22.26±2.95	25.93±3.04	3.68±2.68$
MCHC (gm/dl)	9	29.43±2.71	31.03±1.81	1.6±2.45#
RBC count ($\times10^{12}$/l)	9	3.81±0.48	4.07±0.69	0.26±0.51#

*p<0.001; $: p<0.05, statistically significant difference; # p value >0.05, non-significant difference, by paired t-test as compared to baseline

Primigravida status

Response to FCM was analyzed according to primigravida status, Hb increased significantly by 1.78 gm/dl and serum ferritin increased significantly by 103.14 ng/ml at 4 weeks as compared to baseline; similarly, there was a significant increase in hematocrit, MCV. There was a non-significant rise in RBC count, MCH and MCHC at 4 weeks (Table 6).

Multigravida status

Response to FCM was analyzed according to multigravida status, Hb increased significantly by 2.21 gm/dl and serum ferritin increased significantly by 85.1 ng/ml at 4 weeks as compared to baseline; similarly, there was a significant increase in, hematocrit, MCV, MCH as compared to baseline. There was a non-significant rise in MCHC and RBC count at 4 weeks (Table 6).

Table 6: Comparing hematological parameters before and after administration of ferric carboxymaltose according to primigravida status.

	N	Baseline (mean±SD)	At 4 weeks (mean±SD)	Mean improvement ±SD
Primigravida				
Hemoglobin (g/dl)	13	8.68±0.95	10.47±1.58	1.78±1.47*
Hematocrit (%)	11	29.91±3.34	33.45±5.73	3.54±4.42$
Serum ferritin (ng/dl)	13	42.08±44.23	145.22±109.43*	103.14±115.74*
MCV (fl)	12	81.13±9.11	85.73±8.4	4.6±3.89$
MCH (pg)	12	23.93±4.21	31.55±17.23	7.62±16.89#
MCHC (g/dl)	12	29.35±2.36	30.63±2.28	1.28±2.35#
RBC count ($\times 10^{12}$/l)	11	3.75±0.63	4±0.93	0.25±0.48#
Multigravida				
Hemoglobin (gm/dl)	14	8.56±1.04	10.78±1.56	2.21±1.99*
Hematocrit	13	28.88±3.1	35.35±6.11	6.47±7.12$
Serum ferritin (ng/dl)	14	50.9±62.64	136±119.97	85.1±142.21$
MCV (fl)	14	78.02±13.61	85.65±11.06	7.63±6.95*
MCH (pg)	14	23.14±4.27	26.34±3.45	3.2±2.59*
MCHC (g/dl)	12	29.66±2.09	30.76±1.34	1.1±2.03#
RBC count ($\times 10^{12}$/l)	13	3.8±0.48	4.23±0.96	0.44±0.83#

*p<0.001; $: p<0.05, statistically significant difference; #p value>0.05, non-significant difference by paired t-test as compared to baseline

DISCUSSION

Iron deficiency (ID) and iron-deficiency anaemia (IDA) affects over a billion individuals globally, most commonly occurring in resource-poor settings. Women of reproductive age (due to iron losses via menstruation) and pregnant women (due to additional iron requirements to support expansion of blood volume/red cell mass and growth of the fetus and placenta) are at increased risk for ID and IDA.[5]

Anemia is a major health problem in pregnancy in India. Further, maternal iron demand increases in the second and third trimester of pregnancy as the majority of iron transfer to the fetus occurs during this period. The average daily iron requirement of a pregnant woman increases from 0.8 mg/day in the first trimester to 7.5 mg/day in the third trimester. Thus, the iron deficiency becomes more severe in pregnancy because of the increased iron demand and inadequate iron intake through nutrition.[6]

Anemia in pregnancy has been associated with increased maternal mortality and postpartum hemorrhage risk; it has been reported that, hemoglobin less than 7 gm/dl doubles the risk of death in pregnancy. For the infant, maternal IDA is a recognized risk factor for preterm birth, low birthweight, and small-for-gestational-age neonates. It is also associated with increased perinatal and neonatal mortality as well as long-term measurable deficits in neurodevelopment. An iron-insufficient diet in pregnancy is common and may compound the problem.[6]

Timely diagnosis and management of anemia in pregnancy are crucial for preventing adverse outcomes.

Treatment, however, is not always straightforward because of adverse effects, which can affect compliance with treatment. Oral iron supplementation is challenging for patients to tolerate and can lead to significant gastrointestinal adverse effects including constipation, nausea, abdominal discomfort, diarrhea, and thick green stools. Pregnancy itself can lead to gastrointestinal disturbances including nausea and vomiting, which may continue beyond the first trimester.[6]

Quick correction of anemia in pregnancy is needed, and this limits the use of oral iron preparations, especially in moderate to severe anemia. Also, parenteral iron helps in restoring iron stores faster and more effectively than oral iron.[7] FCM, given as a single large dose administration per setting, requires lesser dosing frequency and need of lesser hospital visits as compared with other intravenous preparations. The distress to patients is also significantly lower due to lesser needle pricks.[8]

There was significant increase in Hb levels after FCM administration with rise of 2.6/dl in 4 weeks reported in real world studies.[9] Patients treated with FCM were more likely to have normalized serum Hb within 1 year of index date.[10]

In our study, Hb improved significantly at week 4 across the whole study population with mean rise of 2.08 gm/dl. Also, serum ferritin increased by 92.89 ng/ml; similarly, there was a significant increase in RBC count, hematocrit, MCV, MCH and MCHC at 4 weeks as compared to baseline. No adverse events were reported.

According to a retrospective cohort by Shi et al, maternal mortality, shock, admission to the intensive care unit, fetal growth restriction and stillbirth, the increased risks were observed among pregnant females with moderate or severe anemia.[11]

In our study, the Hb, ferritin values increased significantly as compared to the baseline in patients with moderate anemia at 4 weeks. Also, RBC count, hematocrit, MCV, MCHC and MCH increased significantly at 4 weeks. In a study by Rathod et al, the rise in Hb with FCM was 3.61 gm/dl in mild anemia cases as compared to 4.30 gm/dl in moderate anemia cases in 6 weeks.[12]

In the present study, there were only 4 cases were of mild anemia and there was non-significant improvement in Hb and other haematological parameters. Further the response was more positive in increasing Hb, ferritin and other haematological parameters in moderate anemia cases than mild anemia cases which is similar to results by Rathod et al.[12]

Multigravida females have higher prevalence of anemia as their body is more frequently depleted of the reserved iron stores.[13]

In our study, there was significant increase in Hb, haematocrit, ferritin and MCV as compared to baseline in primi and multigravida women at 4 weeks.

Haniff et al, observed that the prevalence of anemia increased with increasing gestational age, being 12% in the first, 32% in the second and 43% in the third trimester.[14]

It was observed in this study that pregnant women in both groups i.e. ≤28 weeks (2nd trimester) and >28 weeks (third trimester) showed a significant increase in Hb, haematocrit, ferritin, MCV at 4 weeks compared to baseline.

CONCLUSION

They key finding in our study was that in women presenting with IDA relatively late in pregnancy, a FCM infusion prior to delivery significantly increased hemoglobin levels and improved iron stores and other haematological parameters at 4 weeks in whole population and also in moderate anemia, primi and multigravida women, gestational age ≤ and >28 weeks.

We have shown that FCM appears to be a well-tolerated and effective treatment for IDA in pregnant women.

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