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Safety and Efficacy of FCM in the Management of Iron Deficiency Anaemia: A Multi-Centre Cohort-Based Study

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Abstract:
This study investigated the efficacy and safety of ferric carboxymaltose (FCM) in the treatment of iron deficiency anaemia (IDA) in a cohort of 100 patients across four locations in West Bengal, India. The results demonstrated significant improvements in various hematological parameters, including a substantial increase in haemoglobin levels, following FCM administration. The study also highlighted the absence of adverse events, showcasing a favorable safety profile of FCM in this population.
The use of FCM, a third-generation parenteral iron formulation, proved effective in addressing moderate-to-severe IDA, aligning with existing evidence supporting its efficacy and safety. The rapid and substantial improvement in haemoglobin levels observed within four weeks of FCM administration emphasizes its efficiency in iron repletion, particularly in cases where oral preparations may be insufficient. The absence of adverse effects further supports the tolerability of FCM, a crucial factor in its consideration for widespread use.
The study contributes valuable real-world data, especially in the context of the high prevalence of anaemia in India. The findings underscore the potential of FCM as a cornerstone in the treatment of severe anaemia, advocating for its inclusion in targeted interventions and public health initiatives. Overall, this study adds to the growing body of evidence supporting FCM as a promising option in the management of iron deficiency anaemia.

Keywords: Iron Deficiency Anaemia, Ferric Carboxymaltose, Safety, Efficacy

1. Introduction

Anaemia stands as a pervasive global public health concern, impacting around one-third (22.8%) of the global population in the year 2019.[1] The 2019–2020 National Family Health Survey (NFHS-5) data reveals a significant prevalence of anaemia in India, where 57% of women and 25% of men between the ages of 15 and 49 exhibit this health condition.[1] These statistics emphasising the urgency of targeted interventions and public health initiatives to address this critical health issue.[1] Moreover, the persistence of severe anaemia remains a significant challenge, delineated by haemoglobin (Hb) levels falling below 7 g/dL, despite the existence of Indian guidelines and dedicated efforts aimed at eradicating anaemia.[1] This underscores the need for a more targeted approach in addressing severe form of the disease.[1]

Iron deficiency anaemia (IDA) stands out as the predominant cause of anaemia, with iron supplementation being the principal mode of treatment.[2] This supplementation may take the form of either oral or parenteral administration.[1-2] Oral preparations prove insufficient in cases of moderate-to-severe anaemia, where a swift elevation of haemoglobin levels and replenishment of iron stores is imperative.[1-2] Consequently, parenteral iron preparations emerge as the cornerstone of treatment for moderate-to-severe anaemia, offering a more effective and expedited means of addressing the condition.[1-2] However, both oral and parenteral iron preparations have their side effects; thus, newer intravenous (IV) iron formulations with a favourable adverse events profile as compared to traditional parenteral iron products have been developed by Eskag Pharma Pvt Ltd.

Ferric carboxymaltose (FCM), a third-generation parenteral iron formulation designed by Eskag Pharma Pvt Ltd could overcome the limitations of existing parenteral iron preparations. FCM, a novel non-dextran IV iron agent, had a very low immunogenic potential and thus predisposed no anaphylactic reactions to any of the participants. Its properties permitted the administration of large dosages (1000 mg/infusion) in a single session (15-minute infusion) without the necessity of a test dose.

2. Materials and methods

2.1. Study design

This was a multicentre, cohort-based, observational, data collection study involving four Eskag Sanjeevani hospitals of West Bengal, India. A cohort of 100 human subjects was enrolled from four distinct centres: Basirhat (location 1), Behala (location 2), ID & BG (location 3), and Howrah (location 4). In the course of the ten-month study, commencing in June 2022 and concluding in March 2023, all participants received intravenous ferric carboxymaltose (FCM) in a diluted form (100 ml normal saline). At the commencement of the study, patient-specific information, encompassing their identities, haemoglobin levels, and batch numbers, were meticulously documented.

2.2. Patient details

Patients details along with their haemoglobin levels were recorded before administration of FCM. Other vitals, encompassing oxygen saturation, blood pressure, body temperature, pulse rate, vision, taste, anaphylactic shock, respiratory problems, and restlessness were documented as well. these are mentioned below:

SL. NO.	DATE	TIME	PROCESS OF DOSAGE	AMOUNT OF FCM	PATIENT'S NAME	Hb.
1	06-04-2022	06:15:00 PM	DIALUTED IN 100 ml Ns	2 ml	KALIPADA SARKAR	9.7
2	06-04-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	GOPAL SARDAR	9.2
3	06-04-2022	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	TILAK KR SARKAR	9.1
4	07-04-2022	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	HASANUR JAMAL MOLLA	8
5	09-04-2022	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	BIDYUT DEY	7.5

6	09-04-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	ARIF BILLA	9.5
7	09-04-2022	10:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	MARJINA BIBI	8.3
8	09-04-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SANTOSH MONDAL	8.4
9	10-04-2022	09:45:00 AM	DIALUTED IN 100 ml Ns	2 ml	HABBIBUL ISLAM SK	8.7
10	10-04-2022	09:45:00 AM	DIALUTED IN 100 ml Ns	2 ml	AKBAR MONDAL	7.9
11	11-04-2022	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	TUSA MONDAL	7
12	11-04-2022	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	GIYAS MONDAL	7.4
13	12-04-2022	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SWAPNA DAS	7.8
14	12-04-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	NAMITA KUNDU	8.4
15	12-04-2022	06:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	HASNA BANU	7.9
16	14-04-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SAHIDA BIBI	8
17	14-04-2022	06:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	BAPI MISTTRI	8.6
18	14-04-2022	12:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	SANTANU DAS	7.8
19	15-04-2022	02:30:00 PM	DIALUTED IN 100 ml Ns	2 ml	PRITIKA DAS	8.5
20	16-04-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	ABID HOSSIAN	7
21	20-04-2022	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SAIFULLA MONDAL	8.9
22	21-04-2022	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	AKBAR ALI MONDAL	9.9
23	22-04-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	BISWANATH BISWAS	8.5
24	19-05-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	GOPAL BISWAS	9
25	21-05-2022	12:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	ARAFAT DAFADAR	7.5

Table 1: Patient details of Location 1 (Basirhat, West Bengal)

SL. NO.	DATE	TIME	PROCESS OF DOSAGE	AMOUNT OF FCM	PATIENT'S NAME	Hb.
1	04-06-2022	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	SK SAMIM AKTAR	7
2	07-06-2022	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	REHANA BIBI	7.5
3	07-06-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SAMBHUNATH DHARA	8.5
4	08-06-2022	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	BASUDEB TUNG	7.4
5	08-06-2022	09:45:00 AM	DIALUTED IN 100 ml Ns	2 ml	JHARNA DAS	8.7
6	08-06-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	JYOTSNA DUTTA	8
7	08-06-2022	06:15:00 PM	DIALUTED IN 100 ml Ns	2 ml	RAJA DHANUK	9.7
8	08-06-2022	02:30:00 PM	DIALUTED IN 100 ml Ns	2 ml	RAJIA BIBI	8.5
9	13-06-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	BASANA MONDAL	9.5
10	13-06-2022	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	LALAN ROY	7.8
11	14-06-2022	06:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	ALPANA DAS	8.6
12	14-06-2022	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	BINOD MONDAL	9.9
13	15-06-2022	12:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	DEB KUMAR TIWARI	7.5
14	21-06-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SOMA DUTTA	9
15	22-06-2022	10:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SOUMEN PAUL	8.3
16	25-06-2022	12:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	DILIP CHOWDHURY	7.8
17	08-07-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	GITA RANI JANA	9.2
18	27-07-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	ASFAR ALI MOLLA	8.4
19	21-08-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	ASUTOSH THAKUR	7
20	22-08-2022	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	TASIR ALI KHAN	9.1

21	04-09-2022	09:45:00 AM	DIALUTED IN 100 ml Ns	2 ml	SUSANTA MUKHERJEE	7.9
22	09-09-2022	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	DIPAK KUMAR DAS	8.4
23	14-09-2022	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	ARUP DOLUI	8.9
24	27-09-2022	06:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	YEASMINA BIBI	7.9
25	16-10-2022	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	FULJAN BIBI	8

Table 2: Patient details of Location 2 (Behala, West Bengal)

SL. NO.	DATE	TIME	PROCESS OF DOSAGE	AMOUNT OF FCM	PATIENT'S NAME	Hb.
1	01-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	BHOLA MAHATO	9.5
2	02-02-2023	09:45:00 AM	DIALUTED IN 100 ml Ns	2 ml	RUPESH KR. ROY	8.7
3	02-02-2023	12:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	RAJA BASU	7.8
4	03-02-2023	12:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	SHIB SANKAR MALAKAR	7.5
5	04-02-2023	06:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	SANDHYA MONDAL	8.6
6	05-02-2023	06:15:00 PM	DIALUTED IN 100 ml Ns	2 ml	MILAN BISWAS	9.7
7	05-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	NITISH KR. MONDAL	8.5
8	08-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	MITHU PODDER	8.5
9	09-02-2023	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SEKHAR MAJHI	7.8
10	09-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	BECHAN SAHA	8.4
11	10-02-2023	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	HARAPRASAD MALIK	9.9
12	10-02-2023	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	ABEDA BIBI	9.1
13	12-02-2023	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	SMRITI DHALI	8
14	12-02-2023	02:30:00 PM	DIALUTED IN 100 ml Ns	2 ml	BHARAT TURI	8.5

15	12-02-2023	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	ASHIM KR. GHOSH	8.9
16	14-02-2023	10:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SUMAN SARKAR	8.3
17	15-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SKBARI KHATOON	9.2
18	18-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SEKHAR MAJHI	9.2
19	20-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SUBRATA ROY	8.4
20	22-02-2023	09:45:00 AM	DIALUTED IN 100 ml Ns	2 ml	LALU GHOSH	7.9
21	24-02-2023	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	CHAMPA DAS	7.4
22	01-03-2023	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	NIDHI KUMARI	8.1
23	10-03-2023	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	SOMNATH GHOSH	7.5
24	15-03-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SADHAN MANDI	8
25	25-03-2023	06:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	SABANA BEGUM	7.9

Table 3: Patient details of Location 3 (ID & BG, West Bengal)

SL. NO.	DATE	TIME	PROCESS OF DOSAGE	AMOUNT OF FCM	PATIENT'S NAME	Hb.
6	16-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	ASTO MONDAL	7.5
1	17-02-2023	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	JAYDUL SAHA	8.5
12	17-02-2023	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	GOPAL GUPTA	9
9	18-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	MADAN PRASAD SHAH	8.9
7	18-02-2023	06:15:00 PM	DIALUTED IN 100 ml Ns	2 ml	PROTIMA KOLEY	9.9
17	20-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	MITHU RAY	7
20	21-02-2023	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	TARUN DAS	8.5

14	22-02-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	DANESWAR BAG	7.8
5	27-02-2023	09:45:00 AM	DIALUTED IN 100 ml Ns	2 ml	HABEE ORANG	8
23	27-02-2023	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	AMAL ADHIKARY	8.6
3	01-03-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SOMNATH CHATTERJEE	7.9
11	02-03-2023	06:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	SUPARNA GHOSH	7.8
8	02-03-2023	02:30:00 PM	DIALUTED IN 100 ml Ns	2 ml	ALOKA DAS	8.4
18	03-03-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	DEBNATH DHARA	7.4
22	04-03-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	TANMAY BARMAN	7
15	06-03-2023	10:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	ALPANA PRAMANIK	7.9
25	08-03-2023	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	KUSUM DEVI	8.7
21	12-03-2023	09:45:00 AM	DIALUTED IN 100 ml Ns	2 ml	SOMA DOLUI	8.4
24	13-03-2023	06:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	PARTHA KOLEY	9.5
10	13-03-2023	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	BABLU ORANG	8.3
16	15-03-2023	12:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	DILIP DAS	7.5
2	17-03-2023	10:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	RATAN DAS	8
13	19-03-2023	12:00:00 AM	DIALUTED IN 100 ml Ns	2 ml	KRISHNA MURARI BARMAN	9.1
4	20-03-2023	06:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	DIPU DEY	9.2
19	22-03-2023	02:00:00 PM	DIALUTED IN 100 ml Ns	2 ml	SUJIT KR TALUKDAR	9.7

Table 4: Patient details of Location 4 (Howrah, West Bengal)

2.3. Treatment characteristics

The cumulative FCM dosage for iron repletion was calculated considering both the patient's body weight and haemoglobin level. As an integral component of the standard care protocol, FCM 500/1K (manufactured by Eskag Pharma Pvt. Ltd., Kolkata, India) was administered intravenously, with each infusion not surpassing 1000 mg of iron.

Body Weight	Cumulative FCM Dose Hb <10 g/dL	Cumulative FCM Dose Hb 10–14 g/dL
<35 kg	500 mg	500 mg
35 kg to <70 kg	1500 mg	1000 mg
≥70 kg	2000 mg	1500 mg

Table 5: Cumulative FCM Dosage for Iron Repletion

2.4. Outcome Measures and Statistical Analysis

Patient data were sourced from their medical records. These records were then anonymized and meticulously documented by trained technicians using designated case record forms (CRF) tailored for the study. Additionally, the clinical opinions of physicians regarding the efficacy and safety of ferric carboxymaltose (FCM) were also recorded in the CRF. The evaluation of efficacy was conducted through a clinical assessment, considering both symptomatic and hematological improvements as documented in the medical records.[3] Safety assessments were based on the scrutiny of adverse events and side effects associated with FCM, all of which were documented in the patients' medical records.

3. Results

3.1. Efficacy outcomes

In the study population, noticeable improvements in various haematological parameters were observed after 4 weeks, demonstrating statistical significance ($P < 0.001$ for all). Specifically, haemoglobin (Hb) levels exhibited a substantial increase of 3.292 g/dL, while serum ferritin levels rose by 36.65 µg/L. Additionally, there were significant enhancements in red blood cell (RBC) count, hematocrit, mean corpuscular volume (MCV), and mean corpuscular haemoglobin (MCH). Although a positive trend was noted, the increase in mean corpuscular haemoglobin concentration (MCHC) at 4 weeks compared to baseline did not reach statistical significance ($P = 0.103$). These findings underscore the effectiveness of the intervention in fostering improvements across a spectrum of haematological indicators, with particular emphasis on Hb levels, RBC characteristics, and iron stores.

Parameter	At Baseline (Mean ± SD)	At 4 Weeks (Mean ± SD)	Mean Improvement ± SD
Haemoglobin (g/dL)	**8.34**	11.632	2.327796
Ferritin (µg/L)	40.20	76.85	36.65
RBC (mn/mm³)	4	4.80	0.80
Haematocrit (%)	30.20	35.50	5.30
MCV (fL)	69	77.2	8.2
MCH (pg)	26	29	3
MCHC (g/dL)	28.5	35.8	7.3

Table 6: Comparing Haematological Parameters Before and After Administration of FCM

3.2. Safety

The commonly documented adverse effects associated with ferric carboxymaltose (FCM) administration, such as nausea, headache, constipation, diarrhea, and allergic reactions, were notably absent in the present study.[4] Strikingly, no adverse events, especially anaphylactic shock, were reported among the patients following FCM administration, resulting in a remarkable low rate of adverse events in the study, with 0% anaphylactic shock experienced by the patients (In the following images, value 1 depicts no adverse events). Previous studies have reported a high rate of anaphylaxis reaction after FCM injection.[5] The present study proves potentiality and safety of Eskag sponsored FCM injection in this regard, with 0% rate of anaphylactic shock in the patients. This observation holds significance, particularly in the context of the study being sponsored by Eskag Pharma and involving the use of FCM injection. The absence of adverse effects underscores the potential safety profile and tolerability of FCM in the studied population.

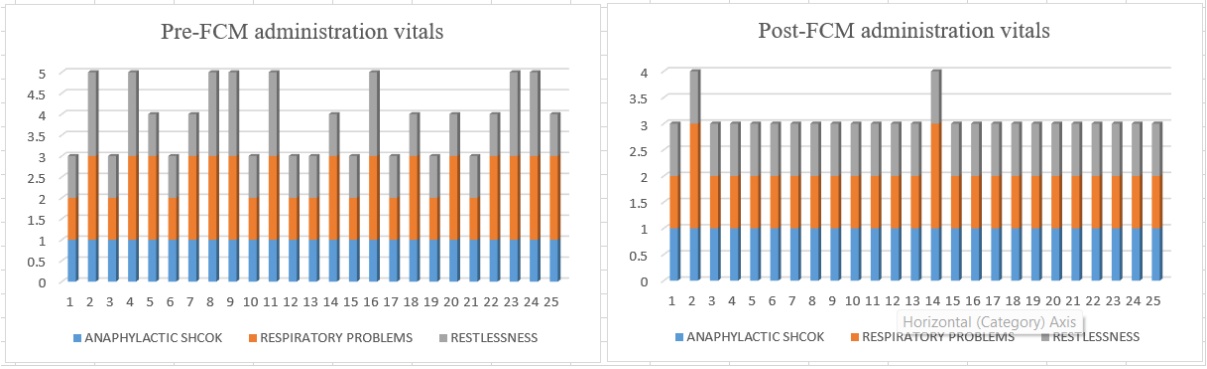

Table 7: Pre-and-post FCM administration vitals of patients in Location 1 (Basirhat, West Bengal)

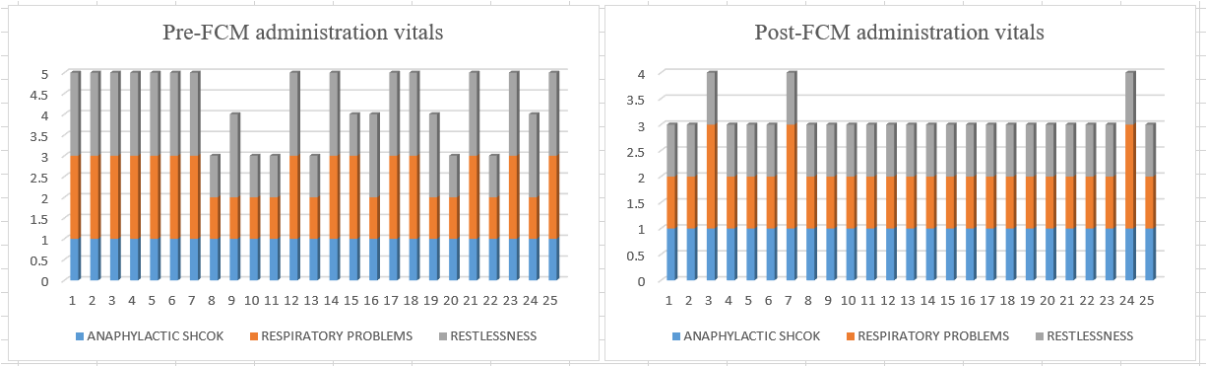

Table 8: Pre-and-post FCM administration vitals of patients in Location 2 (Behala, West Bengal)

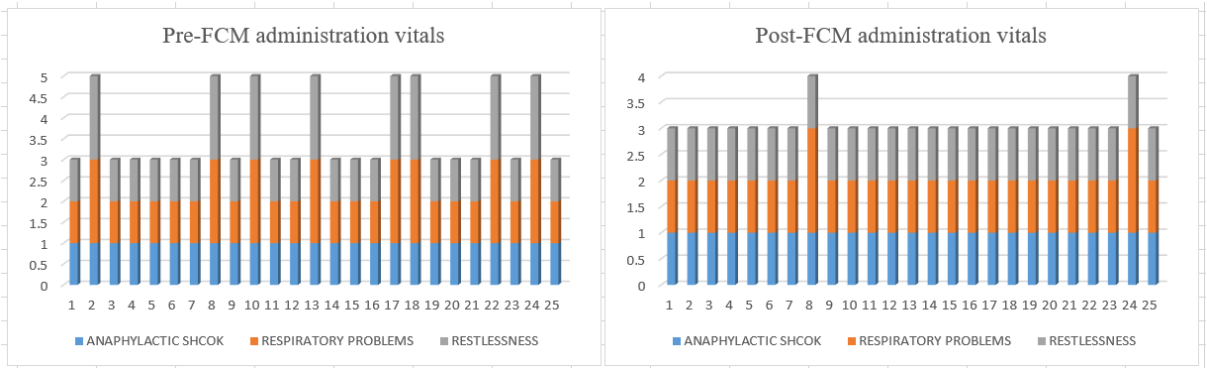

Table 9: Pre-and-post FCM administration vitals of patients in Location 3 (ID & BG, West Bengal)

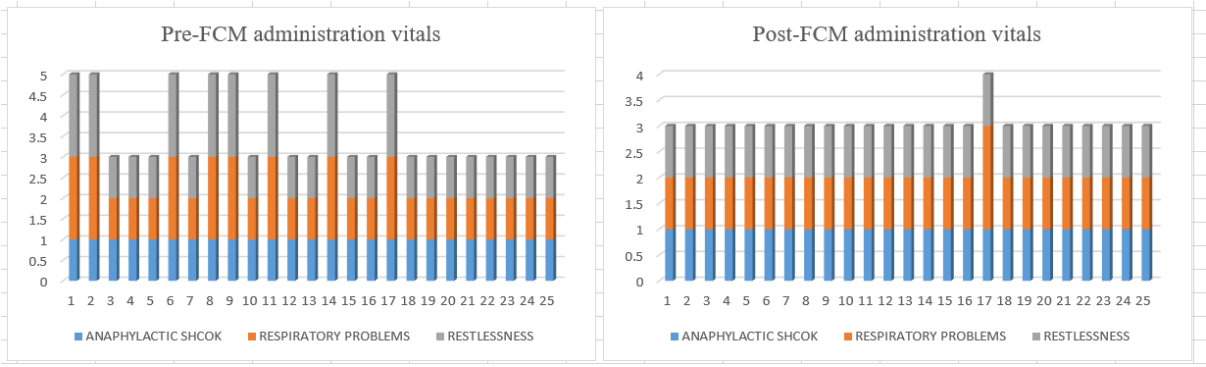

Table 10: Pre-and-post FCM administration vitals of patients in Location 4 (Howrah, West Bengal)

4. Discussion

Expert consensus regarding the use of ferric carboxymaltose (FCM) in treating iron deficiency anaemia (IDA) underscores compelling evidence supporting both its efficacy and safety across various acute and chronic conditions. A comprehensive systematic review and network meta-analysis of 21 randomised controlled trials demonstrated significant improvements in serum ferritin levels (µg/L) with FCM compared to oral iron (Δ 172.8; 95% confidence interval [CI] 66.7–234.4). Furthermore, haemoglobin (Hb) levels (g/dL) showed significant improvement with FCM compared to intravenous ferric gluconate (Δ 0.6; 95% CI 0.2–0.9), oral iron (Δ 0.8; 95% CI 0.6–0.9), and placebo (Δ 2.1; 95% CI 1.2–3.0). Notably, FCM demonstrated a lower incidence of side effects compared to other parenteral therapies.

Despite a scarcity of real-world studies on FCM, particularly from India, existing evidence suggests that haematological parameters in patients with moderate-to-severe IDA exhibit improvement within 6 to 12 weeks following intravenous (IV) iron supplementation. Oral iron supplementation, however, requires a more extended period for normalization. In contrast, Hb levels may significantly improve within two to four weeks of IV FCM supplementation, as evident in our study where Hb improvement was significant at week 4 across the entire study population, regardless of IDA severity.

A positive response to iron therapy, manifested by improved haematological parameters, serves as a reliable indicator of IDA. While Hb and ferritin are commonly used measures, their assessment can be influenced by various factors. Thus, evaluating a comprehensive array of haematological parameters provides a more thorough assessment of therapy response. In patients with hemodynamically stable IDA, FCM enables the rapid administration of high iron doses with low immunogenicity. Importantly, the observed improvements in Hb and ferritin levels are sustained for up to six months following a single IV infusion, aligning with the findings in our study, which demonstrated significant improvements in Hb, serum ferritin, RBC count, haematocrit, and MCH in subjects with severe IDA ($P < 0.001$ for all).

5. Conclusion

In conclusion, this study investigated the efficacy and safety of ferric carboxymaltose (FCM) in the treatment of iron deficiency anaemia (IDA) in a cohort of 100 patients across four locations in West Bengal, India. The results demonstrated significant improvements in various hematological parameters, including a substantial increase in haemoglobin levels, following FCM administration. The study also highlighted the absence of adverse events, showcasing a favorable safety profile of FCM in this population.

The use of FCM, a third-generation parenteral iron formulation, proved effective in addressing moderate-to-severe IDA, aligning with existing evidence supporting its efficacy and safety. The rapid and substantial improvement in haemoglobin levels observed within four weeks of FCM administration emphasizes its efficiency in iron repletion, particularly in cases where oral preparations may be insufficient. The absence of adverse effects further supports the tolerability of FCM, a crucial factor in its consideration for widespread use.

The study contributes valuable real-world data, especially in the context of the high prevalence of anaemia in India. The findings underscore the potential of FCM as a cornerstone in the treatment of severe anaemia, advocating for its inclusion in targeted interventions and public health initiatives. Overall, this study adds to the growing body of evidence supporting FCM as a promising option in the management of iron deficiency anaemia.

References

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