

## Comparative Study of Effectiveness and Safety of Ferric Carboxymaltose with Iron Sucrose Injections in Postpartum Iron Deficiency Anemia in Women Delivered by Caesarean Section

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### Abstract

**Introduction:** Anemia, a major global health issue, affects over 50% of pregnant women in India, with higher rates in postpartum cases, especially after cesarean deliveries. Iron deficiency is the leading cause, often worsened by blood loss and poor oral iron compliance. Intravenous treatments like iron sucrose and ferric carboxymaltose offer faster recovery and better outcomes. This study compares their safety and efficacy in managing postpartum anemia after cesarean section.

**Aims:** To assess the effectiveness and safety of iv iron substitute like ferric carboxy maltose with iron sucrose in women following primary caesarean section in postpartum iron deficiency anemia.

**Materials and Methods:** This prospective comparative observational study was conducted over 18 months in the postnatal wards of Chittaranjan Seva Sadan College of Obstetrics, Gynecology and Child Health. Data collection spanned 12 months, with planning, analysis, and writing covering the remaining 6 months (December 2022 to May 2024). A total of 200 women were included, with 100 in each treatment group.

**Results:** In this study of 200 postpartum women, both FCM and iron sucrose groups were comparable in baseline characteristics. FCM showed significantly better improvement in serum ferritin and TIBC at 6 weeks, indicating superior iron store replenishment. Though adverse reactions were slightly higher in the FCM group, they were mild and manageable.

**Conclusion:** Both ferric carboxymaltose (FCM) and iron sucrose (IS) are safe and effective for treating postpartum anemia after cesarean delivery, with FCM showing superior serum ferritin improvement and better patient compliance due to single dosing. However, IS is more cost-effective. Both treatments pose no risk to breastfed infants and can be used interchangeably to reduce maternal and infant morbidity.

**Keywords:** Postpartum Anemia, Iron Deficiency, Ferric Carboxymaltose, Iron Sucrose, Caesarean Section.

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### Introduction

Anemia is the most common nutritional deficiency and remains a significant public health problem in the entire world. Menstrual blood loss, pregnancy and delivery are the main causes of anemia in reproductive age women. NFHS 5 showed that the prevalence of anemia in pregnant women in India is 51.1% and in west Bengal it is 62%. Anemia is an important cause of maternal mortality. It is estimated that 20- 40% of maternal deaths in India are due to anemia [1]. Iron deficiency anemia, is the most common cause of anemia in the postpartum period, with rates as high as 37% reported in the 1<sup>st</sup> postpartum week [2]. Postpartum anemia is caused primarily by inadequate iron

intake prior to and during pregnancy and acute blood loss at the time of delivery (peripartum blood loss during caesarean section is approximately 1000ml). [3,4] Caesarean section has been shown to increase the risk of PPA by twofold due to the increase of uterine atony and bleeding from vessels when opening the abdominal wall. According to WHO, caesarean delivery is rising globally 1 in 5(21%) of all child births. Our institute recorded 6475 deliveries (January 2023 to October 2023), 3546 were via caesarean section and the incidence is 51.4%, due to big number of pregnant women are referred from lower-level health facility for operative delivery. Majority ends up as emergency

caesarean section due to obstructed labor, malpresentation, repeat caesarean section, multiple pregnancy, failed labor induction, placental anomalies and non-reassuring fetus. Postpartum anemia has been associated with postpartum depression, stress, anxiety, cognitive impairment, poor mother interaction and delayed infant development. Oral iron therapy is currently the treatment of choice for majority of patients with iron deficiency anemia however, the utility of oral iron is limited by gastrointestinal complaints and patient noncompliance [5,6].

World Health Organization has defined postpartum anemia (PPA) as hemoglobin (Hb) of  $<10$  gm% during the postpartum period [7]. The prevalence of PPA varies from 4% to 27% [8]. A survey was done in a north Indian village, where about 70% women in the postpartum period were found to be anaemic [9]. About 29.8% of women who were not previously anemic during pregnancy become anemic after delivery [10]. In India about 36% of the total maternal deaths are attributable to postpartum hemorrhage or anaemia [11].

Overall longer hospital stay was noted in women with severe postpartum anemia and they were more likely to receive a blood transfusion and higher hospitalization costs were seen. About 18% of women hospitalized with anemia and postpartum bleeding receive a blood transfusion. Currently the treatment of choice for the majority of patients with iron deficiency anemia is oral iron therapy but its disadvantages like gastro-intestinal (GI) side effects, poor absorption and poor compliance makes it inferior. Presently, parenteral iron is helping in restoring iron stores faster and more effectively than oral iron. Intravenous iron preparations have been used for treating iron-deficiency anemia with a promising result and making it possible to avoid blood transfusion and side effects of oral iron preparation. Iron sucrose (IS) has been widely used for treating anemia with promising result. The efficacy and safety of IS have been established. IS requires multiple dosing which decreases the patient compliance. Ferric carboxy maltose (FCM) is designed to be administered in large doses in a short period of time, with very less side effects overcoming the limitations. Intravenous (IV) iron sucrose is safe, effective, and economic in comparison to the repeated and painful intramuscular iron injections [12]. In this study, we compare and evaluate the safety and efficacy of FCM and iron sucrose injections in the treatment of postpartum iron deficiency anemia in patient delivered by caesarean section. Iron deficiency anemia affects more women than any other condition, constituting an epidemic public health crisis world wise. It is generally present with subtle manifestations and should be considered as chronic slowly progressing disease that is often

underestimated and untreated worldwide despite several warnings and awareness campaigned by the WHO. To assess the effectiveness and safety of iv iron substitute like ferric carboxy maltose with iron sucrose in women following primary caesarean section in postpartum iron deficiency anemia.

## Materials and Methods

**Type of Study:** Prospective comparative observational study .

**Place of Study:** Postnatal wards, of Chittaranjan Seva Sadan College of Obstetrics, Gynecology and Child Health.

**Study Duration:** 18 months, planning and review of literature were done for 1st 3 months, for next 12 months data were collected followed by data compilation, analysis and writing for next 3 months (December 2022 to may2024).

**Sample Size:** 200 (100 in each group).

## Inclusion Criteria

- Women delivered by uncomplicated primary caesarean section.
- One having uneventful postoperative period.
- Mother clinically present with moderate to severe iron deficiency anemia
- Postpartum hemoglobin level less than 10gm%
- Postpartum ferritin level less than 30 micro gram/L.
- Patient who gave consent.

## Exclusion Criteria

- Active malaria and helminthic infected patient.
- Patient who received blood transfusion, and taking erythropoiesis stimulating agent.
- Patient having significant postpartum hemorrhage requiring blood transfusion.
- Those who has history of anemia due to other cause.
- Who has hepatitis, HIV infection and hematological disorder other than iron deficiency anemia.
- Patients with chronic fever.
- Psychiatric disorder.
- Any serious underlying medical condition (at the judgment of the investigator) which could impair the ability of the patient to participate in the trial.
- Known allergy or hypersensitivity to study drug.

**Statistical Analysis:** For statistical analysis, data were first entered into a Microsoft Excel spreadsheet and subsequently analyzed using SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism (version 5). Continuous numerical variables were summarized as mean  $\pm$  standard deviation, while categorical variables were

expressed as counts and percentages. The Z-test (Standard Normal Deviate) was employed to assess significant differences between proportions. For comparisons involving means, the student's t-test was used, with the corresponding p-value obtained from the t-distribution table. A p-value  $\leq 0.05$  was

considered statistically significant, indicating rejection of the null hypothesis in favor of the alternative hypothesis.

## Results

**Table 1: Association between Baseline Characteristics and Clinical Profile of Study Participants (Age, Socioeconomic Status, Antenatal Anemia, PPH, and Adverse Reactions)**

Age	Age	FCM	Iron sucrose	Total
	20-25	56(46%)	46(46%)	102(51%)
	26-30	30(30%)	30(30%)	60(30%)
	31-35	10(10%)	18(18%)	28(14%)
	35-40	0(0%)	2(2%)	2(1%)
	36-40	4(4%)	4(4%)	8(4%)
	Total	100(100%)	100(100%)	200(100%)
SES	Lower Class	30(30%)	35(35%)	65(65%)
	Upper lower Class	26(26.0 %)	28(28.0 %)	54(54.0 %)
	Lower middle Class	15(15%)	23(23%)	38(38%)
	Upper middle Class	19(19%)	10(10%)	29(29%)
	Upper Class	10(10%)	4(4%)	14(14%)
	Total	100(100%)	100(100%)	200(100%)

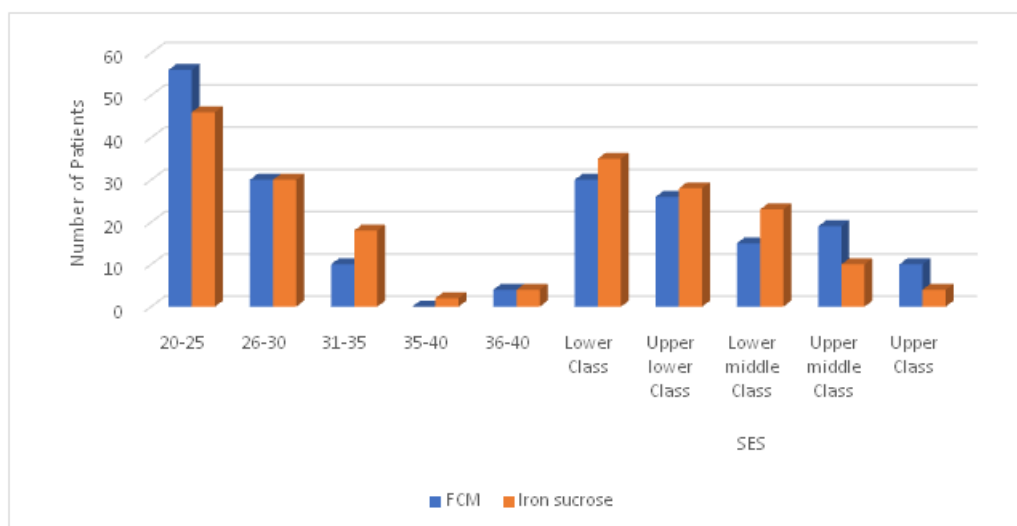
**Table 2: Association between Antenatal Anemia, Postpartum Hemorrhage (PPH), and Adverse Reactions in FCM and Iron Sucrose Groups**

		FCM	IS	Total
Antenatal anemia	No	85(85%)	80(80%)	165(165%)
	Yes	15(15%)	20(20%)	35(35%)
	Total	100(100%)	100(100%)	200(100%)
PPH	No	96(96%)	94(94%)	190(190%)
	Yes	4(4%)	6(6%)	10(10%)
	Total	100(100%)	100(100%)	200(100%)
Adverse reactions	No	86(86%)	94(94%)	180(90%)
	Yes	14(14%)	6(6%)	20(10%)
	Total	100(100%)	100(100%)	200(100%)

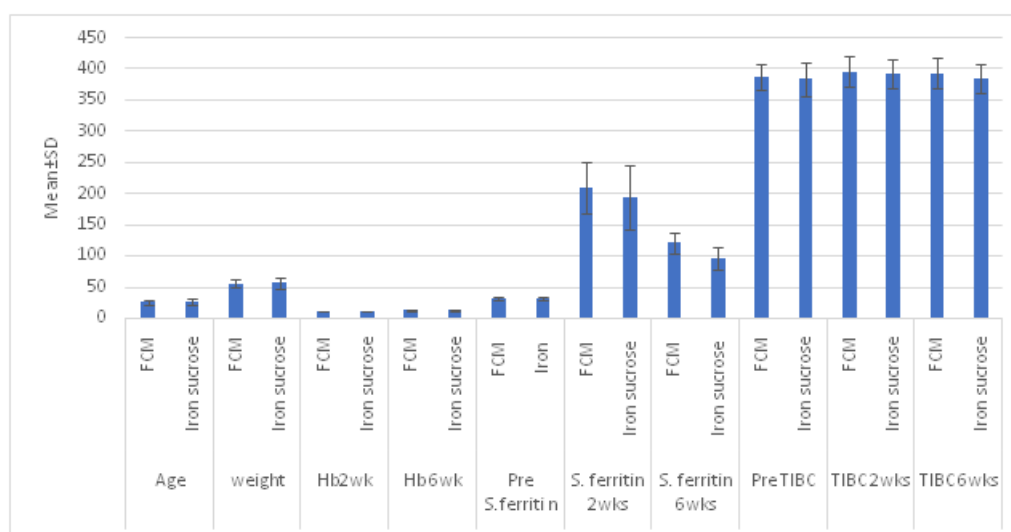
**Table 3: Distribution of mean Comparison of Hematological and Biochemical Parameters between FCM and Iron Sucrose Groups**

		Number	Mean	SD	Minimum	Maximum	Median	p-value	T Statistic
Age	FCM	100	25.46	4.246	20	37	25	0.1531	1.4342
	Iron sucrose	100	26.4	4.9929	20	37	26		
Weight	FCM	100	55.6	7.4752	40	73	54.5	0.4568	0.7456
	Iron sucrose	100	56.44	8.4283	35	72	56		
Hb2wk	FCM	100	10.624	0.6857	9.2	12.1	10.6	0.2336	1.1948
	Iron sucrose	100	10.744	0.7339	9.3	11.9	10.7		
Hb 6wk	FCM	100	12.102	0.7436	10.7	14	12	0.2146	1.2449
	Iron sucrose	100	11.968	0.7804	10.6	13.6	11.9		
Pre S. ferritin	FCM	100	31.272	2.8715	24.4	36.7	31.65	0.1307	1.5177
	Iron	100	31.836	2.359	26.4	35.7	32.1		
S. ferritin 2wks	FCM	100	209.8254	41.3108	127.1	279.98	221.87	0.0143	2.4709
	Iron sucrose	100	193.709	50.476	0.148	260.62	206.04		
S.	FCM	100	120.3046	15.5108	80.3	160.56	121.785	<0.0001	10.068

ferritin 6wks	Iron sucrose	100	96.3994	17.9756	69.2	130.2	96.2		5
Pre TIBC	FCM	100	387.04	20.626	349	430	390	0.4562	0.7467
	Iron sucrose	100	384.5	27.053	349	430	375		
TIBC 2wks	FCM	100	396.5	24.86	349	430	401	0.2428	1.1716
	Iron sucrose	100	392.56	22.647	349	430	392		
TIBC 6wks	FCM	100	394.08	23.752	349	430	392	0.0058	2.7899
	Iron sucrose	100	384.98	22.355	349	430	380		



**Figure 1: Association between Baseline Characteristics and Clinical Profile of Study Participants (Age, Socioeconomic Status, Antenatal Anemia, PPH, and Adverse Reactions)**



**Figure 2: Distribution of mean Comparison of Hematological and Biochemical Parameters between FCM and Iron Sucrose Groups**

In this study of 200 postpartum women (100 in each group), the majority belonged to the 20–25 age group, accounting for 51% of the total population, with equal distribution in both FCM and iron sucrose groups. Most participants were from lower socioeconomic backgrounds, with 65% in the lower and upper-lower classes combined.

The distribution of age and socioeconomic status was comparable between both groups, indicating well-matched baseline characteristics for analysis. Among the 200 postpartum women studied, 35 (17.5%) had antenatal anemia, with a slightly higher prevalence in the iron sucrose group (20%) compared to the FCM group (15%). Postpartum

hemorrhage (PPH) was observed in 10 women (5%), occurring more frequently in the iron sucrose group (6%) than in the FCM group (4%). Adverse reactions were more common in the FCM group (14%) compared to the iron sucrose group (6%), though most reactions were mild and self-limiting.

The comparative analysis of hematological and biochemical parameters between the FCM and iron sucrose groups showed no significant difference in age, weight, hemoglobin levels at 2 and 6 weeks, and pre-treatment serum ferritin and TIBC values ( $p > 0.05$ ). However, serum ferritin levels at 2 and 6 weeks were significantly higher in the FCM group ( $p = 0.0143$  and  $p < 0.0001$ , respectively), indicating a more effective replenishment of iron stores. Additionally, TIBC at 6 weeks was significantly lower in the FCM group ( $p = 0.0058$ ), further supporting the superior efficacy of FCM in correcting iron deficiency anemia postpartum.

### Discussion

This study demonstrating ferric carboxymaltose (FCM) significantly increases serum ferritin and reduces TIBC at six weeks compared to iron sucrose, with comparable hemoglobin responses and mild adverse effects—align well with several prior studies. Bashir Reshi et al. reported that FCM yielded a mean hemoglobin rise of 3 g/dL versus 2.03 g/dL for iron sucrose at two weeks, alongside high patient satisfaction and minimal side effects [13]. Singh et al. observed that significantly more women in the FCM group reached Hb  $>11$  g/dL, with greater ferritin elevation (67.6 mg/mL vs. 47.9 mg/mL;  $p < 0.001$ ), reinforcing FCM's superior efficacy [14].

Karwasara et al. similarly found that FCM produced faster and greater improvements in hemoglobin and ferritin compared to iron sucrose, with the added convenience of large single-dose administration [15]. A meta-analysis that included FCM, iron sucrose, and oral iron demonstrated that FCM delivered the fastest and highest increases in Hb and ferritin (mean Hb rise 4.4 g/dL vs. 3.4 g/dL for iron sucrose at six weeks;  $p < 0.0001$ ) [16]. In randomized trials, H.S. Sheela and colleagues reported that FCM produced significantly greater Hb increases at weeks 2 and 6 ( $\Delta 2.64$  vs.  $2.17$  g/dL at week 2,  $\Delta 4.65$  vs.  $3.96$  g/dL at week 6; both  $p < 0.01$ ), and a higher proportion reached target hemoglobin  $\geq 12$  g/dL (77.3% vs. 50%;  $p = 0.013$ ), with similar safety profiles [17]. These consistent outcomes across different settings confirm that FCM enables more rapid iron repletion and superior iron store replenishment than iron sucrose, echoing our biochemical findings while maintaining acceptable tolerability.

### Conclusion

From our study we conclude that both injection FCM and IS are equally effective and safe in increasing Hb level in postpartum anemia in patients delivered by caesarean section. But FCM injections were more superior in increasing serum ferritin level as compared to IS injections. Even though there were no serious adverse reactions in both the groups, minor side effects were seen more in FCM groups. Hospital stay for both the groups were not a factor to be considered in our study since, our study population (post caesarean mothers) were discharged only after stitch off on day 7-8 depending on the number of previous caesarean sections and abdominal wall thickness. Although the patient compliance was better in FCM group due to single dosing but in terms of cost-effectiveness IS takes the upper hand. Both IS and FCM are safe and effective for treating postpartum iron deficiency anemia and there is no evidence of risk to their breastfed infants. Hence both can be used interchangeably for treatment of iron deficiency anemia which intern decreases maternal morbidity, morbidity and infant morbidity in order to facilitate a prosperous future for mother and children in a continuing globalize world. A healthy mother will always bring up healthy babies.

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