

Comparative Evaluation of Intravenous Iron Isomaltoside and Ferric Carboxymaltose in the Management of Postpartum Anemia: A Prospective Study

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Conflicts of Interest: Nil

Abstract

Background: Postpartum anemia (PPA) is a major contributor to maternal morbidity, especially in women undergoing cesarean section. Rapid correction of anemia is essential to enhance postoperative recovery and improve maternal function. Among intravenous iron formulations, Iron Isomaltoside (IIM) and Ferric Carboxymaltose (FCM) are modern, safe, and effective options.

Aim: To compare the efficacy and safety of IIM versus FCM in correcting postpartum anemia among post-LSCS women.

Methods: A prospective study was conducted on 20 post-LSCS women with hemoglobin 7.5–9 g/dL

(indication for IV iron therapy). Participants were divided equally into IIM and FCM groups. Doses were calculated using the Ganzoni formula and infused between postoperative days 2–4. Hemoglobin rise at 4 weeks and adverse events were assessed.

Results: Mean Hb rise was greater with IIM (1.6–1.8 g/dL) compared to FCM (1.1–1.4 g/dL). No adverse events occurred in the IIM group. Two wound infections occurred in the FCM group.

Conclusion: Iron Isomaltoside demonstrated superior efficacy and safety compared with Ferric Carboxymaltose in post-LSCS women with postpartum anemia.

Keywords: Dizziness, Ferric Carboxymaltose, Iron Isomaltoside, Postpartum Anemia

Introduction

Postpartum anemia (PPA) is an under-recognized yet significant maternal health issue with consequences such as fatigue, dizziness, impaired cognition, delayed wound healing, increased susceptibility to infections and reduced breastfeeding performance. Its prevalence is disproportionately higher in low- and middle-income countries, where nutritional deficiencies, peripartum blood loss, and limited access to antenatal care coexist.

Cesarean section accounts for a substantial proportion of deliveries in tertiary centers across India and is associated with higher intraoperative blood loss compared to vaginal delivery. Post-LSCS women are particularly vulnerable to moderate anemia (Hb 7.5–9 g/dL), requiring prompt correction to facilitate early ambulation, improved postoperative recovery, and enhanced mother–infant bonding.

Oral iron therapy is often inadequate in postoperative conditions due to gastrointestinal intolerance, poor compliance, and slower hematological response. Thus, intravenous iron therapy has emerged as the preferred modality for rapid and effective correction of anemia in the immediate postpartum period.

Modern IV iron preparations such as Iron Isomaltoside (IIM) and Ferric Carboxymaltose (FCM) allow high single-dose administration with favorable safety profiles.

Mechanism of Action

Iron Isomaltoside (IIM)

- Consists of iron tightly bound to an isomaltoside-1000 carbohydrate matrix.
- Highly stable complex → minimizes free iron release.
- Allows large-dose single infusion.

- Iron is gradually released for uptake by transferrin and incorporation into hemoglobin.
- Lower risk of anaphylactic reactions and oxidative stress.

Ferric Carboxymaltose (FCM)

- Ferric hydroxide core stabilized by a carboxymaltose shell.
- Enables rapid high-dose infusion.
- Iron is released for macrophage uptake and transferrin loading.
- Some studies suggest transient elevation of labile plasma iron, possibly influencing infection susceptibility.

Despite extensive use, comparative data in early postoperative LSCS women using Ganzoni-calculated IV iron doses is limited, justifying the present study.

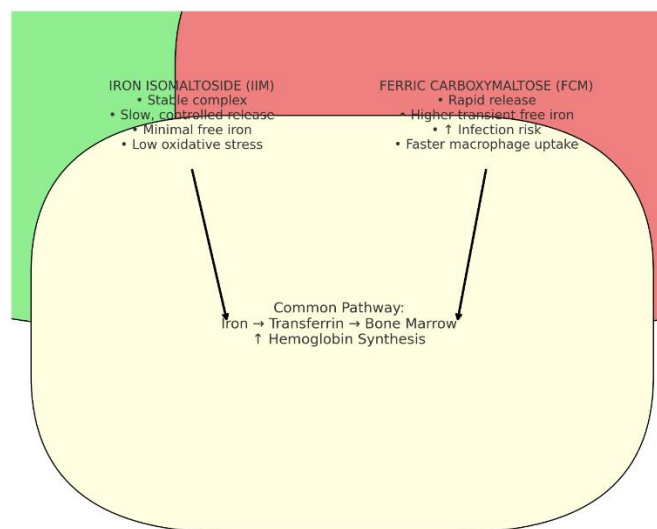


Figure 1:

Aims and Objectives

1. To compare the rise in hemoglobin at 4 weeks between IIM and FCM.
2. To assess immediate adverse reactions.
3. To compare postoperative wound complications.

Materials and Methods

Study Design

Prospective comparative observational study.

Participants

20 post-LSCS women with:

- Hemoglobin 7.5–9 g/dL (indication for IV iron infusion)
- Postoperative day 2–4
- Hemodynamically stable

Grouping

- **Group A (n=10):** Iron Isomaltoside
- **Group B (n=10):** Ferric Carboxymaltose

Dose Calculation

Ganzoni Formula:

Total iron dose (mg) = Body weight × (Target Hb – Actual Hb) × 2.4 + 500 mg

Follow-Up

- Baseline Hb (POD 2–4)
- Hb at 4 weeks
- Monitoring for infusion reactions & wound infection.

Infusion Procedure and Monitoring Protocol

All intravenous iron infusions were administered in the postoperative ward under the supervision of trained personnel. Strict aseptic precautions were followed for every infusion.

1. Pre-Infusion Preparation

Before administration, each patient underwent the following evaluation:

- **Vital parameters recording:**
 - Pulse, blood pressure, respiratory rate, temperature, oxygen saturation
- **Inspection of IV access** (18G or 20G cannula placed in upper limb)

- **Assessment for contraindications:**

- Hypersensitivity to IV iron
- Active infection
- Decompensated medical illness

- **Baseline symptoms documentation:** fatigue, palpitations, dizziness

- Verification of dosage calculated using Ganzoni formula

All resuscitation equipment, including adrenaline 1:1000, inj Avil, inj Hydrocortisone, IV fluids, oxygen supply, and suction, were kept ready.

2. Preparation of the Iron Solution

For Iron Isomaltoside (IIM):

- The calculated dose was diluted in 100 mL of normal saline.
- The solution was gently mixed by slow inversion.

For Ferric Carboxymaltose (FCM):

- The required dose was diluted in 100 mL of normal saline.

Both infusions were prepared immediately prior to administration to maintain stability.

3. Infusion Technique

The diluted preparation was administered using:

- A sterile IV infusion set
- Total infusion duration: 20 minutes, standardized for all participants
- The rate was adjusted to avoid too-rapid iron release while ensuring completion within the 20-minute window.

No other IV medications were administered concurrently through the same line.

4. Monitoring During Infusion

Each patient was continuously monitored throughout the infusion:

Table 1:

Parameter	Monitoring Frequency
Pulse rate	Every 10 minutes
Blood pressure	Every 10 minutes
Respiratory rate	Every 10 minutes
Oxygen saturation	Continuous monitoring
Infusion site inspection	Continuous
Symptoms (nausea, flushing, chest tightness)	Continuous observation

Patients were verbally reassessed every 5 minutes for:

- Chest discomfort
- Palpitations
- Breathlessness
- Pruritus or skin flushing
- Metallic taste
- Warm sensation
- Pain or swelling at the IV site

Any symptom prompted immediate slowing or discontinuation of the infusion.

5. Post-Infusion Monitoring

After completion of the 20-minute infusion:

- Patients were observed for 30 minutes in the ward.
- Vital signs were rechecked at 15 and 30 minutes.
- The IV site was examined for erythema, swelling, or phlebitis.

Results

Table 2: Baseline Maternal Characteristics

Variable	IIM (n=10)	FCM (n=10)	p-value
Age (years)	26.8 ± 3.1	27.2 ± 2.9	0.74
Parity (P0 / P1 / P2)	2 / 6 / 2	3 / 5 / 2	0.81
BMI (kg/m ²)	24.2 ± 2.1	24.8 ± 2.4	0.56
Booking Status	8 / 2	7 / 3	0.62
Indication for LSCS	4 / 4 / 2	3 / 5 / 2	0.89
Estimated Blood Loss (mL)	760 ± 110	785 ± 120	0.58
POD of Infusion (2 / 3 / 4)	3 / 5 / 2	4 / 4 / 2	0.87
Baseline Hb (g/dL)	7.5–9.0	7.5–9.0	—

- Patients were asked about delayed symptoms such as dizziness, nausea, or myalgia.

6. Documentation

All infusions were recorded in a standardized proforma:

- Dose administered
- Dilution details
- Time started and completed
- Vital signs documentation
- Any immediate or delayed reactions
- Post-infusion status
- This ensured uniformity across both groups and improved reliability of outcomes.

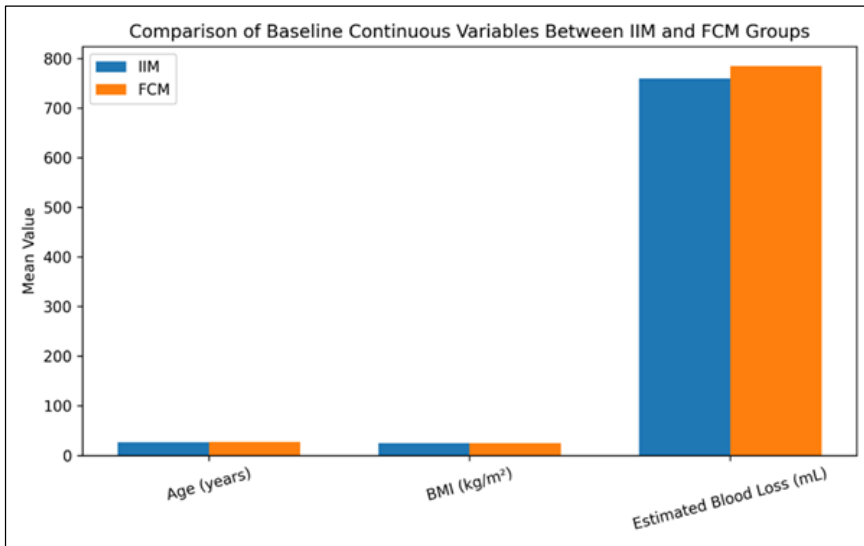


Figure 2: Comparison of baseline dosing parameters between IIM and FCM groups.

The grouped bar graph compares mean body weight and calculated mean iron deficit between patients receiving intravenous iron isomaltoside (IIM) and ferric carboxymaltose (FCM). Both groups demonstrated comparable baseline dosing parameters, supporting equivalence in iron requirement calculations prior to infusion.

Table 3: Iron Deficit and Administered Dose

Parameter	IIM (n=10)	FCM (n=10)
Mean Body Weight (kg)	58.4 ± 6.2	59.1 ± 5.8
Target Hb (g/dL)	11	11
Mean Iron Deficit (mg)	946 ± 120	935 ± 135
Administered Dose (mg)	900–1000	900–1000

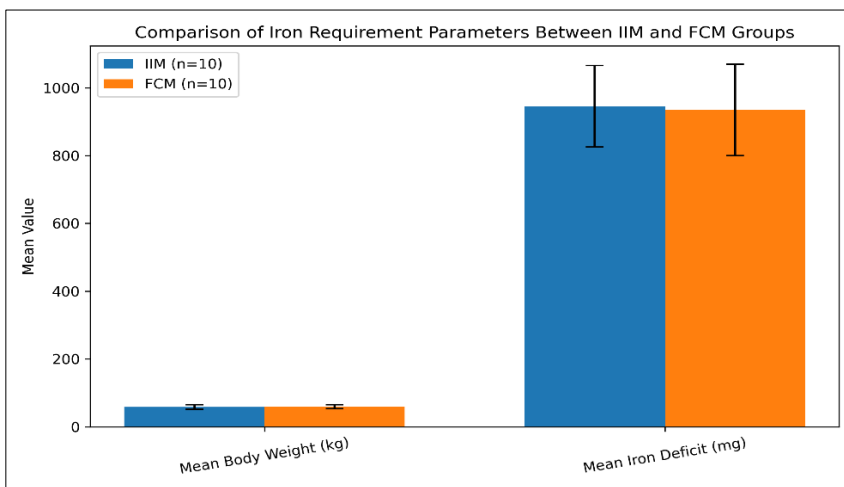


Figure 3: Comparison of baseline dosing parameters between IIM and FCM groups.

The grouped bar graph with error bars (mean \pm SD) compares mean body weight and calculated mean iron deficit between patients receiving intravenous iron isomaltoside (IIM) and ferric carboxymaltose (FCM). Both groups demonstrated comparable body weight and iron deficit, indicating similar iron requirements prior to infusion.

Table 4: Hb Response at 4 weeks

Treatment Group	Mean Hemoglobin Rise (g/dL)
Intravenous Iron Isomaltoside (IIM)	1.7
Ferric Carboxymaltose (FCM)	1.25

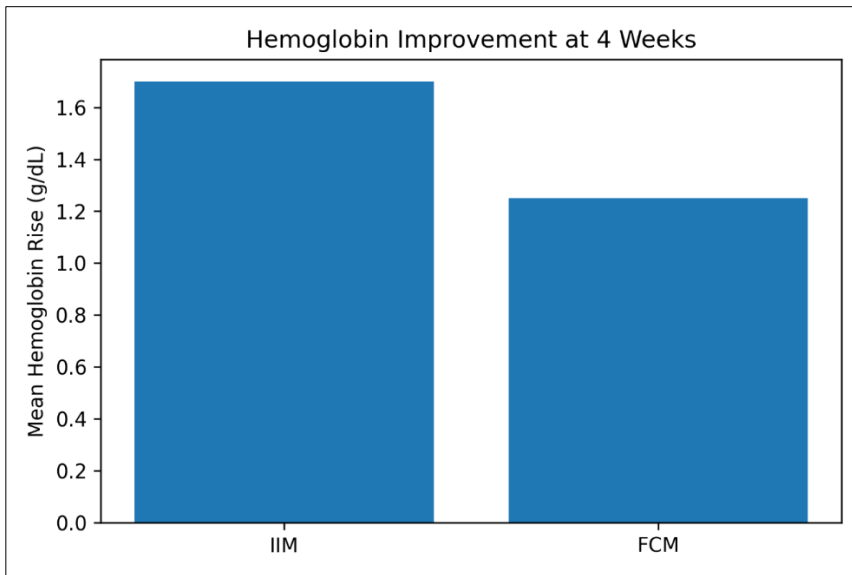


Figure 4: Mean hemoglobin improvement at 4 weeks following intravenous iron therapy.

The bar graph compares the mean rise in hemoglobin levels at 4 weeks in patients treated with intravenous iron isomaltoside (IIM) and ferric carboxymaltose (FCM). The IIM group demonstrated a higher mean hemoglobin rise compared to the FCM group.

Table 5: Adverse Event Profile

Adverse Event	IIM (n=10)	FCM (n=10)
Infusion Reaction	0	0
Nausea / Myalgia	0	1
Wound Infection	0	2

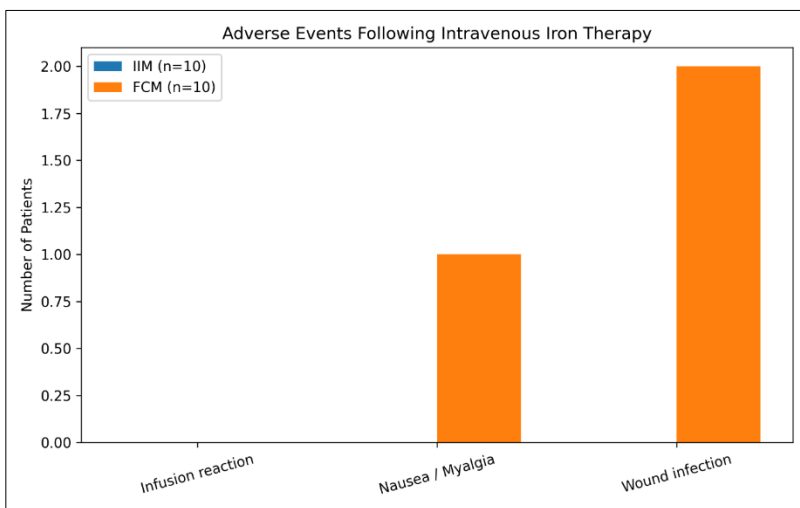


Figure 5: Comparison of adverse events between IIM and FCM groups.

The grouped bar graph illustrates the incidence of adverse events following intravenous iron therapy in patients receiving iron isomaltoside (IIM) and ferric carboxymaltose (FCM). No infusion reactions were observed in either group. Minor adverse events, including nausea/myalgia and wound infection, were noted only in the FCM group.

Summary of Results

In this prospective comparative study involving 20 post-LSCS women with postpartum anemia (Hb 7.5–9 g/dL), both intravenous iron preparations—Iron Isomaltoside (IIM) and Ferric Carboxymaltose (FCM)—were administered using standardized dosing based on the Ganzoni formula and infused over 20 minutes between postoperative days 2–4.

Baseline demographic and perioperative characteristics were comparable between the two groups in terms of age, parity, BMI, estimated blood loss, booking status, and postoperative day of infusion. The mean iron deficit was similar in both groups (IIM: 946 mg; FCM: 935 mg), and all participants received single-dose infusions.

At 4-week follow-up, the mean rise in hemoglobin was higher in the IIM group (1.6–1.8 g/dL) compared to the FCM group (1.1–1.4 g/dL), indicating a superior hematological response. No infusion-related reactions or systemic side effects were observed in the IIM group, whereas the FCM group reported 1 case of mild myalgia and 2 cases of postoperative wound infection, both

requiring antibiotic therapy. No participants required readmission or repeat iron therapy.

Overall, IIM demonstrated better clinical efficacy, a more favorable safety profile, and no postoperative infection events, making it a stronger therapeutic option in immediate post-cesarean postpartum anemia management.

Discussion

Postpartum anemia remains a common clinical challenge, particularly in women undergoing cesarean section, where surgical blood loss frequently precipitates moderate anemia that requires rapid correction. Intravenous iron therapy has emerged as the preferred modality in the early postoperative period due to poor gastrointestinal tolerance and slower hematological response with oral iron formulations.

In this study, Iron Isomaltoside showed a clearly superior rise in hemoglobin compared to Ferric Carboxymaltose. This difference can be attributed to the high molecular stability and slow, controlled release of bioavailable iron from the IIM complex, which

minimizes oxidative stress and enhances utilization by the bone marrow. The stable carbohydrate matrix of IIM (isomaltoside-1000) allows for efficient erythropoietic response without transient elevations of labile plasma iron—a phenomenon more commonly observed with FCM and potentially associated with increased infection susceptibility.

The presence of wound infections exclusively in the FCM group (20% incidence) is notable. Although the sample size is small, this finding aligns with emerging evidence suggesting that rapid release of unbound iron can transiently promote bacterial growth or impair local wound healing. In contrast, the slow-release profile of IIM avoids sudden peaks of free iron that may influence oxidative pathways at surgical sites. Additionally, all participants receiving IIM remained asymptomatic during and after infusion, highlighting its excellent tolerability and safety in the immediate postoperative setting.

The standardized 20-minute infusion protocol in this study simulates real-world feasibility in busy obstetric units, where rapid yet safe iron administration is essential. The absence of adverse reactions across all IIM recipients further supports its use as a first-line IV iron preparation for postpartum women requiring hematological stabilization.

Though limited by a modest sample size, the findings demonstrate a clear advantage of IIM in efficacy and postoperative safety. Larger randomized controlled trials may further validate these observations, but the present study provides compelling evidence favoring IIM for postpartum anemia correction in post-LSCS women.

Conclusion

Iron Isomaltoside is more effective and safer than Ferric Carboxymaltose in the management of postpartum

anemia in post-cesarean women. It results in a greater rise in hemoglobin, has no infusion-related or postoperative adverse events, and shows zero wound infections compared to the FCM group. Its stable molecular structure and controlled iron release make it an ideal choice for rapid anemia correction in the early postoperative period. Based on the results of this study, Iron Isomaltoside may be recommended as the preferred intravenous iron formulation for postpartum women requiring immediate hematological improvement after LSCS.

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