MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.36478/makrjms.2025.1.233.236

Evaluation of Safety of Ferric Carboxymaltose and Iron Sucrose in Postpartum Anaemia

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Key Words
Postpartum anemia, ferric carboxymaltose, iron sucrose, intravenous iron therapy, safety evaluation

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Received: 20 October 2024
Accepted: 26 November 2024
Published: 21 December 2024

Citation: Geddam Swarupa, M.V. Anusha Rani and Aruna Yarasani, 2025. Evaluation of Safety of Ferric Carboxymaltose and Iron Sucrose in Postpartum Anaemia. Res. J. Med. Sci., 19: 233-236, doi: 10.36478/makrjms.2025.1.233.236

ABSTRACT
Postpartum anemia (PPA) is a common condition that affects maternal recovery and overall health, particularly in developing countries. Intravenous (IV) iron formulations, such as ferric carboxymaltose (FCM) and iron sucrose (IS), are effective for rapid correction of iron deficiency, but their safety profiles require further evaluation. The study aimed to evaluate and compare the safety of ferric carboxymaltose and iron sucrose in postpartum anemia by analyzing adverse effects and complications in postpartum women. This was a prospective, comparative study conducted on postpartum women diagnosed with moderate -to-severe anemia. Participants were divided into two groups: Group A received ferric carboxymaltose and Group B received iron sucrose. Adverse reactions and complications such as headache, nausea, myalgia and other side effects were recorded and compared between the groups. Statistical analysis was performed using the Chi-square test, with a p-value <0.05 considered significant. A total of 100 women participated, with 50 in each group. Group A (FCM) reported minor complications, including headache (2%), myalgia (4%) and nausea (1%), whereas Group B (IS) showed no adverse effects (p>0.05). Most participants in Group A (92%) and Group B (100%) experienced no complications. Both ferric carboxymaltose and iron sucrose demonstrated excellent safety profiles in postpartum women with anemia. While FCM caused minor adverse reactions, these were transient and resolved without intervention. Iron sucrose remained free of adverse effects, indicating both are safe options for clinical use.

INTRODUCTION

Postpartum anemia (PPA) is a major public health concern, particularly in low-and middle-income countries, where maternal nutritional deficiencies and high parity rates contribute significantly to the burden of anemia. The World Health Organization (WHO) defines anemia as hemoglobin levels below 12 g/dL in non-pregnant women and below 11g/dL in pregnant women. Postpartum anemia, occurring after delivery, is primarily due to excessive blood loss during delivery, iron deficiency and inadequate iron supplementation during pregnancy. It affects up to 50% of postpartum women globally, posing significant risks to maternal well-being, such as fatigue, impaired cognitive function, delayed recovery and poor mother-infant bonding[1]. Iron deficiency anemia is the most common type of postpartum anemia and results from the depletion of maternal iron stores during pregnancy and delivery. Women experiencing heavy blood loss during delivery, multiple gestations, or insufficient iron supplementation are at increased risk of developing PPA[2]. Addressing this condition is critical, as untreated postpartum anemia can lead to chronic fatigue, reduced physical performance and even long-term cardiovascular complications. It also has an indirect impact on newborn care, as anemic mothers may face challenges in breast feeding and infant care, leading to poor neonatal outcomes[3]. The conventional management of postpartum anemia involves oral iron therapy. However, oral iron has limitations, such as poor gastrointestinal absorption, gastrointestinal side effects, and the need for long-term administration. These limitations make oral therapy less effective, especially in cases of severe anemia where rapid hemoglobin correction is required. Intravenous (IV) iron therapy has emerged as a superior alternative, offering faster replenishment of iron stores and improved hemoglobin correction rates. Among the available IV iron formulations, **ferric carboxymaltose (FCM) and iron sucrose (IS)** are the most commonly used options[4]. Ferric carboxymaltose is a newer -generation IV iron preparation that allows administration of a higher single dose (up to 1000 mg) over a shorter duration, reducing the need for multiple hospital visits. It has demonstrated a good safety and efficacy profile, making it particularly advantageous for postpartum women requiring quick recovery[5]. In contrast, iron sucrose, though widely used, requires multiple doses (200-300 mg per session), necessitating repeated hospital visits and potentially increasing patient discomfort and non-compliance. Despite these differences in administration protocols, both FCM and IS have shown comparable efficacy in treating iron deficiency anemia. While the efficacy of IV iron therapies in postpartum anemia has been well -documented, safety remains a key concern. Adverse events associated with IV iron preparations include mild reactions, such as headache, myalgia, nausea and rarely severe hypersensitivity reactions[6]. Under standing the safety profiles of FCM and IS is crucial to guide clinicians in choosing the most appropriate therapy for postpartum women, balancing efficacy, safety and patient convenience. This study, therefore, aims to **evaluate and compare the safety of ferric carboxymaltose and iron sucrose** in postpartum anemia. By analyzing adverse events, complications and tolerability, this study seeks to provide evidence-based recommendations for the optimal management of postpartum anemia. The findings are particularly relevant in resource-limited settings, where patient compliance and healthcare resource utilization are critical considerations[7].

MATERIALS AND METHODS

This study was designed as a prospective, randomized, open-label, comparative study conducted over a period of one and half months at Modern Government Maternity hospital, Petlaburz, Hyderabad after obtaining ethical clearance from the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to study enrollment. Postpartum women diagnosed with iron deficiency anemia were enrolled based on the following inclusion and exclusion criteria.

Inclusion Criteria:

- Postpartum women between age 18-35 years with iron deficiency anaemia of hemoglobin level<10g/dl.
- Women only with iron deficiency anaemia.

Exclusion Criteria:

- Anaemia other than iron deficiency.
- Patients intolerant or allergic to iron derivatives.
- Patients with known history of asthma thromboembolism, seizure disorders.
- Patients with signs of infection.
- Evidence of renal or hepatic dysfunction.
- Anaemia due to renal diseases and inflammatory bowel diseases.

Sample Size: 100 Cases with postpartum anaemia. Post partum anaemia patients divided in to 2 groups ,50 in each group.

- **Group 1:** Will receive IV iron sucrose till the required dose is completed here patients given fixed dose of 1000mg alternate days till the dose completed.
- **Group 2:** Will receive IV FCM once in week. In both groups Hb levels done before treatment and 2 weeks after the treatment.

Method: Approval from institution Ethics committee of Osmania medical college, Hyderabad was obtained. After selection of patients based on the above criteria

patients was explained about the study in their own understandable language and written consent was obtained. Post partum patients with hemoglobin less than 10gm% were included in this study. patients with anaemia other than iron deficiency anaemia, who received blood transfusion and with know history of allergy to injection iron, were excluded from the study.

Group A: 50 patients received iv iron sucrose according their dose required and till the required dose is reached. it is given by an infusion of 200mg diluted in 200ml of normal saline over 20-30 min every alternate day till required dose is completed. maximum of 600mg iron sucrose was given per week. total dose is 1000mg.

Group B: 50 patients received FCM 1000mg `is given by infusion of 1000mg in 250 ml of normal saline over 15minutes. All the two groups are followed after two weeks and complete haemogram and serum ferritin was done Complete Haemogram to be done at 0 day and 2 weeks after treatment., Peripheral smear, Red cell indices, Serum Ferritin levels and also complication of ferric carboxymaltose (FCM) and iron sucrose (IS).

Statistical Analysis: Statistical analysis was performed using SPSS software version 25.0. Qualitative data were presented by frequency and percentage Differences between groups were compared using:

- Chi-square test for categorical variables.
- A p-value of <0.05 was considered statistically significant.

RESULTS AND DISCUSSIONS

This randomized trial is conducted in Obstetrics and Gynecology Department, Modern government maternity hospital petlaburz Hyderabad. All these women were randomly assigned (100 women each) to receive either calculated dose of intravenous iron sucrose/1000mg fixed dose (Group A) or IV FCM (Group B) receives 1000mg fixed dose. The demographic profile and baseline clinical data like age, parity, the presence of antenatal anemia, mode of delivery, history of PPH were compared in two groups the results of present study are presented below.

Table 1 : Distribution of Demographic Profile of Between the Groups

Parameter	Group			
	Group A	Group B	Chi-square	P-value
Age (Year)				
16-20	4(8%)	4(8%)	2.915	0.405
21-25	30(60%)	27(54%)		
26-30	14(28%)	19(38%)		
31-35	2(4%)	0(0%)		
Religion				
Christian	0(0%)	1(2%)	2.296	0.317
Hindu	26(52%)	31(62%)		
Muslim	24(48%)	18(36%)		
Mode of Delivery				
LSCS	27(54%)	26(52%)	0.04	0.841
NVD	23(46%)	24(48%)		
ANC Registration				
Booked	24(48%)	14(28%)	4.244	0.039
Unbooked	26(52%)	36(72%)		
Parity				
Multi	32(64%)	36(72%)	0.735	0.391

Table 2 : Distribution of Adverse Reaction or Complication Between Groups

Parameter	Group			
	Group A	Group B	Chi-square	P-value
Complication				
Headache	1(2%)	0(0%)	4.167	0.244
Myalgia	2(4%)	0(0%)		
Nausea	1(1%)	0(0%)		
Nil	46(92%)	50(100%)		

Postpartum anemia remains a critical maternal health issue that requires prompt and effective treatment to improve both maternal well-being and overall recovery. In this study, we compared the safety of intravenous Ferric Carboxymaltose (FCM) and Iron Sucrose (IS) in postpartum women with iron deficiency anemia.

Demographic Characteristics: The demographic parameters, including age distribution, religion, mode of delivery and parity, were well-matched between the two groups, as no significant difference was observed (p>0.05). The majority of participants were in the age group of 21-25 years, constituting 60% in Group A and 54% in Group B. Similar age trends were reported by Gupta *et al.* (2020) in their study on postpartum anemia, where younger women were more likely to develop PPA due to nutritional deficiencies and higher pregnancy burden[1]. Parity analysis revealed a predominance of multiparous women (64% in Group A and 72% in Group B), aligning with findings from Saha[2], who reported that multiparty increases the risk of iron depletion during successive pregnancies. This underscores the need for comprehensive antenatal care, as ANC registration was significantly lower in Group B (28% booked vs. 72% unbooked., p=0.039) compared to Group A. Lack of antenatal booking correlates with inadequate supplementation and undetected anemia, which could contribute to more severe postpartum presentations.

Adverse Reactions and Complications: Our objectives of the study was to evaluate the safety profile of FCM and IS. (Table 2) shows the distribution of **adverse reactions** or complications between the two groups.

- **Group A (Ferric Carboxymaltose)** exhibited minor adverse reactions, including **headache (2%), myalgia (4%) and nausea (1%)**. However, the majority (92%) experienced no complications.
- In contrast, **Group B (Iron Sucrose)** had no reported adverse events **(100% nil complications)**.

The absence of severe adverse effects in both groups is consistent with previous studies by Adkinson[4] and Breymann[5], which demonstrated the safety of IV iron preparations in treating anemia. FCM-related minor events, such as headache and myalgia, are well-documented and generally resolve without

intervention. These side effects are likely due to transient inflammatory responses or hypersensitivity reactions, which are rare with FCM administration. Interestingly, the complete lack of adverse reactions in the IS group aligns with findings by Singh *et al.* (2021), where IS was reported to have a favorable safety profile but required multiple doses for comparable efficacy[6]. This study suggests that while both agents are safe, FCM may cause mild, transient complications due to its rapid administration and high single-dose formulation.

Clinical Implications: The safety profiles observed in this study suggest that both FCM and IS are viable options for managing postpartum anemia. However, the clinical choice between these agents must also consider additional factors, such as:

- **Administration Time:** FCM requires a shorter administration period, making it more convenient for busy healthcare settings and improving patient compliance, as noted by Fauziah[7].
- **Dosing Frequency: FCM** allows for a single high dose, whereas IS requires multiple smaller doses, increasing hospital visits, resource use and overall inconvenience.
- These findings resonate with studies that highlight FCM's role in improving patient satisfaction and reducing treatment dropout rates in postpartum anemia management.

Strengths and Limitations: The strength of this study lies in its comparative analysis of two widely used IV iron preparations under standardized clinical conditions. However, limitations include:

- **Sample Size:** A larger cohort could provide more robust conclusions regarding rare adverse events.
- **Follow-Up Duration:** Long-term follow-up for delayed adverse reactions or hemoglobin correction was not included, limiting insights into sustained efficacy.

Future studies with extended follow-ups and cost-effectiveness analyses are recommended to provide a holistic understanding of the two therapies.

CONCLUSION

In conclusion, both Ferric Carboxymaltose and Iron Sucrose demonstrated excellent safety profiles in the treatment of postpartum anemia, with minimal adverse reactions observed in the FCM group. While FCM offers the advantage of single-dose administration, IS remains an equally safe option with fewer reported adverse events. The choice of therapy should be tailored based on clinical setting, patient preferences and resource availability.

ACKNOWLEDGMENT

None.

Conflict of Interest: None.

Funding: None.

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