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## Original Research Article

# Management of iron deficiency anemia in Indian women using ferric carboxymaltose: a sub-group analysis from the PROMISE multi-center real-world study in India

Jamunadevi Gudidevuni<sup>1</sup>, Jignesh Shah<sup>2</sup>, Ketan Kulkarni<sup>3\*</sup>, Rutuja Tope<sup>3</sup>,  
Prashant Katke<sup>3</sup>, Sachin Suryawanshi<sup>3</sup>

<sup>1</sup>Yashoda Hospital, Secunderabad, Telangana, India

<sup>2</sup>Shah Maternity Nursing Home, Ahmedabad, Gujarat, India

<sup>3</sup>Emcure Pharmaceuticals Ltd, Mumbai, Maharashtra, India

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### \*Correspondence:

Dr. Ketan Kulkarni,

E-mail: Ketan.Kulkarni@emcure.com

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## ABSTRACT

**Background:** To evaluate the effectiveness of intravenous ferric carboxymaltose (FCM) in patients with iron deficiency anaemia (IDA) across 269 centres in India, we conducted a retrospective, observational, real-world investigation. The present analysis was done to evaluate FCM in Indian women with IDA in a real-world scenario.

**Methods:** Haematological parameters were examined for the study population's baseline and 4±1 week follow-up data on females with anaemia who regularly received FCM for anaemia management.

**Results:** 1666 females with IDA, the hematological parameters improved significantly at 4 weeks ( $p<0.001$ ) Hb increased by 2.78 g/dl, serum ferritin increased by 35.26 µg/l, haematocrit, red blood cell (RBC) count, mean corpuscular haemoglobin (MCH) and mean corpuscular volume (MCV). Subjects with severe IDA ( $n=304$ ), significant increase in Hb (by 3.32 g/dl), serum ferritin (by 34.96 µg/l) ( $p<0.001$  for both), RBC count ( $p<0.001$ ), haematocrit ( $p=0.004$ ), MCH ( $p<0.001$ ) at 4 weeks. Subjects with moderate IDA ( $n=1227$ ), significant increase in Hb (by 2.66 g/dl), serum ferritin (by 35.42 µg/l), haematocrit, RBC count, MCH and MCV ( $p<0.001$  for all) at 4 weeks. Subjects with mild IDA ( $n=26$ ), significantly higher mean Hb values were seen at 4 weeks (by 1.99 g/dl) Hematological parameters improved compared to baseline at 4 weeks mean difference was statistically insignificant. Physicians rated efficacy and safety of FCM as very good to good in 97.4% and 97.1% of subjects, respectively.

**Conclusions:** FCM corrects anemia in all subsets of Indian women in short span of 4 weeks and thus supports evidence of efficacy and safety.

**Keywords:** Anemia, Efficacy, Females, Ferric carboxymaltose, India, Iron deficiency, Safety, Women

## INTRODUCTION

Anemia is a global public health concern that affected 22.8% of the world population in 2019.<sup>1</sup> More than half (57%) of all Indian women in the reproductive age group have anemia (National Family Health Survey, 2019-2020).<sup>2</sup> Despite national programs to tackle anemia, severe anemia (haemoglobin (Hb) levels  $<7$  g/dl) continues to be

a substantial problem in India women.<sup>3-5</sup> The most frequent cause of anaemia in women is iron deficiency anaemia (IDA).<sup>6</sup> Oral iron preparations are commonly used to treat IDA, however, oral preparations do not produce the desired quick improvement in hematological parameters in moderate to severe anemia.<sup>6,7</sup> Also, iron requirement in women is often much more than what can be replenished and sustained orally.<sup>7</sup> Such situations are

commonly encountered in clinical practices during management of heavy menstrual bleeding due to any cause.<sup>7</sup> Blood transfusions have serious infectious and non-infectious complications and therefore not routinely practiced in clinics.<sup>8</sup> They are usually reserved as a life-saving measure in seriously symptomatic anemia, sickle cell crisis and acute blood loss of >30% of blood volume.<sup>8</sup> The parenteral iron preparations quickly improve anemia, replenish iron stores and avoid the need for blood transfusion in moderate to severe anemia.<sup>9</sup> Ferric carboxymaltose (FCM) is a third-generation parenteral iron formulation with very low immunogenic potential and reduced risk of anaphylactic reactions.<sup>6</sup> FCM can be administered quickly (15 minutes) in large doses (maximum of 1000 mg/infusion) in a single infusion without the need of a test dose.<sup>6,10,11</sup> There is an immense amount of clinical evidence establishing the efficacy and safety of intravenous FCM in rapidly replenishing iron stores and correcting IDA in Indian women, irrespective of its etiology.<sup>12-16</sup> The clinical evidence also states FCM leads to a faster improvement compared to other commonly used parenteral irons.<sup>14,15,17,18</sup> Charmila et al, had earlier reported real-world evidence from PROMISE study (N=1800) demonstrating efficacy and safety of intravenous FCM in the management of IDA in the adolescent and adult Indian population.<sup>19</sup> The PROMISE study population comprised of both men and women. The present sub-group analysis was done to evaluate efficacy and safety of FCM in iron deficiency anemia in Indian women.

## METHODS

### *Study type and place*

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

### *Study period*

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

### *Selection criteria*

Included in the analysis were women (excluding anemia in pregnancy and postpartum anemia) aged  $\geq 14$  years with a diagnosis of anemia based on haemoglobin level between 4.0 and <12 g/dl. 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.

### *Procedure*

Hematological parameters were anonymously captured from the subject's medical records at baseline and/or at 4 $\pm$ 1 week (henceforth reported as 4 weeks).

World Health Organization's (WHO's) Hb cut-off values for anemia<sup>21</sup> were used to define normal Hb values for the study: non-pregnant women  $\geq 12$  g/dl and pregnant women  $\geq 11$  g/dl. Similarly, World Health Organization's Hb cut-off values<sup>21</sup> were used to categorize the severity of anemia: severe anemia (non-pregnant women Hb <8 g/dl, pregnant women <7 g/d for 1), moderate anemia (non-pregnant women: Hb 8-10.9 g/dl, pregnant women 7 to 9.9 g/dl) and mild anemia (non-pregnant women: Hb 11-11.9 g/dl, pregnant women: 10-10.9 g/dls).

Based on the clinical improvement (symptomatic and haematological improvement) and adverse events/side effects of FCM reported in the medical records, physicians' clinical opinions of the efficacy and safety of FCM were assessed as very good, good, average, or bad, respectively.

### *Ethical approval*

This sub-group analysis is 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.

### *Statistical analysis*

Descriptive statistical methods were used to analyze demographic and hematological parameters. Data were analyzed for the sub-group (women included in the study) and by the severity of anemia. Quantitative data was described as mean standard deviation (SD) and categorical data was described as frequencies and percentages. The hematological parameters at baselines and 4 weeks after FCM infusion were compared using a paired t-test.

## RESULTS

### *Baseline characteristics*

The sub-group analysis included 1,666 women with IDA, mean age 31.63 years with mean Hb of 8 g/dl and mean serum ferritin at 41.24  $\mu$ g/l. The mean cumulative FCM dose was 993.8 mg and the mean FCM infusion time was 18.34 minutes. The values of various hematological parameters at baseline are shown in Table 1.

### *Efficacy outcomes*

The study population showed significant improvement in the following hematological parameters at 4 weeks after FCM therapy ( $p < 0.001$  for all): Hb increased by 2.78 g/dl, serum ferritin increased by 35.26  $\mu$ g/l, similarly, there was significant increase in red blood cell (RBC) count, haematocrit, mean corpuscular volume (MCV) and mean corpuscular haemoglobin (MCH). There was non-significant improvement in mean corpuscular haemoglobin concentration (MCHC) ( $p = 0.139$ ) (Table 2). In subjects with severe IDA ( $n = 304$ ), Hb increased significantly by 3.32 g/dl and serum ferritin increased

significantly by 34.96 µg/l at 4 weeks as compared to baseline ( $P<0.001$  for both) (Figure 1). Similarly, there was a significant increase in RBC count ( $P<0.001$ ), haematocrit ( $P=0.004$ ) and MCH ( $P<0.001$ ) in subjects with severe anemia. The improvement in MCHC and MCV in these subjects was not significant (MCV  $p=0.771$  and MCHC:  $p=0.375$ ) (Table 3).

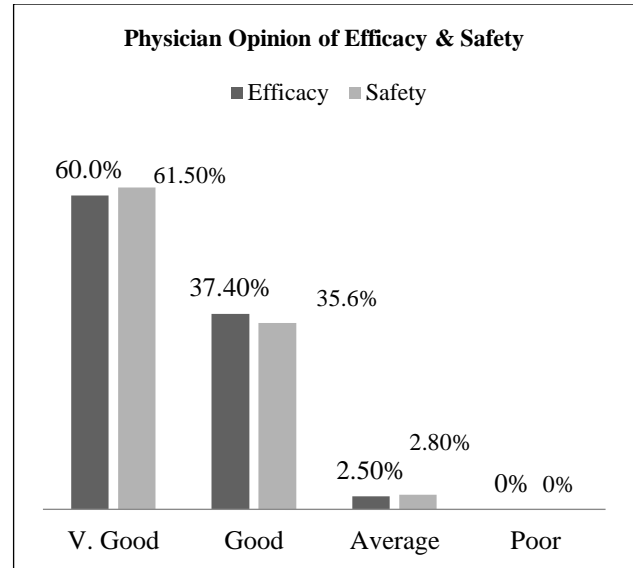
In subjects with moderate IDA ( $n=1227$ ), Hb increased significantly by 2.66 g/dl and serum ferritin increased significantly by 35.42 µg/l at 4 weeks as compared to baseline ( $P<0.001$  for both) (Figure 1). In these subjects, RBC count, haematocrit, MCV and MCH improved significantly ( $p<0.001$  for all), whereas MCHC improved insignificantly at 4 weeks as compared to baseline ( $p=0.209$ ).

In subjects with mild IDA ( $n=26$ ), mean Hb value at 4 weeks was significantly higher by 1.99g/dL as compared to baseline ( $p<0.001$ ) (Figure 1). Serum ferritin, RBC count, haematocrit, MCH and MCHC improved at 4 weeks as compared to baseline, but the mean difference was not statistically significant (Figure 1, Table 3).

Since the MCV value was available for only one subject which improved from 61.4 fl (femtoliters) at baseline to 80.6 fl at 4 weeks, the statistical significance of this increase could not be computed.

### Safety

7.6% (127/1666) of the individuals experienced adverse reactions (AEs). The most frequently reported adverse events (AEs) were allergic reaction (0.4%), constipation (0.5%), headache (3.5%) and nausea (4%). In any of the individuals, there were no major adverse events (SAEs) reported.



The % indicates the percentage of subjects.

**Figure 1: Physicians' assessment on efficacy and safety of ferric carboxymaltose in females.**

### Physician's efficacy and safety assessment based on data available in medical records

In 97.4% of the subjects, the FCM's effectiveness was rated as very good (60%) or good (37.4%). Only 2.5% of the participants had an average effectiveness and none of the subjects had a poor reaction.

In 97.1% of participants, safety was rated as very good (61.5%) or good (35.6%). Only 2.8% of the subjects had an average level of safety indicated and none of the subjects' doctors had any reports of poor safety.

**Table 1: Patient characteristics at baseline.**

|  | N    | Mean±SD       | Median (IQR)      | Range (min-max) |
|--|------|---------------|-------------------|-----------------|
| Age                                      | 1624 | 31.63±7.22    | 30(27,34.75)      | 14 to 80        |
| Weight                                   | 1467 | 57.57±9.42    | 57(51,64)         | 30 to 98        |
| Baseline Hb (g/dl)                       | 1597 | 8±0.95        | 8(7.4,8.7)        | 4 to 11.04      |
| Baseline serum ferritin (µg/l)           | 351  | 41.24±43.6    | 31(8.2,59)        | 0.1 to 238      |
| Baseline RBC Count (mn/mm <sup>3</sup> ) | 371  | 3.86±0.9      | 3.9(3.3,4.2)      | 1.8 to 12.5     |
| Baseline Hematocrit (%)                  | 333  | 31.34±6.11    | 31.3(26.4,35)     | 16.5 to 46      |
| Baseline MCV (fl)                        | 352  | 68.67±11.56   | 68.44(61.93,75)   | 11.3 to 102.1   |
| Baseline MCH (pg)                        | 346  | 24.05±6.24    | 22.6(20,29)       | 2.8 to 38.8     |
| Baseline MCHC (g/dl)                     | 340  | 29.88±3.18    | 30(28.4,32)       | 14 to 43.1      |
| FCM Infusion duration (minutes)          | 1495 | 18.34±5.91    | 15 (15, 20)       | 5 to 60         |
| FCM dose (mg)                            | 1522 | 993.76±344.19 | 1000 (1000, 1000) | 500 to 3000     |

Abbreviations: %- percentage, µg/l-micrograms per liter, FCM-ferric carboxymaltose, 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<sup>3</sup>-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: Change in hematological parameters after ferric carboxymaltose infusion.**

| Parameter                      | N    | At baseline (Mean±SD) | At 4 weeks (Mean±SD) | Mean improvement±SD      |
|--------------------------------|------|-----------------------|----------------------|--------------------------|
| <b>Hemoglobin (g/dl)</b>       | 1557 | 8.01±0.95             | 10.79±1.07           | 2.78±1.04*               |
| <b>Ferritin (µg/l)</b>         | 300  | 40.02±44.6            | 75.28±66.64          | 35.26±52.32*             |
| <b>RBC (mn/mm<sup>3</sup>)</b> | 265  | 4.02±0.91             | 4.63±0.87            | 0.61±1.15*               |
| <b>Hematocrit (%)</b>          | 246  | 32.37±6.12            | 35.19±8.01           | 2.81±6.9*                |
| <b>MCV (fl)</b>                | 300  | 69.7±10.79            | 77.06±16.67          | 7.36±19.54*              |
| <b>MCH (pg)</b>                | 296  | 24.48±6.32            | 28.16±6.4            | 3.68±7.6*                |
| <b>MCHC (g/dl)</b>             | 292  | 29.76±3.21            | 30.93±14.1           | 1.17±13.49 <sup>NS</sup> |

\*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, Hb-Haemoglobin, MCH-mean corpuscular haemoglobin, MCHC-mean corpuscular haemoglobin concentration, MCV-mean corpuscular volume, min-minutes, mn/mm<sup>3</sup>-million per millimetre cube, N-number of participants, pg-picograms, RBC-red blood cell, SD-Standard deviation, Note: 4 weeks is 4±1 week.

**Table 3: Change in RBC indices after ferric carboxymaltose infusion in severe, moderate and mild anemia.**

| Severity of anemia       | Parameter                 | N   | At baseline (Mean±SD) | At 4 weeks (Mean±SD) | Mean improvement±SD      |
|--------------------------|---------------------------|-----|-----------------------|----------------------|--------------------------|
| <b>Severe (n=304)</b>    | RBC (mn/mm <sup>3</sup> ) | 71  | 3.47±0.7              | 4.48±0.72            | 1.01±1*                  |
|                          | Hematocrit (%)            | 64  | 29.71±8.05            | 33.58±11.38          | 3.87±10.39*              |
|                          | MCV (fl)                  | 78  | 72.99±12.95           | 73.8±21.2            | 0.81±24.53 <sup>NS</sup> |
|                          | MCH (pg)                  | 77  | 25.18±6.24            | 29.04±7.29           | 3.86±8.28*               |
|                          | MCHC (g/dl)               | 80  | 29.72±3.8             | 30.54±9.2            | 0.83±8.29 <sup>NS</sup>  |
| <b>Moderate (n=1227)</b> | RBC (mn/mm <sup>3</sup> ) | 192 | 4.22±0.9              | 4.69±0.92            | 0.47±1.18*               |
|                          | Hematocrit (%)            | 180 | 33.32±5               | 35.77±6.4            | 2.45±5.16*               |
|                          | MCV (fl)                  | 221 | 68.57±9.7             | 78.19±14.68          | 9.62±16.95*              |
|                          | MCH (pg)                  | 217 | 24.22±6.34            | 27.79±6.01           | 3.58±7.39*               |
|                          | MCHC (g/dl)               | 210 | 29.76±2.97            | 31.07±15.64          | 1.31±15.07 <sup>NS</sup> |
| <b>Mild (n=26)</b>       | RBC (mn/mm <sup>3</sup> ) | 2   | 3.93±0.1              | 4.13±0.18            | 0.2±0.28 <sup>NS</sup>   |
|                          | Haematocrit (%)           | 2   | 32.25±1.34            | 34.25±2.33           | 2±0.99 <sup>NS</sup>     |
|                          | MCV (fl)                  | 1   | 61.4±0                | 80.6±0               | 19.2±0                   |
|                          | MCH (pg)                  | 2   | 26.15±8.27            | 33.4±9.33            | 7.25±1.06 <sup>NS</sup>  |
|                          | MCHC (g/dl)               | 2   | 31.6±2.55             | 31.65±2.33           | 0.05±4.88 <sup>NS</sup>  |

\*p value<0.001, Statistically significant difference, NS p value>0.05, non-significant difference, Abbreviations: %-percentage, fl-femtoliters, MCH-mean corpuscular hemoglobin, MCHC-mean corpuscular haemoglobin concentration, MCV-mean corpuscular volume, mn/mm<sup>3</sup>-million per millimeter cube, N-number of participants, pg- picograms, RBC- red blood cell, SD-Standard deviation, Note: 4 weeks is 4±1 week.

## DISCUSSION

Anemia is highly prevalent in Indian women, right from adolescence through child-bearing age.<sup>5,22</sup> It is a matter of great concern that the prevalence of anemia in Indian women in reproductive age group has increased from 53% as recorded by the National Family Health Survey 4 (NFHS-4) to 57% in NFHS-5.<sup>2</sup> Women in the reproductive age are more prone to IDA due to increased iron demand caused by menstruation, pregnancy (especially multiple pregnancies) and post-partum hemorrhage, lactation or increased blood loss during menstrual disorders and less commonly gastrointestinal bleeds.<sup>7,13,23</sup> Therefore, to address all causes of iron deficiency anemia in women and adolescent girls≥14 years of age, this subgroup study included anemia due to abnormal uterine bleeding, perioperative anemia, postpartum anemia and anemia during pregnancy. The efficacy and safety of FCM have been convincingly demonstrated in the correction of anemia associated with

menorrhagia, menorrhagia and preoperative menorrhagia.<sup>10,13,24,25</sup> The present sub-group analysis also adds to the growing body of evidence by demonstrating that FCM quickly, effectively and safely corrects anemia in women regardless of the cause. Indian women are also more prone to anemia than their Western counterparts due to some regional peculiarities. They often do not play a role in decisions regarding diet and medical care.<sup>5,26</sup> Other than this, the family food allocation in Indian households largely favours men and women often eat leftover food which has poor nutritional quality and insufficient iron.<sup>5,26,27</sup> Because of such practices, Indian women are not able to build up sufficient iron stores during adolescence and often have mild asymptomatic anemia which goes undetected. Thus, they become prone to moderate to severe anemia when the iron demand increases (e.g. pregnancy, lactation).<sup>5,26</sup> It is also seen that Indian women normalize anemia, especially in pregnancy and thus ignore it until it becomes serious.<sup>5</sup> Women consider fatigue and weakness, a common symptom of anemia, as synonym



with female gender.<sup>5</sup> In this context, a randomized placebo-controlled study in women with iron deficiency, fatigue and normal or borderline low Hb showed that FCM improved erythropoiesis and resulted in significant improvement in fatigue, cognitive function and mental quality-of-life.<sup>30</sup> Moderate to severe anemia in pregnancy and post-partum period is a major concern in India and evidence from India shows that FCM significantly improved anemia and replenished iron stores within a short span in this patient population.<sup>12,16,20</sup> Oral iron is usually used to correct anemia in India. However, oral iron is not tolerated in IDA caused by gastrointestinal bleeds, thus necessitating the need for parenteral preparations. Evidence shows that FCM infusion effectively and safely corrects anemia and replenishes iron stores.<sup>9</sup>

Another major concern in India is that despite national programs to tackle anemia, severe anemia (Hb levels <7 g/dL) continues to be a substantial problem in Indian women.<sup>3-5</sup> This could be because the programs have not penetrated deep at grassroot levels and focus on oral pill supplementation which have poor compliance.<sup>31</sup> Oral iron takes time to replenish iron stores and needs continued adherence to therapy. However, due to various reasons, including gastrointestinal side effects, Indian women show poor adherence to oral iron.<sup>32</sup> In such a situation parenteral iron (FCM) therapy has shown significant improvement in Hb and ferritin compared to oral iron, irrespective of the cause of IDA.<sup>7,14,33,34</sup> It is also seen that the national programs focus on referring patients with Hb levels <7 g/dl to higher centres for parenteral iron therapy. However, given the peculiar scenario of women in India, IDA often remains undetected at mild to moderate stage.<sup>5,31</sup> This sub-analysis also shows that that 98.3% of Indian women in this sub-group study had moderate (78.8%) to severe (19.5%) anemia.

Thus, there is often a clinical need to correct moderate to severe anemia quickly and often it is not logistically possible to send patient to a referral center for treatment. Intravenous FCM fulfils that need with abundant clinical evidence that supports its ability to effectively and safely correct anemia in a short span, by giving large iron doses in a single infusion.<sup>6,10-16,35</sup> This sub-analysis also showed that FCM significantly increased Hb and ferritin in women with moderate to severe anemia. Women have reported satisfaction with FCM treatment but there are no studies reporting the satisfaction of physicians with the FCM response in women with IDA.<sup>14,17,36</sup> This sub-analysis is probably the first to provide physicians' assessment of efficacy and safety of FCM in women with IDA.

The study is limited by its retrospective design, missing data and the inability to control the number and dose of FCM given (few subjects received two FCM 500 mg infusions instead of a single 1000 mg infusion). However, to the best of our knowledge, this is the largest real-world study (N=1666) in Indian women with IDA demonstrating the efficacy and safety of FCM in real life management scenarios. This sub-analysis showed that a single FCM

injection improved anemia and iron stores in all women in the study, irrespective of the cause of IDA. Importantly, no new safety signals or SAEs were identified, thereby showing that FCM is a safe therapy in all sub-sets of Indian women with diverse causes of anemia.

## CONCLUSION

IDA is very common in Indian women. This sub-group analysis of data from 1666 Indian women, who were a part of a large real-world study, reported significant improvement in haematological parameters with favorable tolerability and hence supports the use of intravenous FCM in clinical practice. Therefore, FCM can be the preferred treatment option with favorable tolerability for rectifying moderate-to-severe anemia and replenishing iron stores in women and adolescent girls with anemia due to various obstetric and gynecological conditions. Physicians' clinical impression of efficacy and safety supports usage of FCM in daily clinical practice.

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