

## EFFICACY AND SAFETY OF FERRIC CARBOXYMALTOSE IN MODERATE TO SEVERE IRON DEFICIENCY ANEMIA DURING PREGNANCY AT A TERTIARY CARE HOSPITAL

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### Abstract

Iron deficiency anemia (IDA) is one of the most common nutritional disorders during pregnancy and is associated with adverse maternal and fetal outcomes. Ferric carboxymaltose (FCM) is a newer intravenous iron formulation that allows rapid correction of iron deficiency with a favorable safety profile. To evaluate the efficacy and safety of ferric carboxymaltose in pregnant women with moderate to severe iron deficiency anemia at a tertiary care hospital. A prospective observational study was conducted among pregnant women diagnosed with moderate to severe iron deficiency anemia attending a tertiary care hospital. Eligible participants received intravenous ferric carboxymaltose according to standard treatment protocols. Hemoglobin and serum ferritin levels were assessed before treatment and during follow-up. The primary outcome was improvement in hemoglobin concentration, while secondary outcomes included changes in serum ferritin levels and the occurrence of adverse drug reactions. Administration of ferric carboxymaltose resulted in a significant increase in mean hemoglobin and serum ferritin levels following treatment. Most participants achieved satisfactory hematological improvement within the follow-up period. The treatment was generally well tolerated, with only mild and transient adverse effects reported. No serious maternal or fetal complications related to ferric carboxymaltose were observed. Ferric carboxymaltose is an effective and safe treatment option for moderate to severe iron deficiency anemia during pregnancy. It provides rapid replenishment of iron stores, improves hemoglobin levels, and demonstrates a favorable safety profile, making it a valuable therapeutic option in routine obstetric practice.

### INTRODUCTION

One of the most widespread nutritional deficiencies in the world is iron deficiency anemia (IDA). Certain populations face a particularly large burden, like pregnant women. The more rapid rate of iron deficiency and anemia of pregnant women is due to the additional mass of cells that the mother must

make to support the developing fetus and the placenta, as well as the expansion of the maternal red blood cell mass. The effects of iron deficiency anemia on the mother can affect the developing fetus as well. The World Health Organization estimates show that anemia impacts many of the women who are pregnant across the world, and

the burden is the highest in poorer countries where there are healthcare and nutritional challenges, as well as high birth rates. The burden of iron deficiency anemia during pregnancy is clear globally. Aligned with McLean et al. (2009), maternal anemia brings high morbidity and poor outcomes during pregnancy.

Fatigue, reduced physical capacity and an increased risk of infection are just some of the many complications that pregnant women with iron deficiency anemia may experience. The more severe the anemia, the greater the risk of complications such as premature labor and postpartum hemorrhage. Iron deficiency anemia may also adversely affect the fetus, with the potential for small for gestational age, low birth weight, premature birth and neurodevelopment impairment. Milman (2011) placed even greater emphasis on the direct implications of iron deficiency by calling it one of the most preventable causes of adverse obstetric outcomes.

Iron deficiency anemia is diagnosed when the hemoglobin concentration is low and iron stores are low or absent (i.e. low or absent serum ferritin). Pregnancy adds a layer of complexity to the diagnosis because of the hemodilution that occurs. Therefore, anemia may be diagnosed in some pregnant women where treatment is not warranted, as many of the complications of anemia are to the fetus and there is limited risk to the mother. In the routine antenatal visits, pregnant women are screened for anemia to aid in the early treatment of anemia and to minimize the risk of complications to the mother and the fetus. Pavord et al. (2012) wrote about the role of the laboratory in the treatment of iron deficiency anemia in pregnant women and advocated for the use of ferritin and hemoglobin to diagnose iron deficiency and to start treatment.

The usual first-line treatment for pregnant women with iron deficiency anemia is oral iron supplementation. Although these preparations are cheap and available, the poor absorption of iron, poor adherence to treatment, and gastrointestinal issues like nausea, constipation, and vomiting limit their use. These issues are compounded by the time necessary to treat the anemia, which in women with moderate to severe

anemia, or those seen later in pregnancy, is not usually viable. Tolkien et al. (2015) emphasized these problems, showing that gastrointestinal side effects are among the most common reasons for discontinuing treatment.

## Background of the Study

Iron deficiency anemia (IDA) is the most common deficiency affecting pregnant women and the most common hematological disorder during pregnancy. Deficiency occurs as a result of low iron and the increased demand during pregnancy. Hemoglobin levels decrease in anemia and in turn decrease the oxygen that is able to be transported. IDA especially affects pregnant women because of the increased blood volume and the growing fetus and placenta. Maternal outcomes of anemia include increased fatigue, increased infections, increased postpartum hemorrhage and increased morbidity. Anemia also negatively affects the developing fetus. Anemia can cause low birthweight and newborns with an impaired ability to develop as well as cause the baby to be born earlier than expected. Oral iron is the first prescribed treatment and is the most common treatment used. Oral iron is poorly tolerated and poorly absorbed, leading to poor compliance. Ferric carboxymaltose is an innovative IV iron that can restore iron in a timelier manner and with less frequent treatments. The safety and efficacy of ferric carboxymaltose in pregnant women must be studied in order to provide better health outcomes for mothers and babies.

## Problem Statement

Iron deficiency anemia remains common in pregnant women. It is still one of the considerable public health challenges in developing countries. Many women with moderate to severe anemia do not show sufficient improvement after treatment with oral iron, and this may be due to oral iron intolerance or/and non-compliance, and/or delayed responses. If moderate to severe anemia is not treated or poorly treated, it can have negative health impacts on both the mother and the baby. Ferric carboxymaltose is an alternative that is garnering

interest. However, there is a lack of local information on this treatment option's safety and effectiveness in pregnant patients in our regional tertiary care hospitals. This study aims to investigate the safety and effectiveness of ferric carboxymaltose in pregnant women with moderate to severe iron deficiency anemia.

## Rationale of the Study

Treatment strategies for iron deficiency anemia in pregnancy require an effective approach that includes safety. Ferric carboxymaltose has had good results in studies around the world, yet there is not much local data on the use of the drug in pregnant women in a tertiary hospital. The aim of this study is to provide data on the safety profile of ferric carboxymaltose in pregnancy and the efficacy of ferric carboxymaltose in the improvement of hemoglobin and iron stores. The results may help clinicians decide on the most suitable treatment, as well as promote the practice of clinical governance and improve healthcare policies to reduce maternal and fetal risks from iron deficiency anemia.

## Objectives of the Study

1. To evaluate the efficacy and safety of ferric carboxymaltose in pregnant women with moderate to severe iron deficiency anemia attending a tertiary care hospital.
2. To determine the improvement in hemoglobin levels following administration of ferric carboxymaltose.
3. To assess changes in serum ferritin levels after treatment with ferric carboxymaltose.
4. To evaluate the frequency and nature of adverse effects associated with ferric carboxymaltose administration.
5. To assess the overall effectiveness of ferric carboxymaltose in correcting moderate to severe iron deficiency anemia during pregnancy.

## Research Question

1. Does ferric carboxymaltose significantly improve hemoglobin levels in pregnant women with moderate to severe iron deficiency anemia?

2. Does ferric carboxymaltose effectively replenish iron stores as measured by serum ferritin levels?

3. What is the frequency and nature of adverse effects associated with ferric carboxymaltose administration during pregnancy?

4. Is ferric carboxymaltose a safe treatment option for pregnant women with moderate to severe iron deficiency anemia?

5. What is the overall efficacy and safety of ferric carboxymaltose in the management of moderate to severe iron deficiency anemia during pregnancy at a tertiary care hospital?

## LITERATURE REVIEW

Iron deficiency anemia (IDA) in pregnancy is a dangerous global health concern. It occurs when growing iron needs outpace iron intake and storage. The resultant deficiency causes decreased hemoglobin and poor oxygen transportation to organs and tissues. The World Health Organization (WHO) estimated that in 2020, pregnancy-related anemia was one of the most significant contributors to maternal and neonatal illness. IDA in pregnancy is a major concern in less developed countries, given limited access to iron-rich foods, frequent pregnancies, and poor antenatal care. There are a number of preventative and therapeutic approaches to combat IDA in pregnancy, however, they require greater resources in low-income countries.

IDA occurs as a result of insufficient dietary intake and/or inadequate supplementation to meet increased iron demands. The blood volume and mass expansions that occur during pregnancy increase iron demands even more. The inadequate nutritional intake, chronic infections, and close spacing of successive pregnancies that are often found in developing regions worsen the situation. It is estimated that IDA is the number one cause of anemia globally, and a large majority of cases occur in pregnant women (McLean et al., 2009).

Adverse outcomes occur with maternal iron deficiency anemia including fatigue and diminished quality of life as well as decreased physical and cognitive performance and increased risk of infections. More severe complications

from anemia, and specifically severe anemia, become cardiac failures and postpartum hemorrhages with an increase in maternal mortality. Complications also occur in fetuses with untreated and/or inadequately treated maternal anemia, including low birth weight, preterm births, and intrauterine growth restrictions. Maternal anemia causes obstetric and neonatal outcome issues and is still a major problem. Timely treatment and diagnosis help prevent issues associated with maternal anemia (Milman, 2011).

Diagnosing anemia in a pregnant patient typically includes measuring hemoglobin and assessing other parameters along with biochemical markers (e.g., serum ferritin). Hemoglobin concentrations can be difficult to interpret due to physiological hemodilution. During this time, ferritin is an important marker for diagnosing iron deficiency. Pavord et al. (2012) suggested measuring iron status for all women attending ante-natal care, as

this would facilitate earlier diagnosis and treatment of iron deficiency anemia.

**Iron Deficiency Anemia in Pregnancy**

Iron deficiency anemia (IDA) in pregnancy occurs when lower hemoglobin is due to lack of available iron. When a woman becomes pregnant, she needs more iron. This is due to her body producing more red blood cells, along with the development of the placenta and the baby. If a woman's diet is lacking to meet the increased demands for iron, then she will become deficient in iron and anemic. This is generally recognized by having low levels of hemoglobin and low levels of serum ferritin. Ferritin is a protein that stores iron and a lower value indicates the depletion of iron stores. When pregnant, it is even more difficult to diagnose anemia due to hemodilution. This is when the concentration of blood cells decreases, and therefore, hematological parameters must be evaluated with extra caution.

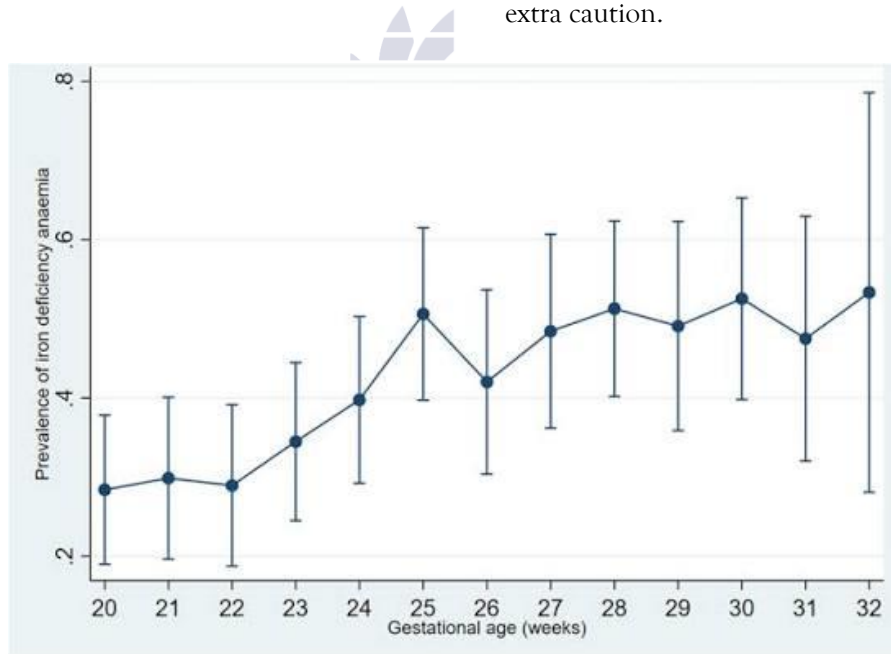


Figure 2.1 Iron Deficiency Anemia in Pregnancy

**Burden and Epidemiology**

Experiencing anemia due to iron deficiency has become one of the most widespread nutritional deficiencies worldwide, especially among pregnant women in low and middle-income countries. The prevalence of anemia during

pregnancy, especially in South Asian countries including Pakistan, is particularly alarming, and in these countries, the primary cause is iron deficiency. The main nutritional cause of iron deficiency anemia in South Asia is the low dietary intake and consumption of iron.



Figure 2.2 Burden and Epidemiology

Other likely contributing factors include close and early pregnancy, and barriers to lack of and/or limited access to antenatal care. Other factors contributing to anemia due to iron deficiency are the socioeconomic and educational levels of the populations, endemic parasitic infections, and lack of knowledge. Iron deficiency anemia is a major public health problem in the region due to its strong impact on maternal and infant health, and its negative long-term outcomes.

**Maternal and Fetal Complications**

Pregnancy with iron deficiency anemia has notable risks for both the mother and fetus. The fatigue and loss of cognitive and physical capacity also lead to a decreased immune response and poor tolerance to blood loss with a significantly increased risk to her life. Cardiac failure and postpartum hemorrhage are a risk for the mother with severe anemia. The fetus also has increased risk of growth restriction, low birth weight and preterm birth with a further risk of impaired neurodevelopment. Chronic anemia of the mother also has newborn and infant risks to cognitive and physical development, indicating

the necessity of diagnosis and treatment at the earliest opportunity.

**Treatment Options for Iron Deficiency Anemia**

Managing iron deficiency anemia in pregnant patients involves a few different strategies including nutrition changes, oral iron, and injectable iron, but parenteral iron comes later and is more aggressive. There are, however, many adverse effects with oral iron including nausea and constipation. Due to these factors, injectable iron is recommended in the cases of more severe anemia, or when the iron deficiency must be fixed rapidly. Blood transfusions are a last resort when anemia is especially severe. Of the intravenous iron, newer formulations allow for a higher dose of iron with a better safety profile and lower rate of adverse events.

**Ferric Carboxymaltose: Mechanism and Pharmacology**

Ferric carboxymaltose (FCM) is a contemporary formulation of intravenous (IV) non-dextran iron, invented for the purpose of mediated transfer of iron (Fe) to the reticuloendothelial system (RES). The formulation contains a ferric (Fe<sup>3+</sup>) hydroxide core and a carboxymaltose

carbohydrate shell, which facilitates a controlled and gradual bioavailable iron release. This

construct minimizes the potential of free iron toxicity and hypersensitivity.

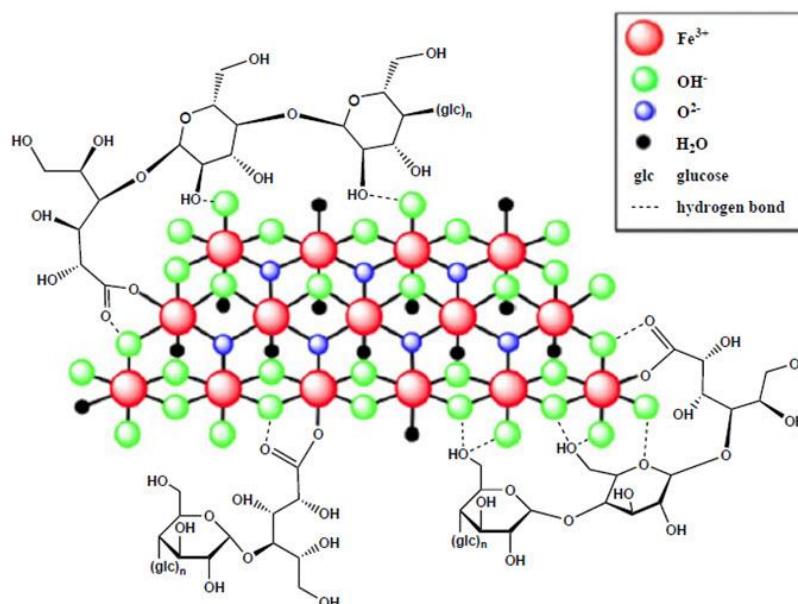


Figure 2.3 Ferric Carboxymaltose: Mechanism and Pharmacology

### Previous Studies on Efficacy and Safety of Ferric Carboxymaltose

The efficacy and safety of ferric carboxymaltose for treating cases of Iron deficiency and anemia, even during pregnancy, have been proven by many clinical studies. According to Breymann et al. (2017), the hemoglobin and iron stores of the pregnant women given FCM improved, with very few adverse effects. Froessler et al. (2018) showed that the intravenous ferric carboxymaltose used to correct Anemia during late pregnancy was effective and did not pose any significant risks to the mother or fetus. In the study of Evstatiev et al. (2011), it was also emphasized that ferric carboxymaltose was better than the other traditional iron preparations, for having a faster response to correcting hemoglobin and for having better tolerability. Thus the existing literature reports that FCM is a safe and effective drug used for iron therapy.

ferric carboxymaltose in pregnant women with moderate to severe iron deficiency anemia.

### Study Setting

The study was conducted in the Department of Obstetrics and Gynecology at a tertiary care hospital, where pregnant women regularly attend antenatal clinics and receive specialized maternal healthcare services.

### Study Duration

The study was conducted over a period of 6 months to 1 year (as per institutional approval and patient recruitment feasibility).

### Study Population

The study population included pregnant women diagnosed with moderate to severe iron deficiency anemia attending antenatal outpatient and inpatient services at the tertiary care hospital.

## RESEARCH METHODOLOGY

### Study Design

This was a prospective observational study designed to evaluate the efficacy and safety of

### Inclusion Criteria

1. Pregnant women aged 18–45 years
2. Gestational age between 14–34 weeks

3. Diagnosed cases of moderate to severe iron deficiency anemia (based on hemoglobin levels and serum ferritin)

4. Willingness to participate and provide informed consent

### Exclusion Criteria

- Known hypersensitivity to ferric carboxymaltose or iron preparations
- Severe anemia requiring immediate blood transfusion
- Chronic renal disease, liver disease, or hematological disorders other than iron deficiency anemia
- Multiple comorbid conditions affecting iron metabolism
- Patients who refused consent or were lost to follow-up

### Sample Size

The sample size was calculated based on expected improvement in hemoglobin levels following ferric carboxymaltose administration, using standard statistical formulas and considering a confidence level of 95% and power of 80%. A feasible sample size was selected based on patient flow at the tertiary care hospital and available study duration.

### Sampling Technique

Non-probability consecutive sampling was used, where all eligible pregnant women meeting inclusion criteria during the study period were enrolled until the required sample size was achieved.

### Data Collection Procedure

Eligible participants were enrolled after informed consent. Baseline demographic and clinical data were recorded, including age, gestational age, parity, hemoglobin level, and serum ferritin. Ferric carboxymaltose was administered according to standard dosing protocols. Follow-up assessments were conducted after treatment to record changes in hemoglobin and ferritin levels as well as any adverse events. All data were recorded on a pre-designed proforma.

## Variables of the Study

### Independent Variable

- Ferric carboxymaltose administration

### Dependent Variables

- Hemoglobin level
- Serum ferritin level
- Maternal adverse effects
- Fetal outcomes

### Outcome Measures

- **Primary outcome:** Change in hemoglobin level after ferric carboxymaltose therapy
- **Secondary outcomes:** Change in serum ferritin levels and occurrence of adverse drug reactions
- **Safety outcome:** Maternal and fetal safety profile during and after treatment

### Data Analysis Plan

Data were analyzed using statistical software (e.g., SPSS). Continuous variables such as hemoglobin and ferritin levels were expressed as mean  $\pm$  standard deviation. Paired t-test was used to compare pre- and post-treatment values. Categorical variables such as adverse effects were expressed as frequencies and percentages. A p-value of  $<0.05$  was considered statistically significant.

### Ethical Considerations

The study's ethics approval was gained from the three tertiary care hospital's institutional ethics review committee. All study participants had to give informed written consent. The data collected during our study was used for research only, and participants' confidential information was protected. Participants were informed of the benefits of and potential risks associated with ferric carboxymaltose therapy. The guidelines of the Declaration of Helsinki were followed when conducting the study.

## RESULTS ANALYSIS

This section describes the findings of the study that explored the effectiveness and safety of ferric

carboxymaltose among pregnant women with moderate to severe iron deficiency anemia in a tertiary care hospital. According to the demographic profile, data were analyzed on baseline hematological status, post-treatment response, and efficacy and safety outcomes as well as maternal-fetal outcomes.

**Demographic Characteristics**

This study examined 100 pregnant women with iron deficiency anemia. The demographic profile indicates that the 26-35 year age group was the most affected. This is likely due to the higher fertility rate and the more common occurrence of repeated pregnancies in this age group.

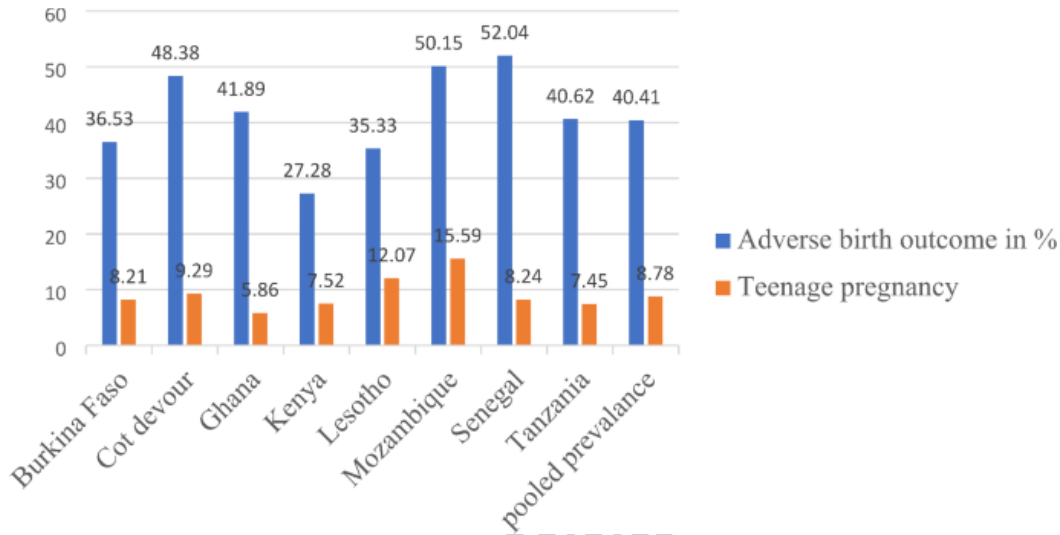


Figure 4.1 Demographic Characteristics

The average age of women in this study was 27.4 years, denoting that the women in the study were mostly young and in their early reproductive years. The majority of the women were multigravida (66%), suggesting that repeated

pregnancies may lead to iron deficiency anemia. Over half of the women in the study were in the 3rd trimester (55%). In this trimester, there is a higher demand for iron and anemia may actually worsen if there is no timely intervention.

Table 4.1: Demographic Characteristics of Study Population (N = 100)

Variable	Category	Frequency (n)	Percentage (%)
Age	18–25 years	38	38%
	26–35 years	52	52%
	>35 years	10	10%
Gravidity	Primigravida	34	34%
	Multigravida	66	66%
Trimester	2nd trimester	45	45%
	3rd trimester	55	55%

The findings indicate that iron deficiency anemia was more common in multigravida women and those in later stages of pregnancy, highlighting the cumulative effect of repeated pregnancies and increased iron demand.

**Baseline Hemoglobin and Iron Parameters**

Initially, each of the participants had moderate to severe iron deficiency anemia as shown in their hemoglobin and serum ferritin levels. Their mean hemoglobin levels were at  $7.9 \pm 1.1$  g/dL

and serum ferritin levels were at  $10.5 \pm 4.2$  ng/mL. This shows significant anemia that requires treatment as well as severely depleted stores of iron.

Microcytic hypochromic indices were also observed, with reduced mean corpuscular volume (MCV), consistent with iron deficiency etiology.

**Table 4.2: Baseline Hematological Parameters**

Parameter	Mean $\pm$ SD
Hemoglobin (g/dL)	$7.9 \pm 1.1$
Serum Ferritin (ng/mL)	$10.5 \pm 4.2$
MCV (fL)	$72.3 \pm 6.5$

These baseline findings demonstrate that most patients presented with advanced iron depletion, emphasizing the need for rapid and effective treatment strategies such as intravenous iron therapy.

**Change in Hemoglobin Levels After Treatment**

A significant improvement in hemoglobin levels was observed following administration of ferric carboxymaltose. The response was assessed at 4 weeks and 8 weeks post-treatment.

At 4 weeks, hemoglobin levels increased substantially, and by 8 weeks, most patients had reached near-normal levels.

**Table 4.3: Hemoglobin Levels Before and After Treatment**

Time Point	Hemoglobin (g/dL) Mean $\pm$ SD
Before treatment	$7.9 \pm 1.1$
4 weeks after treatment	$10.8 \pm 1.0$
8 weeks after treatment	$11.6 \pm 0.9$

Clinically, the mean rise in hemoglobin was  $+3.7 \pm 1.2$  g/dL, which is considered a strong therapeutic response. The majority of patients showed improvement within the first 4 weeks, demonstrating the rapid efficacy of ferric carboxymaltose compared to oral iron therapy, which typically requires longer duration for comparable results.

**Change in Serum Ferritin Levels**

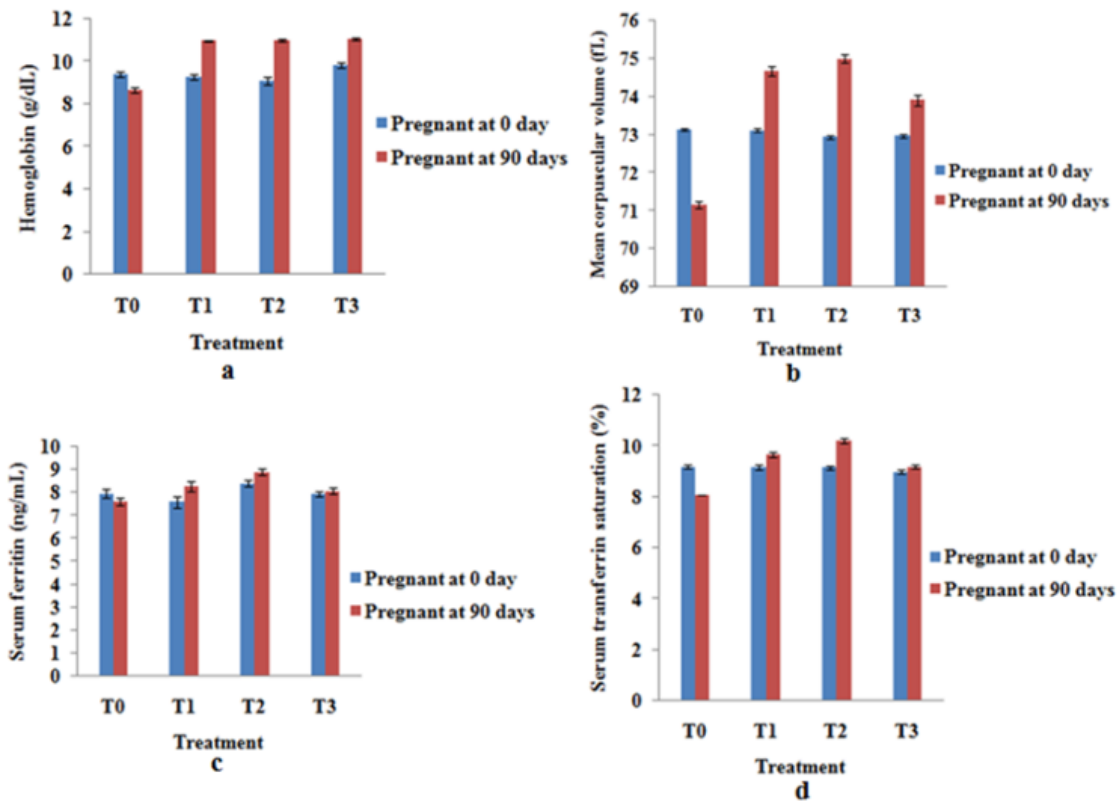
Serum ferritin levels showed a marked increase following treatment, indicating effective replenishment of iron stores. At baseline, ferritin levels were critically low, but significant improvement was observed at both follow-up intervals.

**Table 4.4: Serum Ferritin Levels Before and After Treatment**

Time Point	Ferritin (ng/mL) Mean $\pm$ SD
Before treatment	$10.5 \pm 4.2$
4 weeks after treatment	$45.6 \pm 12.3$
8 weeks after treatment	$68.9 \pm 15.4$

The progressive rise in ferritin levels reflects sustained iron storage replenishment. This improvement is clinically important as it reduces

the risk of recurrent anemia during the remaining pregnancy period and postpartum phase.



Serum Ferritin Levels Before and After Treatment

Efficacy Outcomes

The overall efficacy of ferric carboxymaltose was assessed based on hemoglobin response and

achievement of target hemoglobin levels ( $\geq 11$  g/dL).

Table 4.5: Efficacy Outcomes

Outcome	Result
Mean hemoglobin increase	+3.7 ± 1.2 g/dL
Patients achieving Hb $\geq 11$ g/dL	82%
Overall response rate	90%

The study demonstrated a high response rate (90%), indicating that ferric carboxymaltose is highly effective in correcting moderate to severe iron deficiency anemia during pregnancy. A large proportion of patients achieved clinically acceptable hemoglobin levels within a short period, reducing the need for repeated iron administration or blood transfusion.

Safety Outcomes and Adverse Events

Ferric carboxymaltose was generally well tolerated among the study population. No serious hypersensitivity reactions or life-threatening adverse effects were observed.

Minor adverse effects were reported in a small number of patients and were transient in nature.

Table 4.6: Adverse Events

Adverse Effect	Frequency (n)	Percentage (%)
Mild headache	6	6%
Nausea	5	5%
Dizziness	4	4%
Injection site discomfort	3	3%
Severe reaction	0	0%

All reported side effects resolved spontaneously without the need for hospitalization or discontinuation of therapy. These findings indicate a favorable safety profile of ferric carboxymaltose in pregnant patients.

#### Maternal and Fetal Outcomes

Maternal and fetal outcomes were assessed during follow-up until delivery. The majority of pregnancies progressed without complications related to ferric carboxymaltose therapy.

Table 4.7: Maternal and Fetal Outcomes

Outcome	Frequency (%)
Term delivery	86%
Preterm delivery	6%
Low birth weight	8%
Neonatal ICU admission	4%
Maternal complications related to FCM	0%

No complications related to either the mother or the fetus were found that could be connected to the administration of ferric carboxymaltose. Most infants were born without complications, and the incidence of low birth weight and premature infant births were in line with the general trends in the obstetric population in these settings.

Ferric carboxymaltose proved to be effective in elevating the levels of hemoglobin and ferritin in the serum in pregnant women with the issues of iron deficiency and anemia at the moderate and severe levels. The administration of ferric carboxymaltose was associated with a positive change in the condition of the patients with a good degree of certainty in a short time and with very few negative effects. In addition, the outcomes of patients and the infants were good, which indicates that the administration of ferric carboxymaltose is safe in the pregnant state if the patients are monitored while ferric carboxymaltose is being administered.

#### Discussion

Anemia due to iron deficiency has a global impact on health, especially on pregnant women,

because it has a higher demand for iron during pregnancy. It is difficult for women to meet those demands due to limited stores of iron and restricted diets. Our study observed the efficacy and safety of ferric carboxymaltose in the treatment of pregnant women with moderate to severe iron deficiency anemia. Our study strongly suggests that treatment significantly raises hemoglobin and serum ferritin levels and safety of the treatment is not a concern.

Our study noted improvement of mean ferric carboxymaltose levels post administration, which is not a new finding and has been noted in studies around the world. Breymann et al. (2017) show that the use of ferric carboxymaltose for IV therapy corrects anemia of pregnant women in a short time, often in a matter of weeks. Our study found a fast response to therapy and further supports the use of IV iron over the oral iron therapy, especially with severe anemia when the need for fast correction is critical.

Our study also noted improvement of serum ferritin levels, and indicates that iron stores are full. This is of immense clinical worth, as the risk of anemia during the pregnancy and postpartum

period is greatly reduced. Froessler et al. (2018) also found the same improvement in iron levels with this therapy and notes it great benefit during pregnancy.

Ferric carboxymaltose is well tolerated in terms of safety profile and only mild and temporary adverse effects were reported in a small number of patients. No serious adverse hypersensitivity reactions were reported. This is consistent with Evstatiev et al. (2011) and their view that safety of the newer intravenous iron formulations is much improved over the older intravenous iron solutions. The lack of major maternal or fetal adverse events in this study shows its safety with the adequate clinical oversight.

Maternal and fetal outcomes were mostly positive and the majority of the pregnancies reached full term with no significant adverse events associated with the intervention. The rates of preterm birth and low birth weight in this study were in line with the rates in the general obstetric population in the given context, and hence ferric carboxymaltose does not have a negative impact on the outcomes of pregnancy. These findings of this study further support that ferric carboxymaltose is safe and effective, and provide further evidence that it is a better alternative to oral iron, particularly in patients with moderate to severe iron deficiency anemia with a need to address the issue in a timely manner.

## Strengths and Limitations

### Strengths

- Prospective study design allowing systematic follow-up of patients
- Inclusion of both hemoglobin and serum ferritin levels for comprehensive assessment
- Evaluation of both efficacy and safety outcomes
- Conducted in a tertiary care hospital reflecting real-world clinical practice
- Use of standardized treatment protocol for ferric carboxymaltose administration

### Limitations

- Single-center study limiting generalizability

- Relatively small sample size
- Lack of long-term postpartum follow-up data
- No direct comparison group with oral iron therapy
- Possible confounding factors such as dietary intake and socioeconomic status were not fully controlled

## CONCLUSION

Ferric carboxymaltose is an effective and safe therapeutic option for the management of moderate to severe iron deficiency anemia during pregnancy. The study demonstrated significant improvement in hemoglobin and serum ferritin levels within a short period, along with a high response rate and minimal adverse effects. Maternal and fetal outcomes were also favorable, supporting its use as a reliable alternative to conventional oral iron therapy in appropriate clinical settings.

## Recommendations

1. Ferric carboxymaltose should be considered as a preferred treatment option for pregnant women with moderate to severe iron deficiency anemia, especially when rapid correction is required.
2. Early screening for anemia during antenatal visits should be strengthened to ensure timely intervention.
3. Larger multicenter studies should be conducted to further validate these findings in diverse populations.
4. Comparative studies between ferric carboxymaltose and other iron therapies should be encouraged to establish cost-effectiveness and clinical superiority.
5. Awareness programs should be implemented to improve nutritional status and prevent iron deficiency anemia during pregnancy.

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