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Original Research Article

Comparative Study of the Efficacy & Safety of Ferric Carboxy Maltose V/S Iron Sucrose in Management of Mild to Moderate Iron Deficiency Anemia in Pregnant Women

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Conflict of interest: Nil

Abstract

Objective: Anemia one of the common medical conditions affecting pregnancy and responsible for maternal and perinatal mortality and morbidity. The study was done to compare efficacy and safety of ferric carboxy maltose versus iron sucrose in iron deficiency anemia during pregnancy.

Method: This study is a prospective observational study carried out at C U Shah Medical College and Hospital, Surendranagar, Gujarat, covered 100 pregnant women with mild to moderate iron deficiency anemia were selected and were randomized into two groups in a 1:1 ratio. Group A: consisted of 50 antenatal women who received iron sucrose. Group B: consisted of 50 antenatal women who received Ferric carboxymaltose.

Results: A total of 100 pregnant women with iron deficiency anemia were included in the study, with 50 patients in the Iron Sucrose group and 50 in the Ferric Carboxymaltose (FCM) group. Baseline characteristics including age, baseline hemoglobin, and serum ferritin were comparable between the two groups with no statistically significant difference. Both groups showed a significant improvement in hemoglobin levels during follow-up; however, the rise in hemoglobin was significantly higher in the FCM group. At 8 weeks, the mean hemoglobin level increased to 12.5 ± 1.0 g/dl in the FCM group compared to 11.2 ± 1.1 g/dl in the Iron Sucrose group ($p < 0.001$). Serum ferritin levels also showed a significantly greater increase in the FCM group, reaching 110.6 ± 18.2 ng/ml at 4 weeks compared to 45.3 ± 12.4 ng/ml in the Iron Sucrose group ($p < 0.001$). The mean number of doses required was significantly lower in the FCM group (1.3 ± 0.5 doses) compared to the Iron Sucrose group (4.8 ± 1.2 doses). Both treatments were well tolerated, and the incidence of adverse effects such as nausea, headache, and injection site pain was low and comparable between the two groups. No hypersensitivity reactions were observed.

Discussion: Our study showed significant increase in hemoglobin level in both the group but FCM was safe and very effective in improving HB concentration as well as early replenishment of iron stores as compare to iron sucrose in patients with mild to moderate anemia

Keywords: Ferric carboxymaltose, Iron sucrose, Iron Deficiency anemia, hemoglobin.

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Introduction

Anemia is a common medical condition affecting pregnancy and is a significant contributor to maternal and perinatal mortality and morbidity.

Among various types, Iron Deficiency Anemia (IDA) is the leading cause in both developed and developing countries. Globally, it affects 41.8% of the population; in India, prevalence ranges from 23.6% to 61.4%. IDA is responsible for 40% of maternal deaths in developing countries, accounting for 25% of direct maternal mortality. The high prevalence in India is attributed to low dietary iron intake, phytate-rich diets, poor nutritional habits, and the high prevalence of infections such as malaria and hookworm infestation. This condition is further aggravated during pregnancy due to physiological changes and the increased nutritional demands of the growing fetus.

Classifications: The World Health Organization (WHO) defines anemia in pregnancy as a hemoglobin level of less than 11 g/dl. The Indian Council of Medical Research (ICMR) categorizes anemia during pregnancy as follows:

Category Hemoglobin Level

- Mild 10.0 – 10.9 g/dl
- Moderate 7.0 – 9.9 g/dl
- Severe 4.0 – 6.9 g/dl
- Very Severe < 4.0 g/dl

Complications and Treatment: IDA can cause various complications during pregnancy, including increased susceptibility to infections, reduced physical and cognitive function, an increased need for blood transfusions during delivery, cardiovascular complications, intrauterine growth retardation (IUGR), preterm delivery, and perinatal mortality.

While prophylactic oral iron supplementation is recommended to meet physiological needs, non-compliance is a major hurdle due to side effects such as bloating, nausea, vomiting, and constipation. Consequently, parenteral iron treatment is indicated for moderate to severe anemia, especially during the late second and third trimesters, as it can reduce the need for antenatal or postnatal blood transfusions.

Iron Sucrose and Ferric Carboxymaltose (FCM) are dextran-free iron preparations used for parenteral therapy:

Iron Sucrose: Currently the most common preparation used during pregnancy. It has an excellent safety profile and requires no test dose. However, its main disadvantage is the limited dose per session, requiring multiple visits and increasing the total cost of therapy.

Ferric Carboxymaltose: A newer, dextran-free Type-1 iron complex. It features a neutral pH, physiological osmolarity, and high bioavailability, allowing for the administration of a high single dose over a short period. It does not react with dextran antibodies and does not require a test dose.

Aim of the study: To compare the efficacy and safety of Ferric Carboxymaltose versus Iron Sucrose in the management of mild to moderate iron deficiency anemia in pregnant women.

Objectives

1. To compare the effectiveness of both drugs at intervals of 4, 8, and 12 weeks.
2. To evaluate the safety and tolerability of both drugs.
3. To analyze the subsequent need for additional supplementation or blood transfusion.

Inclusion criteria

- Pregnant women between 18-35 year
- Gestational age 14-34 weeks
- Hemoglobin 7-10.9
- Diagnosed iron deficiency anemia

Exclusion criteria

- Severe anemia (Hb <7 g/dl)
- Hemoglobinopathies
- Chronic kidney disease
- Active infection
- Hypersensitivity to IV iron
- Previous blood transfusion

Methodology

This study was conducted at CU Shah Medical College and Hospital using a prospective observational methodology. The study included 100 pregnant women with mild to moderate anemia between October 1, 2024, and April 30, 2025.

Participants were randomized into two groups in a 1:1 ratio:

Group A: 50 pregnant women who received Iron Sucrose.

Group B: 50 pregnant women who received Ferric Carboxymaltose

Results

Table 1: Baseline characteristics of study population (N=100)

Parameter	Iron Sucrose (n=50)	FCM (n=50)	p-value
Age (years, mean ± SD)	26.8 ± 4.2	27.1 ± 4.5	0.74 (NS)
Baseline Hb (g/dl)	8.2 ± 0.8	8.3 ± 0.7	0.56 (NS)
Serum Ferritin (ng/ml)	12.5 ± 5.2	13.1 ± 5.6	0.61 (NS)
Gravida (mean ± SD)	2.1 ± 1.0	2.0 ± 0.9	0.82 (NS)
Comorbidities (%)	14%	12%	0.79 (NS)

Table 2: Hemoglobin Levels during Follow-up

Time Point	Iron Sucrose (Hb g/dl, mean ± SD)	FCM (Hb g/dl, mean ± SD)	p-value
Baseline	8.2 ± 0.8	8.3 ± 0.7	0.56 (NS)
2 weeks	9.3 ± 0.9	10.1 ± 0.8	0.001
4 weeks	10.4 ± 1.0	11.6 ± 0.9	<0.001
8 weeks	11.2 ± 1.1	12.5 ± 1.0	<0.001

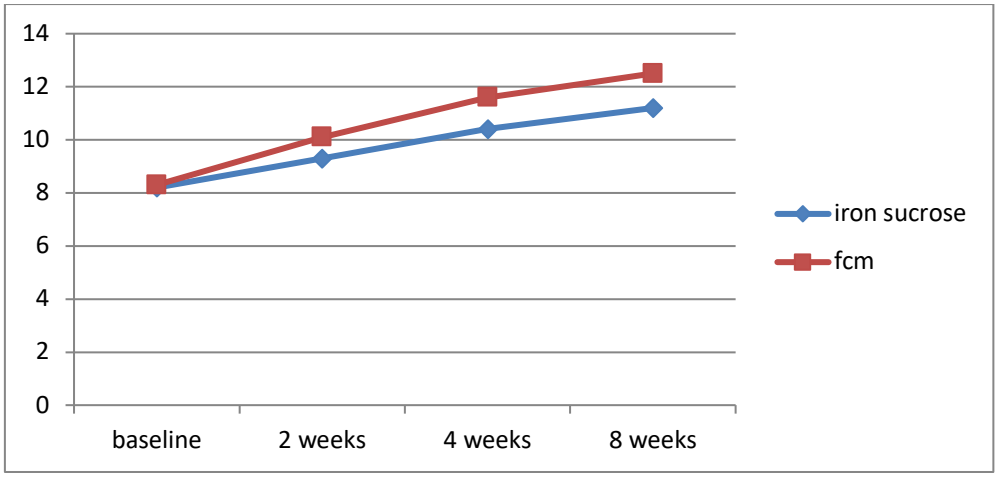

Figure 1:

Table 3: Serum Ferritin Levels during Follow-up

Time Point	Iron Sucrose (ng/ml, mean ± SD)	FCM (ng/ml, mean ± SD)	p-value
Baseline	12.5 ± 5.2	13.1 ± 5.6	0.61 (NS)
4 weeks	45.3 ± 12.4	110.6 ± 18.2	<0.001
8 weeks	60.2 ± 14.1	95.7 ± 16.5	<0.001

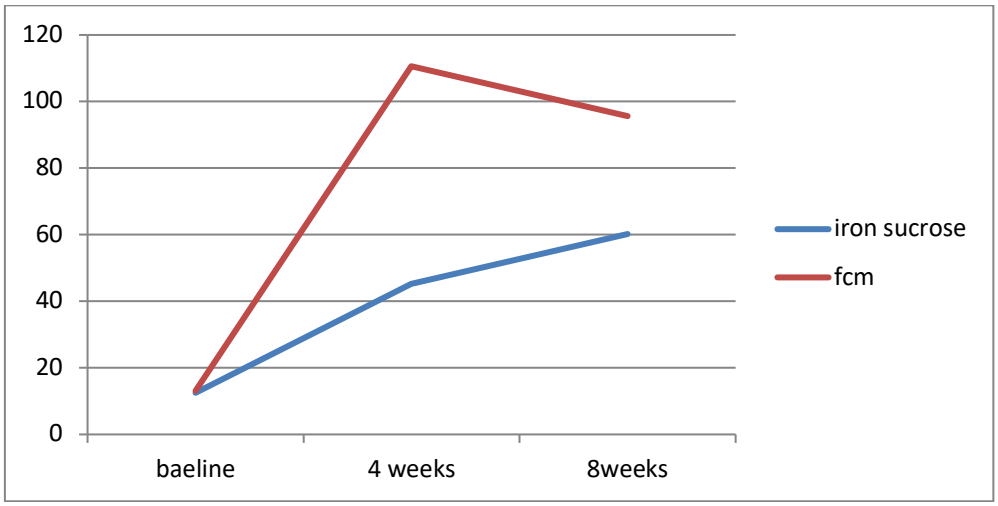

Figure 2:

Table 4: Number of Doses Required

Parameter	Iron Sucrose (n = 50)	FCM (n = 50)
Mean number of doses required	4.8 ± 1.2	1.3 ± 0.5
Range of doses	3 – 6	1 – 2

Table 5: Adverse Events

Adverse Event	Iron Sucrose (n = 50)	FCM (n = 50)	p-value
Nausea	4 (8%)	2 (4%)	0.68 (NS)
Headache	3 (6%)	2 (4%)	0.71 (NS)
Injection site pain	5 (10%)	2 (4%)	0.44 (NS)
Hypersensitivity reaction	0	0	–
Total patients with AEs	9 (18%)	6 (12%)	0.58 (NS)

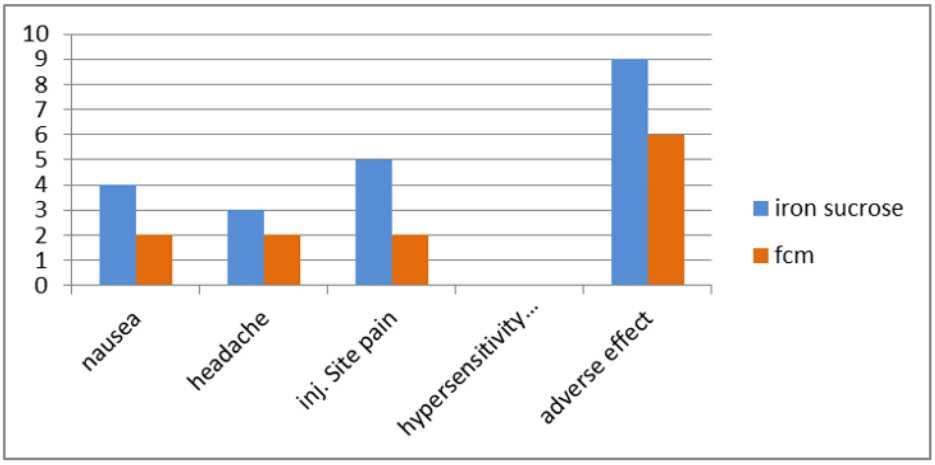

Figure 3:

Discussion

Iron deficiency anemia (IDA) is a prevalent complication in pregnancy that necessitates rapid and effective correction to prevent adverse maternal and fetal outcomes. Intravenous (IV) iron therapy is increasingly preferred in cases where oral iron is ineffective or poorly tolerated. This study compared the efficacy and safety of Iron Sucrose and Ferric Carboxymaltose (FCM) in pregnant women diagnosed with IDA.

In the current study, baseline characteristics—including age, baseline hemoglobin, serum ferritin, gravidity, and comorbidities—were comparable between the two groups, with no statistically significant differences. This indicates that both cohorts were well-matched at the onset of the study.

Hematological Response: Both treatment groups demonstrated a significant increase in hemoglobin levels during the follow-up period. However, the rise in hemoglobin was significantly greater in the FCM group compared to the Iron Sucrose group at the 2-week, 4-week, and 8-week intervals. By week 8, the mean hemoglobin level reached 12.5 ± 1.0 g/dl in the FCM group, compared to 11.2 ± 1.1 g/dL in the Iron Sucrose group, indicating a faster and more effective correction of anemia with FCM.

Similarly, serum ferritin levels, which reflect total iron stores, showed a significantly greater increase in the FCM group. At 4 weeks, serum ferritin levels rose to 110.6 ± 18.2 ng/mL in the FCM group, whereas the Iron Sucrose group reached only 45.3 ± 12.4 ng/ml. This disparity remained significant at 8 weeks, suggesting that FCM is superior in replenishing iron stores.

Clinical Utility and Safety: A notable observation in this study was the difference in the number of doses required. Patients receiving Iron Sucrose required a mean of 4.8 ± 1.2 doses, whereas those receiving FCM required only 1.3 ± 0.5 doses. This highlights a major practical advantage: FCM reduces hospital visits, improves patient compliance, and decreases the overall treatment burden.

Regarding safety, both treatments were well-tolerated. While the incidence of minor adverse events—such as nausea, headache, and injection-site pain—was slightly higher in the Iron Sucrose group, the difference was not statistically significant. Most importantly, no hypersensitivity reactions were observed in either group, confirming that both therapies are safe for use during pregnancy.

The findings of this study are consistent with previous literature, which has demonstrated that Ferric Carboxymaltose produces a more rapid rise in hemoglobin, superior replenishment of iron stores, and requires fewer administrations than Iron Sucrose. Overall, our results support the growing evidence that FCM is a more convenient and effective intravenous iron preparation for managing IDA in pregnancy.

Limitations:

Sample Size: The study was limited by a relatively small sample size.

Scope: As a single-center study, the findings may not be fully generalizable to broader populations.

Duration: The short follow-up duration limits the assessment of long-term maternal and neonatal outcomes.

Conclusion

This study demonstrates that both Iron Sucrose and Ferric Carboxymaltose are effective and safe for treating iron deficiency anemia in pregnancy.

However, Ferric Carboxymaltose exhibited superior efficacy, resulting in a significantly greater increase in hemoglobin and serum ferritin levels. Additionally, FCM required significantly fewer

doses, enhancing patient convenience and compliance.

Since adverse effects were minimal and comparable between the two groups, Ferric Carboxymaltose may be considered the preferred option for managing moderate to severe IDA in pregnancy—particularly when rapid correction and minimized hospital visits are required.

Ethical committee approval: Yes

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