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Safety and Effectiveness of Intravenous Ferric Carboxymaltose for Moderate Anaemia in Pregnancy

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Abstract— Background: Anaemia in pregnancy is a major global health concern linked to adverse maternal and foetal outcomes. Intravenous ferric carboxymaltose (FCM) is a relatively new therapy that enables rapid correction of iron deficiency with minimal adverse effects. **Aim:** To evaluate the safety and effectiveness of intravenous FCM in pregnant women with moderate anaemia during the second and third trimesters.

Methods: This prospective observational study was conducted at the Department of Obstetrics and Gynaecology of the Government Medical College in Srinagar, India, over 18 months. One hundred pregnant women with moderate anaemia (Hb 7–9.9 g/dL) received a single intravenous infusion of FCM (maximum 1000 mg). Haemoglobin and serum ferritin levels were measured before and four weeks after infusion. Adverse events and foetal outcomes were monitored.

Results: Mean baseline haemoglobin was 7.81 ± 0.43 g/dL, which increased to 9.47 ± 0.48 g/dL ($p < 0.001$). Mean serum ferritin rose from 16.70 ± 6.97 ng/mL to 122.20 ± 15.98 ng/mL ($p < 0.001$). Only 2% of participants experienced minor allergic reactions; no serious maternal or foetal adverse events occurred.

Conclusion: FCM is a safe and effective option for treating moderate anaemia in pregnancy, offering rapid correction with minimal side effects.

Index Terms— Ferric Carboxymaltose; Hemoglobin; Intravenous Iron; Iron Deficiency;

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Pregnancy Anemia; and Serum Ferritin.

I. INTRODUCTION

Anaemia in pregnancy remains a major public health issue worldwide, with considerable consequences for both mothers and newborns. According to the World Health Organization (WHO), anaemia during pregnancy is diagnosed when haemoglobin is below 11 g/dL in the first and third trimesters, and below 10.5 g/dL in the second trimester [1].

Anaemia may be categorised using several criteria, including its severity, red blood cell (RBC) morphology, and underlying cause. Both WHO and the Indian Council of Medical Research (ICMR) categorise the severity of anaemia in pregnancy as mild when haemoglobin is 10–10.9 g/dL, moderate when it ranges from 7–9.9 g/dL, and severe when it falls below 7 g/dL [1,2]. Classification by RBC morphology includes microcytic anaemia (small-sized RBCs, typically seen in iron deficiency), normocytic anaemia (normal-sized RBCs, as observed in haemolytic or aplastic anaemia), and macrocytic anaemia (large RBCs, often associated with vitamin B12 or folate deficiency). From an etiological perspective, anaemia may result from nutritional deficiencies (iron, folate, vitamin B12), hereditary disorders (such as thalassemia or sickle cell disease), chronic illnesses, or pregnancy-related complications.

The prevalence of anaemia in pregnancy shows marked regional variation, with developing nations carrying the greatest burden. According to WHO, approximately 38.2% of pregnant women are affected globally, with the highest prevalence reported in South Asia (52.5%) and sub-Saharan Africa (46.3%) [3]. In South Asia, Bangladesh continues to face a high burden, with approximately 38.6% of pregnant women affected [4], while India reports a prevalence of 52.2% according to the National Family Health Survey-5 (NFHS-5) [5]. Similarly, Nepal (41%) and Pakistan (51%) continue to face high maternal anaemia rates [6].

Recent pooled analyses and surveys (2020–2025) indicate that prevalence among pregnant women in sub-Saharan Africa is typically 45–55% (moderate to severe public health significance per WHO clas-

sification: $\geq 40\%$ is severe). West and Central Africa often have the highest burdens (~50–60% in some sub-regions), while Eastern and Southern Africa show lower rates in recent data [7]. Even in relatively better-resourced countries such as South Africa, about one-third (33%) of pregnant women are anaemic [8]. In the Eastern Mediterranean region, prevalence remains high (~35–44%), with countries such as Yemen and Somalia often exceeding 45–60% in vulnerable groups [9]. By contrast, lower prevalence is observed in Europe (25.1%) and the Americas (24.9%), although vulnerable groups within these regions remain disproportionately affected [3].

Multiple factors contribute to this high prevalence, including inadequate maternal nutrition, infectious diseases, limited access to quality antenatal services, and socioeconomic inequities [10]. Tackling this issue requires a multidimensional strategy involving nutritional improvement, food fortification, supplementation programs, and stronger healthcare systems [11].

In India, maternal anaemia remains a critical health concern, with NFHS-5 reporting a prevalence of 52.2% among pregnant women [5]. To address this, several initiatives have been launched. The National Iron Plus Initiative (NIPI), introduced in 2013 by the Ministry of Health and Family Welfare, focuses on anaemia prevention and control across all age groups, including pregnant women. The program provides iron and folic acid (IFA) supplementation, offers dietary counselling, and emphasises early detection and timely treatment through routine screening [12,13]. Further, the Anaemia Mukt Bharat (Anaemia-Free India) campaign, launched in 2018, aims to reduce the prevalence of anaemia by 3 percentage points annually. Its comprehensive approach targets both nutritional and non-nutritional causes through measures such as IFA supplementation, deworming, and community-based behaviour change interventions [14,15]. This study aims to examine the safety and effectiveness of intravenous ferric carboxymaltose (FCM) in pregnant women with moderate anaemia in the second and third trimesters.

II. MATERIALS AND METHODS

Study Design and Setting

This was a prospective, observational, single-arm cohort study with a before-and-after design, conducted in the Postgraduate Department of Obstetrics and Gynaecology at the Government Medical

College in Srinagar, India, over a period of 18 months. The study commenced with the ethical clearance of the Institutional Ethics Committee (IRB No. GMC/2022).

Study Population

The study included pregnant women aged 18 years or above who provided informed consent for the future use of their medical records for research purposes. Patients were enrolled after fulfilling the selection criteria and consenting to participate in the study.

Inclusion Criteria

A total of 100 pregnant women with moderate anaemia in the second and third trimesters were enrolled. The sample size was determined based on patient availability and feasibility during the 18-month study period, rather than a priori power calculation, as this was a prospective observational study.

Exclusion Criteria

Women who refused treatment or did not provide consent, those with haemoglobin levels less than 7 g/dL or greater than 9.9 g/dL, women in the first trimester of pregnancy, patients with significant medical or surgical complications, and cases lost to follow-up were excluded from the study.

Outcome Variables

The primary outcome assessed was the change in haemoglobin (Hb) concentration following administration of ferric carboxymaltose (FCM), expressed in grams per decilitre (g/dL). In accordance with WHO criteria, moderate anaemia was defined as haemoglobin levels ranging between 7 and 9.9 g/dL.

The secondary outcome was the change in serum ferritin concentration post-FCM administration. Serum ferritin, measured in nanograms per millilitre (ng/mL), was evaluated as a marker of the body's iron reserves.

Participant Selection

All anaemic pregnant women admitted to the Obstetrics and Gynaecology ward were categorised according to the WHO severity criteria: mild, moderate, or severe anaemia. For the present study, only women with moderate anaemia—defined as haemoglobin levels between 7 and 9.9 g/dL—were enrolled. A total of 100 participants meeting these criteria were included.

Intervention

The maximum weekly dose of 1000 mg FCM was

administered as a single intravenous infusion over 15-20 minutes in 200 mL normal saline.

Study Procedure

Pregnant women admitted to the Obstetrics and Gynaecology Department were screened for anaemia upon admission. Those diagnosed with moderate anaemia (haemoglobin 7–9.9 g/dL) who were in the second or third trimester and met the eligibility criteria were consecutively enrolled after obtaining written informed consent. A pre-infusion assessment was conducted, including vital signs, a brief medical and obstetric history, and physical examination, to confirm eligibility and exclude contraindications for FCM administration. Baseline blood samples were collected, labelled with unique identifiers, and analysed in the hospital laboratory. Haemoglobin concentration was measured using the ASPEN PE-6000 analyser, while serum ferritin was assessed using standard laboratory methods.

Subsequently, participants received a maximum weekly dose of 1000 mg FCM, administered as a single intravenous infusion over 15–20 minutes. The drug was diluted in 200 mL normal saline and infused under the supervision of qualified healthcare staff. Participants were closely monitored during infusion and observed for one-hour post-infusion for any adverse or hypersensitivity reactions. Vital signs were checked regularly, and any adverse events were documented. Participants were discharged once stable, with instructions for follow-up. A follow-up visit was scheduled four weeks after infusion, during which post-infusion blood samples were collected using the same protocol as baseline sampling. Haemoglobin and serum ferritin levels were re-evaluated, and any interim adverse events were recorded.

Statistical Analysis

Data were collected using a pre-structured pro forma and entered into Microsoft Excel before being exported to the Statistical Package for the Social Sciences (SPSS, Version 23) for analysis. Categorical variables were summarised as frequencies and percentages, while continuous variables were expressed as mean ± standard deviation or as median with interquartile range (IQR), depending on distribution. Associations between categorical variables were assessed using the chi-square test, and comparisons of continuous variables at baseline and follow-up were performed using the paired t-

test. A p-value of <0.05 was considered statistically significant.

III. RESULTS

All enrolled participants received intravenous ferrous carboxymaltose (FCM) as part of the study protocol, and haematological outcomes were assessed before and four weeks after treatment. The participants’ mean age was 26.44 years, with a standard deviation of 2.31 years, and an age range extending from 22 to 30 years. The mean weight of the study population was 68.94 ± 9.49 kg, with weights ranging from 51 kg to 94 kg. The mean gestational age of the study cohort was 28.71 ± 4.45 weeks (range: 20–36 weeks). Gestational age distribution showed that 35% (n=35) of participants were between 30 and 35 weeks, 34% (n=34) were between 25 and 30 weeks, and the remaining 31% (n=31) were between 20 and 25 weeks of gestation.

The mean haemoglobin (Hb) level of the study participants at recruitment (baseline) was 7.81 ± 0.43 g/dL, with a range of 7.1 to 8.9 g/dL, as detailed in Figure 1.

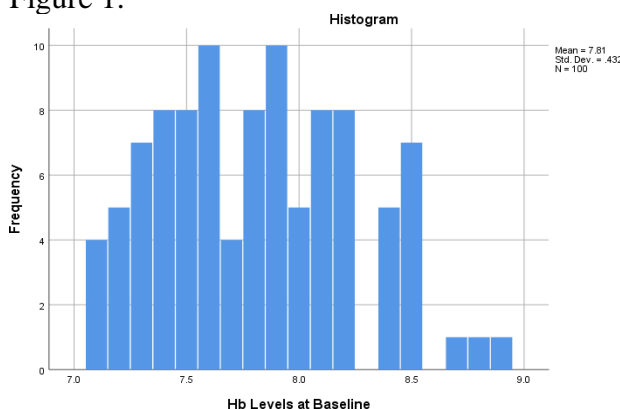


Figure 1. Histogram showing distribution of Hb levels at baseline in study population

Following the intervention with FCM, the recorded mean Hb level was 9.47 ± 0.48 g/dL, with a range of 8.4 to 10.5 g/dL, as detailed in Figure 2.

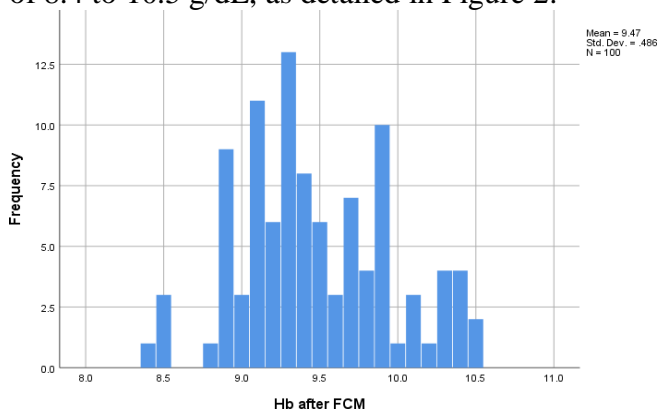


Figure 2. Histogram showing distribution of Hb levels after FCM intervention in study population

The mean ferritin level of the pregnant cohort in this study was 16.70 ± 6.97 ng/ml at baseline, with a range from 4.0 to 42.1 ng/mL, as detailed in Figure 3.

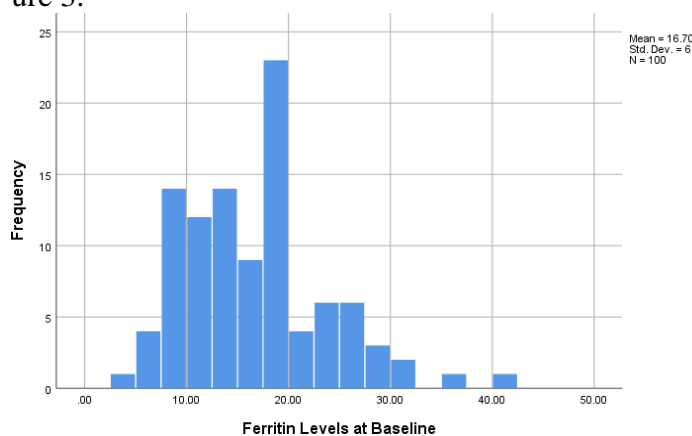


Figure 3. Histogram showing distribution of ferritin levels at baseline in study population

After the intervention with FCM, the recorded mean ferritin level was 122.20 ± 15.98 ng/mL, with a range of 86.7 to 167.1 ng/mL, as detailed in Figure 4.

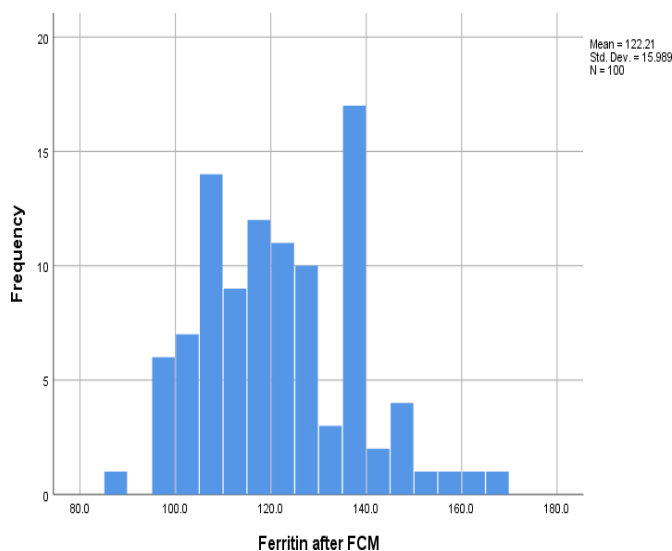


Figure 4. Histogram showing distribution of ferritin levels after intervention of FCM in study population

During the study, it was observed that only 2.0% of the patients experienced minor allergic reactions (rash and itching) after FCM transfusion. However, post-intervention with FCM, the foetal heart was normally auscultated in all the pregnant women, indicating the drug's safety.

A history of anaemia was recorded in 43.0% of the study's cohort. A paired t-test was conducted to analyse the statistical difference in Hb levels before and after the intervention, with results indicating a

statistically significant increase in Hb levels, with a mean difference of 1.72 g/dL and a 95% confidence interval of 1.67 to 1.77 ($p < 0.001$).

Similarly, the change in ferritin levels before and after FCM intervention also demonstrated a statistically significant increase, with a mean difference of 105.50 ng/ml and a 95% confidence interval of 102.58 to 108.52 ($p < 0.001$).

Prior to the FCM intervention, the participants' mean corpuscular volume (MCV) was 71.70 ± 2.30 fL, with a range of 62.29 to 76.38 fL. After the intervention, the mean MCV increased to 85.37 ± 3.05 fL, with a range of 80.21 to 92.65 fL. A paired t-test demonstrated a statistically significant increase in MCV following FCM administration, with a mean difference of 13.67 fL (95% CI: 13.05–14.30; $p < 0.001$).

IV. DISCUSSION

The present study demonstrates that intravenous ferric carboxymaltose (FCM) is a safe and highly effective therapy for the treatment of moderate anaemia during the second and third trimesters of pregnancy. A single infusion of FCM resulted in a statistically and clinically significant rise in haemoglobin levels, accompanied by a marked improvement in iron stores as reflected by increased serum ferritin concentrations. These haematological benefits were achieved with minimal adverse effects and without any detectable compromise in foetal well-being, underscoring the favourable efficacy–safety profile of FCM in this population.

At baseline, the mean haemoglobin concentration was 7.81 ± 0.43 g/dL, consistent with the WHO definition of moderate anaemia in pregnancy (7.0–9.9 g/dL) [16]. The relatively narrow range (7.1–8.9 g/dL) reflects a homogeneous study population in terms of anaemia severity. Mean baseline ferritin was 16.70 ± 6.97 ng/ml, indicating depleted iron reserves. Following FCM administration, haemoglobin rose to 9.47 ± 0.48 g/dL, and ferritin increased to 122.20 ± 15.98 ng/ml, demonstrating marked improvement. These findings are comparable to or exceed results from previous studies. For example, Breyman et al. [17] reported haemoglobin improvement from 9.6 to 11.0 g/dL and ferritin from 39.9 to 568.7 $\mu\text{g/L}$ within three weeks of treatment. Similar efficacy of FCM has been confirmed in other studies [18,19].

The safety profile of FCM was favourable, with only 2% of participants experiencing minor allergic reactions. No serious adverse events were reported,

and foetal heart monitoring remained normal post-infusion [20]. These findings are in line with prior research, though our incidence of adverse events was lower than the 11% reported by Breyman et al. [17], possibly due to differences in study populations or reporting criteria. The results reinforce FCM as a safe therapeutic option during pregnancy.

A notable observation was the high prevalence of prior anaemia (43%) among participants, reflecting the chronic burden of iron deficiency in women of reproductive age. Although lower than the 65% prevalence reported by Beckert et al. [21], this emphasises the need for preconception screening and early antenatal detection to enable timely interventions [22].

In addition, mean corpuscular volume (MCV) improved significantly after treatment, with a post-intervention mean of 85.37 ± 3.05 fL (range: 80.21–92.65 fL). This consistent rise in MCV indicates effective replenishment of iron stores, aligning with the findings of Froessler et al. [23]. The narrow distribution further supports the uniform response to FCM across the study cohort.

Overall, the study provides strong evidence that FCM is both effective and well-tolerated in treating moderate anaemia during pregnancy. The significant rise in haemoglobin and ferritin, coupled with a low incidence of adverse reactions, supports its role as a reliable option for rapid correction of iron deficiency anaemia. The inclusion of participants from diverse demographic and clinical backgrounds strengthens the external validity and applicability of these findings. Given the safety and rapid efficacy of FCM demonstrated in this study, incorporation into national anaemia management programs such as NIPI and Anaemia Mukht Bharat could be considered, particularly for women with moderate anaemia unresponsive to oral iron. Future research could investigate whether moderate anaemia at delivery or its rapid correction with FCM affects caesarean delivery rates, controlling for maternal age, parity, and comorbid conditions.

V. STUDY LIMITATIONS

The present study has certain limitations that should be acknowledged. The sample size of 100 participants was modest and based on patient availability during the study period; therefore, a formal sample size or power calculation was not performed. As this was a prospective observational study, adjustment for potential confounding factors

such as dietary iron intake, nutritional status, and minor comorbidities was not feasible. However, women with significant medical or surgical comorbidities were excluded to minimise confounding. The follow-up duration was limited to four weeks and focused primarily on short-term haematological outcomes, namely changes in haemoglobin and serum ferritin levels. Consequently, long-term maternal and foetal outcomes, including perinatal morbidity and sustained haematological response, could not be assessed. Future studies with larger sample sizes, longer follow-up periods, and adjustment for dietary and clinical confounders are required to evaluate the long-term efficacy and pregnancy-related outcomes associated with FCM therapy.

VI. CONCLUSION

Ferric carboxymaltose (FCM) is effective and safe for managing moderate anaemia during the second and third trimesters of pregnancy. A single FCM infusion led to significant improvements in haemoglobin and ferritin levels, highlighting its role as a rapid and effective treatment for iron deficiency anaemia in this population. The low incidence of adverse events further supports its favourable safety profile. Inclusion of a diverse cohort, including participants from rural areas and those with comorbidities, enhances the applicability of the findings to routine clinical practice. The relatively high rate of caesarean deliveries observed warrants further investigation to explore potential links between anaemia, its treatment, and obstetric outcomes. Overall, these results provide strong evidence that FCM is a reliable therapeutic option for improving maternal haematological status and may contribute to better pregnancy outcomes.

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