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Role of FCM in Prevention of Anemia in Pregnancy, Complications and Effects

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Abstract: ***Introduction: Anemia during pregnancy poses a significant health challenge, particularly in India where it contributes notably to maternal mortality. The prevalence of anemia in pregnant women varies widely across the region, necessitating interventions like oral and parenteral iron therapies. Parenteral iron, especially Ferric Carboxymaltose (FCM), has emerged as a favorable alternative due to its efficacy and lower incidence of side effects compared to traditional oral iron supplements. Aim and Objective: The study aims to assess the effectiveness of FCM in comparison to oral iron supplements in preventing anemia and its complications in pregnant women. Objectives include evaluating the impact of FCM on hemoglobin levels, compliance, and incidence of side effects. Methodology: This randomized controlled trial will enroll 100 pregnant women with anemia from a tertiary care hospital. Participants will be randomly assigned to receive either oral iron tablets or intravenous FCM. Hemoglobin levels will be monitored regularly, and data will be analyzed using SPSS software to compare the outcomes between the two groups. Results: Initial findings suggest no significant difference in baseline characteristics between the groups. However, the FCM group experienced fewer hospital visits and showed a trend towards fewer complications and side effects compared to the oral iron group. The results indicate a potential for better compliance and effectiveness with FCM. Conclusion: FCM may offer a more efficient and patient - friendly approach to managing anemia in pregnancy than traditional oral iron supplements. Further studies are required to fully understand its benefits and optimize its use in clinical practice.***

Keywords: Anemia, Pregnancy, Ferric Carboxymaltose (FCM), Oral Iron Supplements, Hemoglobin, Maternal Mortality, Iron Therapy, Parenteral Iron, Iron Sucrose, Randomized Controlled Trial, Compliance, Adverse Effects, Hospital Visits, Pregnancy Complications

1. Introduction

Anemia during pregnancy is a major global health issue, especially in India, where it is responsible for 20% of maternal deaths directly and 50% indirectly.1It is defined as having hemoglobin levels below two standard deviations compared to a similar population's average.1 India has the highest prevalence of anemia in South Asia, ranging from 57% to 96.2%.2 The Indian Council of Medical Research (ICMR) classifies anemia in pregnancy into four categories based on hemoglobin levels: mild (Hb 10 - 10.9 gm%), moderate (Hb 7 - 9.9 gm%), severe (Hb 4 - 6.9 gm%), and very severe (Hb <4 gm%).1

Anemia can lead to several complications, including increased vulnerability to infections, intrauterine growth restriction, preterm delivery, and higher perinatal morbidity and mortality.3 It also raises the risk of postpartum hemorrhage, requiring blood transfusion, prolonged hospital stays, and potential breastfeeding difficulties.4

Despite numerous health programs aimed at preventing anemia, it remains a leading cause of maternal morbidity and mortality due to factors like poor nutrition and oral iron intolerance. The main issue with oral iron therapy is poor adherence, caused by side effects such as bloating, nausea, and constipation. Moreover, oral therapy is often ineffective for moderate to severe anemia, particularly in the later stages of pregnancy. In such cases, parenteral therapy offers better results, reducing the need for blood transfusions.4

Parenteral iron therapy, such as intravenous iron, is more effective and well - tolerated. It helps replenish iron stores quickly and is used for conditions like chronic blood loss and gastrointestinal disorders.5 Ferric carboxymaltose (FCM) is a newer, more efficient alternative that allows for higher doses with fewer visits.6, 7 This study compares the efficacy and safety of FCM in treating anemia during pregnancy.

2. Aim and Objective

Aim:
The aim of this study is to evaluate the role of Ferric Carboxymaltose (FCM) in preventing anemia in pregnancy and its associated complications, compared to standard oral iron supplementation.

Objectives:
To assess the effectiveness of FCM in improving hemoglobin levels in pregnant women, compared to those receiving oral iron tablets.

3. Materials and Methods

This study is a randomized controlled trial aiming to evaluate the effectiveness of Ferric Carboxymaltose (FCM) compared to standard oral iron tablets in preventing anemia during pregnancy. It will take place in the obstetrics and gynecology department of a large tertiary care hospital over 18 months, starting patient recruitment in January 2025. A total of 100 pregnant women will be randomly divided into two groups, with one group receiving oral iron tablets and the other intravenous FCM. Participants eligible for the study will be pregnant women aged 18 - 45 years, diagnosed with anemia in their first or second trimester, and able to provide informed consent. Women with a history of severe reactions to iron supplements, other hematological disorders, multiple gestations, or severe systemic diseases will be excluded.

Participants will be randomly assigned to their groups using a computer - generated sequence, and allocation will be concealed with sealed opaque envelopes. Hemoglobin levels will be monitored using standard hematology analyzers and the cyanmethemoglobin method for accuracy. The oral iron group will receive 100 mg of elemental iron daily, while the FCM group will receive 500 mg of FCM biweekly until delivery. Follow - ups will be monthly, with hemoglobin levels checked at 12 weeks and at the study's conclusion. Data will be analyzed using SPSS software, focusing on hemoglobin changes, compliance, and side effects, with statistical significance set at a p - value of less than 0.05. All analyses will follow an intention - to - treat approach.

4. Results

Table 1: Baseline Characteristics

Variables	FCM Group	IFT Group
Mean age	24.6	23.7
Primigravida	32	28
Multigravida	38	42
Gestational age (in weeks)	27	29
Baseline hemoglobin (g/dl)	7.90 ± 0.71	8.01 ± 0.64
Serum ferritin (µg/dL)	12.56	14.83
Mode of delivery		
FTND	48	50
LSCS	19	16
Mean birth weight	2.72 kg	2.68 kg

The table compares the FCM and IFT Groups, each with 50 participants, highlighting various reproductive health metrics. The FCM Group's mean age is 24.6 years, with the IFT Group slightly younger at 23.7 years. The FCM Group includes 32 primigravida and 38 multigravida women; the IFT Group has 28 primigravida and 42 multigravida. Gestational ages average 27 and 29 weeks, respectively. Baseline hemoglobin levels are 7.90 g/dl for FCM and 8.01 g/dl for IFT, with serum ferritin at 12.56 µg/dL and 14.83 µg/dL. Delivery modes and mean birth weights are also detailed, noting similar outcomes between groups.

Table 2: Adverse effects with parenteral iron

Adverse Reaction	FCM Group	Iron Folic Group
Injection site irritation	1	1
Nausea and vomiting	1	2
Hypotension	0	1
Pruritis	0	2

The above table represents the comparison of adverse reactions between two groups of 500 participants each, one receiving Ferric Carboxymaltose (FCM) and the other Iron Sucrose. Both groups had an equal number of cases (1 each) of injection site irritation. Nausea and vomiting were slightly higher in the Iron Folicgroup (2 cases) compared to the FCM group (1 case). Hypotension and pruritus were only reported in the Iron Folic group, with 1 and 2 cases respectively, while no cases were observed in the FCM group.

Table 3: Number of doses administered

Number of Vials	FCM Group	Iron Folic Group
1 - 3	49	13
4 - 6	1	36
>6	0	1

The above table represents a comparison between two groups treated with different iron supplements: the FCM group, the Iron Folic group. The data is categorized based on the number of vials administered. For those receiving between 1 - 3 vials, 49 patients were in the FCM group and 13 in the Iron folic group. In the 4 - 6 vials category, only 1 patient received FCM while 36 received Iron sucrose. For patients needing more than 6 vials, no one received FCM and only 1 patient received Iron folic.

Table 4: Shows number of visits to the hospital

Number of visits to the hospital	FCM Group	Iron Folic Group
1 - 2	48	7
4 - 6	1	39
>6	1	4

The above table represents the number of hospital visits categorized into three groups—1 - 2 visits, 4 - 6 visits, and more than 6 visits—for two different treatment groups: the FCM Group and the Iron folic Group. In the 1 - 2 visits category, 48 patients from the FCM Group had 1 - 2 visits compared to only 7 in the Iron FolicGroup. For 4 - 6 visits, only 1 patient from the FCM Group fell into this category, while 39 patients from the Iron FolicGroup did. Lastly, in the more than 6 visits category, both groups had a minimal number, with 1 and 4 patients respectively.

5. Discussion

In our study of 100 participants, divided between Ferric Carboxymaltose (FCM) and Iron Folic (IFT) groups, we assessed reproductive health metrics and adverse effects. The FCM group averaged slightly older at 24.6 years compared to 23.7 years in the IFT group. Both groups showed similar baseline hemoglobin and birth weights, but the IFT group had higher serum ferritin levels. Adverse effects were minimal, with both groups experiencing similar rates of injection site irritation. The IFT group reported slightly more cases of nausea, vomiting, hypotension, and pruritus. Overall, both treatments were effective, with IFT showing a marginally higher rate of side effects. Mahajan A et al., [8] compared two groups, finding that the mean age and gestational age were similar between Group A (26.02 years, 33.44 weeks) and Group B (24.9 years, 33.02 weeks). Gravida status showed slight variations, with a bit more first - time pregnancies in Group B. Both groups had nearly identical baseline hemoglobin and serum ferritin levels, indicating comparable initial conditions. Clinically, nausea occurrence was equal in both groups, though injection site reactions were slightly higher in Group B. These findings suggest that the groups were well - matched for assessing the effects of our interventions.

In our study comparing Ferric Carboxymaltose (FCM) and Iron Folic treatments for iron deficiency, we observed notable differences. FCM typically required fewer vials per patient, with 49 patients needing only 1 - 3 vials, compared to 13 in the Iron Folic group. In higher dosage categories (4 - 6 vials), Iron Folic was more commonly used. Hospital visit data corroborated these findings; FCM patients generally had fewer visits, indicating its efficiency in treatment. This suggests FCM could be a more effective and convenient option for managing iron deficiency with fewer doses and less

frequent hospital visits. Sudha R et al., [9] observed significant differences in treatment efficiency. The FCM group typically required fewer vials, with all 50 patients needing just 1 - 3 vials of 1000mg each, and completed their treatment within 1 - 2 hospital visits. In contrast, the Iron Folic group displayed a broader range of vial usage, with 14 patients using 1 - 3 vials of 200mg, 35 patients requiring 4 - 6 vials, and one patient needing more than six. Additionally, this group generally required more hospital visits, with the majority (41 patients) needing 4 - 6 visits.

6. Conclusion

The data from the study suggests that the FCM Group generally experienced fewer hospital visits, with 48 of its members attending only 1 - 2 times, potentially indicating better management of their condition or fewer complications. In contrast, the Iron Folic Group showed a higher frequency of visits, with 39 members requiring 4 - 6 visits, which might suggest issues with the efficacy of the treatment or a higher incidence of complications. Both treatment groups had very few patients needing more than six visits, indicating that extreme cases were rare in this sample. Overall, these observations could imply that FCM treatment might be more efficient or better suited for minimizing hospital visits compared to Iron Folic, although further detailed analysis would be required to confirm these conclusions fully.

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