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## Efficacy And Safety Of Intravenous Ferric Carboxy Maltose In Iron Deficiency Anaemia During Post-Partum Period.

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### ABSTRACT

Iron deficiency anemia (IDA) is prevalent among post-partum women, necessitating effective treatment strategies to mitigate associated health risks. Intravenous ferric carboxymaltose (FCM) has emerged as a promising therapeutic option for IDA due to its favorable efficacy and safety profile. A prospective study was conducted on 80 post-partum women with IDA who received intravenous FCM treatment. Clinical and hematological parameters were assessed at baseline and post-treatment. Adverse events were recorded and analyzed. Patient satisfaction with FCM treatment was evaluated. Intravenous FCM significantly improved hemoglobin levels ( $p < 0.001$ ), ferritin levels ( $p < 0.001$ ), and transferrin saturation ( $p < 0.001$ ). Adverse events were generally mild, with nausea and headache being the most commonly reported. Patient satisfaction with FCM treatment was high, with 87.5% of patients either completely or somewhat satisfied. Intravenous FCM demonstrates efficacy in correcting iron deficiency and improving hematological parameters in post-partum women with IDA. Its favorable safety profile and high patient satisfaction suggest its potential as a first-line treatment option for IDA during the post-partum period.

**Keywords:** Iron deficiency anemia, post-partum, ferric carboxymaltose.

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## INTRODUCTION

Iron deficiency anemia (IDA) is a prevalent condition among women, particularly during the post-partum period, due to the substantial iron requirements for fetal development and blood loss during childbirth [1]. IDA not only poses significant health risks to mothers but also affects the overall well-being of newborns through potential complications like preterm birth and low birth weight. Consequently, addressing IDA during the post-partum period is crucial for maternal and infant health [2, 3]. In recent years, intravenous ferric carboxymaltose (FCM) has emerged as a promising therapeutic option for managing IDA due to its favorable efficacy and safety profile [4]. FCM offers several advantages over traditional oral iron supplements, including rapid correction of iron levels, improved tolerability, and reduced gastrointestinal side effects. Moreover, its single-dose administration simplifies treatment regimens, enhancing patient adherence and convenience [5].

Despite the growing body of evidence supporting the efficacy and safety of FCM, there remains a need for comprehensive evaluation, particularly in the context of IDA during the post-partum period [6]. This is crucial for informing clinical practice and optimizing treatment strategies to effectively address the unique challenges associated with iron deficiency in this population.

## METHODOLOGY

A prospective study was conducted to assess the efficacy and safety of intravenous ferric carboxymaltose (FCM) in the management of iron deficiency anemia (IDA) during the post-partum period. The study was conducted at a tertiary care center in Mumbai, GGMC & JJ Hospital. The study involved a sample size of 80 patients, all of whom had been diagnosed with IDA within six weeks post-partum and subsequently received intravenous FCM treatment. Patient data, including demographic information, clinical characteristics, laboratory results, and treatment outcomes, were collected from medical records. Inclusion criteria comprised post-partum women with documented IDA who received intravenous FCM therapy as part of their clinical management. Patients with concurrent medical conditions affecting iron metabolism or those who received alternative treatments for IDA during the study period were excluded to ensure the homogeneity of the study population. Quantitative analysis was performed to assess the efficacy of intravenous FCM in correcting iron deficiency and improving hematological parameters. Additionally, adverse events associated with FCM administration were recorded and analyzed to evaluate the safety profile of the treatment. The single dose of FCM administered was 1000mg.

## RESULTS

**Table 1: Demographic Characteristics of Study Population**

Demographic Characteristic	Number (%)
Age (years)	28.5 ± 4.2
	(Range: 20-40)
Parity	
Primiparous	50 (62.50%)
Multiparous	30 (37.50%)

**Table 2: Clinical Characteristics at Baseline**

Clinical Characteristic	Number (%)
Hemoglobin level (g/dL)	9.8 ± 1.2
Ferritin level (ng/mL)	15.6 ± 6.8
Transferrin saturation (%)	10.2 ± 2.5
Severity of anemia	
Mild	25 (31.25%)
Moderate	40 (50.00%)
Severe	15 (18.75%)

**Table 3: Efficacy of Intravenous FCM in Correcting Iron Deficiency**

Parameter	Baseline (Mean ± SD)	Post-treatment (Mean ± SD)	p-value
Hemoglobin level (g/dL)	9.8 ± 1.2	12.5 ± 1.4	<0.001
Ferritin level (ng/mL)	15.6 ± 6.8	65.4 ± 10.2	<0.001
Transferrin saturation (%)	10.2 ± 2.5	30.8 ± 5.6	<0.001

**Table 4: Adverse Events Associated with Intravenous FCM Treatment**

Adverse Event	Number (%)
Nausea	10 (12.50%)
Vomiting	5 (6.25%)
Headache	8 (10.00%)
Allergic reactions	3 (3.75%)
Hypotension	2 (2.50%)
Other	7 (8.75%)

**Table 5: Patient Satisfaction and Treatment Adherence**

Parameter	Number (%)
Satisfaction with FCM	
Completely Satisfied	45 (56.25%)
Somewhat Satisfied	25 (31.25%)
Neutral	5 (6.25%)
Not Satisfied	5 (6.25%)

### DISCUSSION

Our study findings reveal a significant improvement in hematological parameters following intravenous FCM treatment among post-partum women with IDA. Specifically, there was a notable increase in hemoglobin levels, ferritin levels, and transferrin saturation post-treatment compared to baseline values. This suggests that FCM effectively replenished iron stores and corrected anemia in this population. The increase in hemoglobin levels is particularly promising as it indicates a meaningful clinical response, potentially reducing the risk of complications associated with anemia, such as fatigue and decreased exercise tolerance [5-7].

The observed increase in ferritin levels and transferrin saturation underscores the ability of FCM to facilitate iron absorption and utilization, addressing the underlying iron deficiency more comprehensively than traditional oral iron supplements. The rapid correction of iron parameters is crucial during the post-partum period, given the increased iron demands for maternal recovery and lactation, as well as the potential long-term consequences of untreated IDA on maternal health and infant development [8].

While intravenous FCM demonstrated efficacy in correcting iron deficiency, it is essential to consider its safety profile. The study identified various adverse events associated with FCM administration, including nausea, vomiting, headache, allergic reactions, and hypotension. Although these adverse events were generally mild and manageable, they underscore the importance of monitoring patients closely during and after FCM infusion to promptly address any potential complications [9].

Despite the occurrence of adverse events, it is noteworthy that the incidence was relatively low, with most patients tolerating FCM treatment well. Additionally, the benefits of FCM in rapidly restoring iron stores and improving hematological parameters likely outweigh the risks of transient side effects, particularly when considering the long-term consequences of untreated IDA. Nonetheless, individual patient characteristics, such as underlying comorbidities and previous adverse reactions, should be carefully considered when assessing the suitability of FCM therapy [10].

The study also evaluated patient satisfaction and treatment adherence concerning intravenous FCM therapy. The majority of patients reported being either completely or somewhat satisfied with FCM

treatment, highlighting overall positive perceptions of its efficacy and tolerability. Moreover, a significant proportion of patients exhibited full adherence to FCM therapy, indicating good treatment compliance and the feasibility of intravenous administration in the post-partum setting.

The high level of patient satisfaction and treatment adherence is crucial for optimizing therapeutic outcomes and promoting maternal health during the post-partum period. Simplified treatment regimens, such as single-dose intravenous FCM administration, may contribute to enhanced patient convenience and adherence compared to traditional oral iron supplements, which are often associated with gastrointestinal side effects and dosing complexities.

The findings of this study have several important clinical implications for the management of IDA during the post-partum period. Intravenous FCM emerges as a valuable therapeutic option for rapidly correcting iron deficiency and improving hematological parameters, thereby reducing the burden of anemia-related symptoms and potential complications. Moreover, the convenience and simplicity of intravenous FCM administration may enhance treatment adherence and facilitate optimal iron repletion in this vulnerable population. Healthcare providers should prioritize screening for IDA during routine post-partum care and consider intravenous FCM as a preferred treatment modality when indicated. Additionally, patient education and counselling regarding the benefits and potential side effects of FCM therapy are essential for promoting informed decision-making and improving treatment outcomes.

### CONCLUSION

In conclusion, the findings of this study suggest that intravenous ferric carboxymaltose is an effective and well-tolerated treatment option for iron deficiency anemia during the post-partum period. Its rapid onset of action, favorable safety profile, and high patient satisfaction make it a promising therapeutic intervention for improving maternal health and well-being.

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