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Original Research Article

Ferric carboxymaltose in the management of iron deficiency anemia in women and men: sub-group analysis of a multi-center real-world study from India

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ABSTRACT

Background: Ferric carboxymaltose (FCM) is commonly used to treat moderate to severe anemia in India. However, real-world data on its use in the treatment of iron anemia of unspecified etiology is lacking.
Methods: The real-world PROMISE study assessed the efficacy and safety of intravenous FCM in adolescents and adults with IDA across 269 centers in India. This sub-group included non-pregnant women and men with a diagnosis of anemia. Data was analysed by the study population and by severity of anemia.
Results: In 555 anemia patients, there was a significant increase in Hb by 2.71 g/dl, serum ferritin by 58.6 µg/l, hematocrit, mean corpuscular volume (MCV) and mean corpuscular hemoglobin (MCH) ($p<0.001$ for all) at 4 weeks. In severe anemia patients (n=222), there was significant increase in Hb by 3.18 g/dL, serum ferritin by 55.7 µg/l, RBC count, hematocrit, MCV and MCH ($p<0.001$ for all) at 4 weeks. In moderate anemia patients (n=294), there was a significant increase in Hb by 2.37 g/dl and serum ferritin by 62.37µg/L ($p<0.001$ for both); MCV ($p<0.001$) and MCH ($p=0.003$). Only two subjects had mild anemia. No serious adverse events (SAEs) were reported. The physicians rated efficacy and safety of FCM as very good to good in 94.7% and 94.8% of subjects, respectively.
Conclusions: The improvement in the hematological parameters and physicians' clinical impression highlights that FCM can be effectively and safely used in daily clinical practice to quickly correct anemia of unknown etiology in Indian population in short span of 4 weeks.

Keywords: Anemia, Efficacy, Ferric carboxymaltose, India, Iron deficiency, Real-world, Safety

INTRODUCTION

Anemia is a condition caused by a decrease in hemoglobin or red blood cells (RBCs) in the blood.[1] Globally, anemia affected 22.8% of the world population in 2019.[2] In India, 57 percent of women and 25% of men in the age group of 15-49 years had anemia in 2019-2020, according to the fifth National Family Health Survey (NFHS-5).[3] Anemia is a serious health concern in India, and therefore the country is focused on eradicating anemia through national guidelines and programs.[4,5] However, despite this focus, anemia is prevalent across all age groups in India, and

severe anemia (hemoglobin [Hb] <7 g/dL), continues to be a substantial problem.[4,5]

Anemia primarily caused by iron deficiency, is the most common and easily remediable nutrient deficiency in the world, including India.[1,6-8] Consequently, iron deficiency anemia (IDA), is often considered synonymous to anemia, and most programs focused on alleviating anemia are primarily focused on alleviating IDA.[4,10,11]

IDA is primarily treated with oral or parenteral iron supplementation.[12] Though oral preparations are the first line of treatment for IDA, they frequently cause gastrointestinal side effects, reduce compliance and are inadequate for patients with moderate to severe anemia who require a much faster recovery than is possible through oral route.[12] Hence, parenteral iron preparations are the mainstay of treatment in moderate to severe anemia.

Of the parenteral iron preparations, ferric carboxymaltose (FCM) is effective and well tolerated in situations where large iron doses are required for rapid correction of anemia.[12] There is substantial clinical evidence supporting the use of FCM in anemia of different etiologies[12–18], but real-world evidence (RWE) substantiating the efficacy and safety of FCM seen in the clinical trials is largely lacking. Charmila et al had earlier conducted a large (n=1800) multicenter, retrospective, observational data collection study of efficacy and safety of FCM in varied sub-sets of Indian patients with IDA across 269 centers in India.[19] This sub-group analysis of PROMISE study was done with the objective of evaluating effect of FCM in treatment of iron deficiency anemia in Indian non-pregnant women and men.

METHODS

Study type and place

This was a multi-center, retrospective, observational, data collection study across 269 centers in India.

Study duration

This is a sub-group analysis of the PROMISE study conducted from January 01, 2021 and December 31, 2021.[19]

Selection criteria

Included non-pregnant women and men aged ≥14 years with a diagnosis of anemia based on hemoglobin [Hb] level between 4.0 and <12 g/dl and where its cause or etiology was not specified, were included in the analysis. Data of these included subjects who were administered FCM (Inj Orofer FCM 500/1K, Emcure Pharmaceuticals Ltd., Pune, India) as per the standard of care and as per the locally approved prescribing information in real-life clinical practice, was analyzed.

Subjects with a diagnosis of anemia other than IDA, severe iron deficiency with Hb <4 g/dL, known hypersensitivity to FCM or to any of its excipients, known serious hypersensitivity to other parenteral iron products, evidence of iron overload (eg, hemochromatosis/hemosiderosis), malignancy, pregnant women in the first trimester or if participant was considered unsuitable for the study by the investigator, were excluded from the PROMISE study.

Procedure

Anonymized data on hematological parameters at baseline and/or at minimum of 4±1 week (henceforth reported as 4 weeks) available from the subjects' medical records were captured. Demographic details and hematological parameters captured in the CRFs were entered in a Microsoft Excel sheet.

The following Hb values were considered as normal as per WHO's Hb cut-off values for anemia[20]: Non-pregnant women (≥12 g/dl); men (≥13 g/dl). Anemia was categorized as mild, moderate and severe based on the World Health Organization's Hb cut-off values[20]: severe anemia (Hb <8 g/dl for non-pregnant women and men); moderate anemia (Hb 8-10.9 g/dl for non-pregnant women and men); and mild anemia (Hb 11-11.9 g/dl for non-pregnant women; 11-12.9 g/dl for men).

Statistical analysis

Demographic details and hematological parameters were analyzed using descriptive statistical methods. Data were analyzed for the sub-group, and by the severity of anemia. Categorical data was represented as frequencies and percentages. Quantitative data was described as mean ± standard deviation (SD). A paired T-test was carried out to compare the hematological parameters at baseline and four weeks after FCM infusion.

Ethical consideration

This sub-group analysis was part of the PROMISE study that was approved by the Ripon Independent Ethics Committee. The study was registered with the Clinical Trial Registry of India (CTRI) with a wide registration number CTRI/2021/12/039065.

RESULTS

Baseline characteristics

The sub-group analysis included data from 555 women and men with a diagnosis of anemia; mean age 37.09 years (range 14 to 92 years); 87.9% were females. Hb values were available for 536 subjects, but serum ferritin values were available for only 71 subjects; mean Hb value was 7.95 g/dL and mean serum ferritin value was 53.35 µg/L. The mean cumulative FCM dose was 897.06 mg and the average FCM infusion time was 19.42 minutes. Diabetes

and hypertension were the most commonly seen co-morbid conditions in 4.5% and 3.6% of subjects, respectively. The values of various hematological parameters at baseline are shown in Table 1.

Table 1: Patient characteristics at baseline.

	N	Mean±SD	Median (IQR)	Range (min-max)
Age	497	37.09±12.27	34 (29, 43.5)	14 to 92
Weight	429	59.54±9.72	60 (52, 65)	32 to 90
Sex	481	Male: 58 (12.1%)	Female: 423 (87.9%)	
FCM infusion duration (minutes)	467	19.42±7.23	20 (15, 20)	6 to 60
Cumulative FCM dose (mg)	476	897.06±330.73	1000 (500, 1000)	500 to 3000
Baseline Hb (g/dL)	536	7.95±1.07	8 (7.2, 8.7)	4.3 to 11.5
Baseline serum ferritin (µg/l)	71	53.35±34.85	58.4 (14, 76.3)	1 to 180
Baseline RBC count (mn/mm^3)	83	4.15±1.92	3.82 (3.43, 4.2)	1.7 to 12.5
Baseline hematocrit (%)	66	28.16±5.11	28.5 (23.8, 33)	19.9 to 39
Baseline MCV (fl)	80	69.46±13.13	69.55 (59.53, 80.75)	29.3 to 98
Baseline MCH (pg)	74	23.45±6.1	23.3 (19.95, 27)	3.6 to 37
Baseline MCHC (g/dl)	70	30.35±3.61	30 (28.43, 32)	24.2 to 43.1

Abbreviations: %- percentage; µg/l- micrograms per liter; fL- femtoliters; g/dl- grams per deciliter; Hb-Hemoglobin; IQR- Interquartile range; MCH- mean corpuscular hemoglobin; MCHC- mean corpuscular hemoglobin concentration; MCV- mean corpuscular volume; mg- milligrams; Min-Max- Minimum-Maximum; mn/mm^3- million per millimeter cube; N- number of participants; pg- picograms; RBC- red blood cell; SD-Standard deviation; Note: 4 weeks is 4±1 week.

Table 2: Comparing hematological parameters before and after administration of ferric carboxymaltose in men and women with anemia diagnosis.

Parameter	N	At baseline (Mean±SD)	At 4 weeks (Mean±SD)	Mean improvement±SD
Hemoglobin (g/dl)	518	7.95±1.07	10.67±1.01	2.71±1*
Ferritin (µg/l)	53	54.3±28.76	112.9±41.73	58.6±33.15*
RBC (mn/mm^3)	55	4.29±2.25	4.81±1.5	0.52±2.19 ^{NS}
Hematocrit (%)	43	29.32±4.87	35.49±7.14	6.16±7.11*
MCV (fL)	54	72.6±12.2	83.75±8.34	11.15±9.61*
MCH (pg)	51	24.75±5.97	29.06±3.47	4.32±6.03*
MCHC (g/dl)	48	30.37±3.9	30.61±7.5	0.24±7.58 ^{NS}

*P value <0.001, Statistically significant difference; NS-P value >0.05, non-significant difference. Abbreviations: %- percentage; µg/L- micrograms per liter; fL- femtoliters; g/dL- grams per deciliter; MCH- mean corpuscular hemoglobin; MCHC- mean corpuscular hemoglobin concentration; MCV- mean corpuscular volume; min- minutes; mn/mm^3- million per millimeter cube; N- number of participants; pg- picograms; RBC- red blood cell; SD – Standard deviation; Note: 4 weeks is 4±1 week.

Efficacy outcomes

The following hematological parameters improved significantly in the study population at 4 weeks: Hb increased by 2.71 g/dL; serum ferritin increased by 58.6 µg/L; similarly, there was significant increase in hematocrit, mean corpuscular volume (MCV) and mean corpuscular hemoglobin (MCH) (p<0.001 for all). There was non-significant improvement in RBC count and mean corpuscular hemoglobin concentration (MCHC) at 4 weeks as compared to baseline (p=0.084 and 0.825, respectively) (Table 2).

When analysed based on the severity of anemia, the Hb increased significantly in patients with severe anemia (n=222), and moderate anemia (n=294) by 3.18 g/dl and 2.37 g/dl, respectively at 4 weeks after FCM treatment compared to baseline (p<0.001 for both) (Figure 1). The mean increase in patients with mild anemia was non-significant (0.5 g/dl, p=0.5) (Figure 1).

The serum ferritin also increased significantly 4 weeks after FCM treatment by 55.7 µg/l in patients with severe anemia and by 62.37 µg/l in patients with moderate anemia (p<0.001 for both) (Figure 2). The change in serum ferritin in patients with mild anemia could not be analysed since the respective data was not available.

In subjects with severe anemia there was a significant increase in RBC count, hematocrit, MCV and MCH (p<0.001 for all). MCHC improved at 4 weeks as compared to baseline but the difference was not statistically significant (p=0.923) (Table 3).

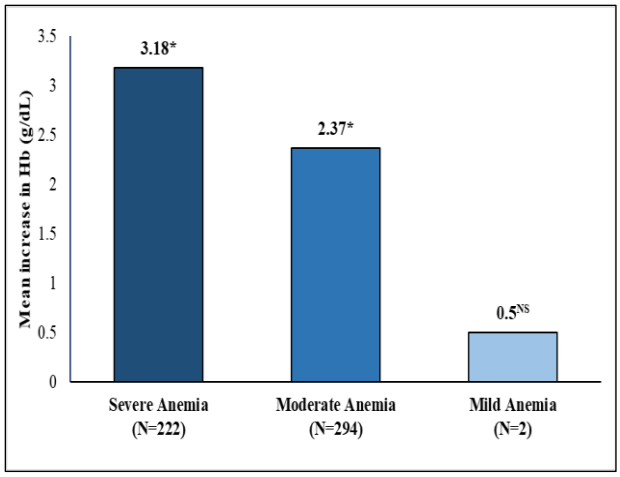

Figure 1: Increase in hemoglobin 4 weeks after ferric carboxymaltose infusion.

*P value <0.001, Statistically significant difference; NS – P value >0.05, non-significant difference. g/dL- grams per deciliter; Hb – hemoglobin; N – number of participants

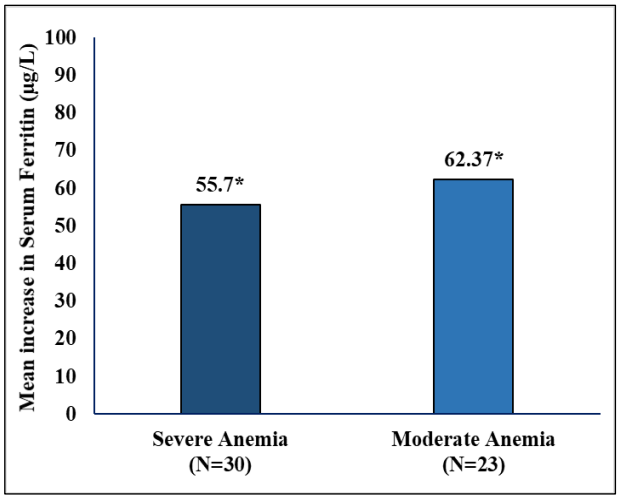

Figure 2: Increase in serum ferritin 4 weeks after ferric carboxymaltose infusion.

*P value <0.001, Statistically significant difference. µg/L- micrograms per litre; N-number of participants

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

Severity of anemia (n=518)	Parameter	N	At baseline (Mean±SD)	At 4 weeks (Mean±SD)	Mean improvement±SD
Severe (n=222)	Hemoglobin (g/dL)	222	7.01±0.69	10.19±1.02	3.18±1.05*
	Ferritin (µg/L)	30	52.52±29.76	108.22±38.38	55.7±30.02*
	RBC (mn/mm^3)	28	3.67±0.58	4.44±0.47	0.77±0.52*
	Hematocrit (%)	23	28.09±5.07	36.56±5.09	8.47±5.52*
	MCV (fl)	28	70.64±12.78	83.16±8.71	12.52±9.74*
	MCH (pg)	27	23.43±6.59	28.73±3.63	5.3±6.88*
	MCHC (g/dl)	30	30.77±3.79	30.91±7.81	0.13±7.39^{NS}
Moderate (n=294)	Hemoglobin (g/dl)	294	8.65±0.66	11.02±0.83	2.37±0.8*
	Ferritin (µg/l)	23	56.62±27.9	119±45.9	62.37±37.2*
	RBC (mn/mm^3)	26	4.95±3.12	5.22±2.06	0.28±3.15^{NS}
	Hematocrit (%)	19	30.31±3.97	34.01±9.11	3.7±8.09^{NS}
	MCV (fl)	25	74.26±11.39	84.32±8.21	10.06±9.4*
	MCH (pg)	23	26.15±5	29.5±3.38	3.35±4.86*
	MCHC (g/dl)	17	29.51±4.15	29.96±7.33	0.45±8.36^{NS}
Mild (n=2)	Hemoglobin (g/dl)	2	11.25±0.35	11.75±0.35	0.5^{NS}

*P value <0.001, Statistically significant difference; NS-P value >0.05, non-significant difference

Abbreviations: %- percentage; µg/L- micrograms per liter; fL- femtoliters; g/dL- grams per deciliter; MCH- mean corpuscular hemoglobin; MCHC- mean corpuscular hemoglobin concentration; MCV- mean corpuscular volume; min- minutes; mn/mm^3- million per millimeter cube; N- number of participants; pg- picograms; RBC- red blood cell; SD-Standard deviation; Note: 4 weeks is 4±1 weeks

In subjects with moderate anemia there was a significant increase in MCV (P=0.003) and MCH (p<0.001). RBC count (p=0.659), hematocrit p=0.061), and MCHC (p=0.826) improved at 4 weeks as compared to baseline but the difference was not statistically significant (Table 3).

Only two subjects had mild anemia and hematological parameters other than Hb were available for only one subject. The change in these parameters after FCM treatment could not be analysed.

Safety

Adverse effects (AEs) were seen in 5.8% of the subjects (32/555). The commonly reported AEs were: headache (2.9%), nausea (1.8%), constipation (1.6%), allergic reaction (0.7%), and diarrhea (0.5%). No serious adverse events (SAEs) were reported in any of the subjects.

Physician reported outcomes

The physicians noted very good to good efficacy of FCM in 94.7% of subjects (very good and good efficacy in

58.3% and 36.4% of subjects, respectively). Very good to good safety was reported in 94.8% of subjects (very good and good safety in 57.2% and 37.6% of subjects), respectively. The physicians noted average efficacy and safety in only 5.3% and 5.2% of subjects, respectively. Poor efficacy or safety was not noted in any of the subjects.

DISCUSSION

The diagnosis of anemia is typically made by doing a complete blood count (CBC), and identifying Hb level below normal for the individual; with normal values set by the World Health Organization (WHO). Once, the diagnosis is established, the CBC values or further laboratory investigations help identify the cause of anemia.[21] It is important to identify the cause of anemia to initiate the right therapy.[21] However, in most primary care settings in India, only Hb levels are estimated for diagnosing anemia, and many health centers do not have the laboratory facilities to conduct other tests.[22]

Iron deficiency anemia is the most common and easily remediable cause of anemia in India.[1,6–8] Consequently, anemia is often considered synonymous to iron deficiency anemia (IDA).[9,23] This is because iron plays the crucial role of carrying oxygen in the heme group of Hb and inadequate iron supply leads to impaired Hb production.[24,25] Also, iron supplementation is shown to improve Hb and anemia in most patients diagnosed with anemia.[1,26]

Serum ferritin is an extremely useful and commonly used test for the diagnosis of IDA.[6,26-29] Also, through MCV, MCH, RBC counts and other laboratory tests play a crucial role in diagnosing and monitoring anemia, comprehensive testing is costlier than doing only Hb.[8,25] Thus, in many resource-limited clinical settings in India, physicians start anemia treatment with iron supplements based on Hb values only.[22,23]

This scenario is reflected in our study too, where Hb levels were measured in 96.6% of subjects (n=536), while ferritin levels were measured in 12.8% of subjects only. Similarly, other parameters like RBC, hematocrit, MCH, MCV, and MCHC were evaluated for very few subjects (<15% each). However, FCM infusion resulted in significant improvement in Hb by 2.71 g/dL and serum ferritin by 58.6 µg/L ($p<0.001$ for both) at 4-weeks. In these subjects, FCM infusion resulted in significant increase in hematocrit, MCH, and MCV and non-significant increase in RBC and MCHC. Thus, it is reasonable to infer from this sub-group analysis that FCM can be routinely started to treat anemia in men and women in India.

Gender differences in anemia with higher prevalence in women become more apparent in women population after menarche, which imply that iron deficiency is likely to be the main cause of anemia.[30] In this sub-analysis, 87.9% of subjects were females, and of ≥14 years of age.

Of the 555 subjects, 40% of subjects (n=222) had severe anemia and 53% of subjects (n=294) had moderate anemia; only two subjects had mild anemia. Oral iron would have been inadequate in these patients with moderate to severe anemia, as they required large parenteral iron doses for improving Hb levels and replenishing the iron stores. There was significant improvement in Hb and ferritin levels in patients with moderate ($p<0.001$ for both values) and severe anemia ($p<0.001$ for both values).

The retrospective study design is limited by the biases introduced by missing data, and inability to control drug dosage and frequency. Limited data on serum ferritin in majority of patients and no data on transferrin saturation is another limitation of the present sub-study. Since, this sub-analysis is a part of a real-world Indian study, comprehensive testing is usually not possible due to limited resources and inability of patients to bear the out-of-pocket expenses required for comprehensive testing. However, to the best of our knowledge this is the first study reporting the efficacy and safety of FCM in real-life patients diagnosed with anemia. Iron deficiency was not confirmed in majority of patients, but FCM infusion resulted in significant improvement in anemia in terms of increase in Hb and ferritin levels. Additionally, this sub-group analysis noted that physicians assessed FCM to have very good/good efficacy and safety in 94.7% and 94.8% of the subjects, respectively. There were no new safety signals and no SAEs were reported during the study period.

CONCLUSION

Anemia is a major health concern in India. This sub-group analysis of the real-world PROMISE study highlights that FCM is an effective and safe treatment option to correct iron deficiency in women and men with moderate to severe anemia in short span of around 4 weeks. These findings, along with the physicians' clinical impression of efficacy and safety, support usage of FCM for correcting moderate to severe anemia in daily clinical practice.

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Ethical approval: The study was approved by the Ripon Independent Ethics Committee

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