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Comparison of IV Sucrose and IV Carboxymaltose in Patients with Anemia in Pregnancy

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ABSTRACT

Background: Pregnancy-associated iron deficiency anemia is a major health problem for its role in causing maternal morbidity and undesirable perinatal outcomes. Standard therapy with intravenous iron sucrose consists of multiple frequent small infusions, with ferric carboxymaltose accepting larger single doses at shorter intervals. There remains sparse direct evidence for a comparison between their effectiveness in pregnancy. **Objective:** To compare the effectiveness of intravenous ferric carboxymaltose and intravenous iron sucrose in pregnant women with moderate to severe iron deficiency anemia. **Study Design:** Randomized controlled trial. **Place and Duration of Study:** This trial was conducted from June 2024 to November 2024 in the Department of Obstetrics and Gynecology, SKBZ Combined Military Hospital, Muzaffarabad. **Methodology:** Sixty pregnant women between 16 and 24 weeks of gestation, with hemoglobin levels ranging from 7 to 10 grams per deciliter, were randomized into two equal groups. One group received ferric carboxymaltose in single doses up to 1000 milligrams, while the other group received iron sucrose in divided doses not exceeding 600 milligrams per week. Hemoglobin and red cell indices were recorded at baseline and during follow-up at 3, 6, and 12 weeks. **Results:** Baseline demographic and clinical features were comparable between the two groups. After 12 weeks, mean hemoglobin significantly increased in the ferric carboxymaltose group (113.45±4.95 g/L) compared to the iron sucrose group (106.29±4.87 g/L). The average rise from baseline was greater with ferric carboxymaltose (29.32±3.23 g/L) than with iron sucrose (22.25±1.75 g/L, $p<0.001$). Stratified analysis confirmed superior outcomes with ferric carboxymaltose across all subgroups, including maternal age, parity, socioeconomic status, and place of residence. No serious adverse reactions were observed. **Conclusion:** Ferric carboxymaltose is more effective than iron sucrose in correcting antenatal iron deficiency anemia, producing a greater and faster rise in hemoglobin with fewer infusions.

INTRODUCTION

Pregnancy anemia is amongst the most frequent disease entities observed in obstetrical practice, particularly for low- and middle-income regions.[1] It almost always results from deficiency of iron, due to the greater pregnancy-related physiological demand overlaid on insufficient intake from the food sources and prevailing deficiencies of the mothers.[2] The disease has been associated with an array of maternal side effects, including fatigue, diminished work performance, increased susceptibility to infection, and higher risk of obstetrical problems such as preterm labor, placental abruption, and postpartum hemorrhage.[3] Fetal and neonatal impacts are also serious, including intrauterine growth retardation, low birth weight, reduced neurodevelopmental status, and elevated perinatal death rate.[4] Even if initial treatment with oral iron supplementation remains the first choice, countless pregnant individuals either fail to achieve adequate correction of anemia due to gut intolerance or inadequate absorption of iron and are thus managed with parenteral iron therapy for immediate restoration of stores of iron and concentrations of hemoglobin.[5]

Intravenous iron sucrose is amongst the most widely used preparations for the treatment of iron deficiency anemia during pregnancy.[6] It has a recognized safety profile and thus still stands as one of obstetrics drug of choice. The drug has polynuclear iron(III) -hydroxide cores stabilized with sucrose molecules for controlled drug delivery of iron for hematopoiesis. Its use has generally been with low risk of serious adverse drug reaction, namely anaphylaxis, compared with previous preparations of iron. Iron sucrose has disadvantages, of which the most glaring are low maximum dosing of drug per administration, typically not more than 200 mg, requiring multiple infusions for total correction of iron deficit.[6] It implies greater use of health care facilities and greater patient burden with multiple attendances at the hospital. Despite these disadvantages, it still has its niche as an ideal drug for those women with slow and stable normalization of iron deficiency and intensive monitoring with base of operations at the hospital.

Ferric carboxymaltose, a newer intravenous iron formulation, has gained considerable attention for its ability to deliver larger single doses, often up to 1,000 mg, within a short infusion time.[7] Its molecular structure, consisting of iron(III) hydroxide tightly bound to a carbohydrate polymer (carboxymaltose), provides a highly stable complex that minimizes the release of labile iron and reduces oxidative stress. This pharmacological advantage allows rapid repletion of iron stores in fewer treatment sessions, improving patient compliance and reducing the overall burden of care.[8] Clinical studies have demonstrated that ferric carboxymaltose leads to a more rapid and sustained increase in hemoglobin compared to iron sucrose, with comparable safety outcomes.[9] While minor adverse effects such as transient hypophosphatemia, headache, or mild infusion-related reactions have been reported, serious complications are rare.[10] In pregnancy, its use has proven effective in correcting anemia, improving maternal well-being, and contributing to favorable neonatal outcomes.[11] For women requiring quick restoration of iron stores close to delivery, ferric carboxymaltose presents an efficient and well-tolerated alternative to iron sucrose.[12]

Jose et al. reported that the mean rise in hemoglobin at 12 weeks was 29.6 ± 8.2 g/L in the ferric carboxymaltose group and 22.1 ± 8.2 g/L in the iron sucrose complex group.[13]

It is imperative that this study should be carried out in Muzaffarabad, Kashmir, since there exists a very high rate of anemia in pregnancy in the region which has been ascribed to prevailing nutritional deficiencies, inadequacy of health facilities, and late antenatal visitation. There are few local data on the comparative efficacy of intravenous sucrose and carboxymaltose such that it is necessary for evidence specific for this population to be generated. This would help clinicians make the best choice of therapy, enhance maternal and neonatal outcome, and facilitate decision-making for appropriate antenatal care policies for the populace of this region.

METHODOLOGY

This randomized controlled trial was conducted from June 2024 to November 2024 at the Department of Obstetrics and Gynecology, SKBZ CMH Muzaffarabad. Pregnant women between 16 and 24 weeks of gestation diagnosed with moderate to severe iron deficiency anemia, having hemoglobin levels between 7 g/dL and 10 g/dL, were included in the study. Patients with anemia due to other causes, chronic infections such as hepatitis or HIV, impaired liver or renal function, or known hypersensitivity to intravenous iron preparations were excluded. Sample size was calculated based on the expected mean rise in hemoglobin of 29.6 ± 8.2 g/L in the ferric carboxymaltose group and 22.1 ± 8.2 g/L in the iron sucrose complex group, as reported in previous literature.[13] Using a 95% confidence level and 80% power, the required sample size was 26 patients per group (52 in total). To accommodate potential dropouts and ensure adequate power, the final sample size was set at 60 patients, with 30 patients in each group. Eligible patients were randomized in a 1:1 ratio into two groups using a computer-generated randomization table. Baseline characteristics including age, parity, gestational age, socioeconomic status, and residential status were recorded.

In the FCM group, intravenous ferric carboxymaltose was administered at a maximum of 1000 mg per sitting, diluted in 200 mL of normal saline, and infused over 30 minutes. Repeat doses, if required, were scheduled at one-week intervals. In the ISC group, intravenous iron sucrose complex was given as 300 mg diluted in 200 mL of normal saline, infused over 15–20 minutes, twice weekly, not exceeding 600 mg per week, until the total calculated iron requirement was achieved. Iron deficit was calculated using Ganzoni's formula. All patients received tablet mebendazole (100 mg twice daily for three days) and folic acid (5 mg once daily). Clinical monitoring was performed during and after infusion, and any adverse reactions were documented. Patients were followed at 3, 6, and 12 weeks after initiation of therapy. At each follow-up, hemoglobin, red cell indices, and serum iron studies were performed. The primary outcome was the change in hemoglobin from baseline after 12 weeks.

Data were analyzed using IBM SPSS version 26. Continuous variables were presented as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages. A p-value < 0.05 was considered statistically significant. The change in hemoglobin between the ferric carboxymaltose and iron sucrose complex groups was compared using the independent samples t-test, and a p-value < 0.05 was considered statistically significant. The association of demographic variables with change in hemoglobin was assessed using independent t-test.

RESULTS

Patient demographics showed similar baseline characteristics between the IV ferric carboxymaltose and IV iron sucrose groups, with mean ages of 27.83±3.39 years versus 27.63±3.73 years respectively, parity of 2.73±1.31 versus 2.63±1.45, and gestational ages of 26.50±3.43 weeks versus 26.27±3.66 weeks (as shown in Table I). Regarding socioeconomic status distribution, the poor category comprised 12 patients (40.0%) in the ferric carboxymaltose group versus 13 patients (43.3%) in the iron sucrose group, middle class included 16 patients (53.3%) in both groups, while the rich category had 2 patients (6.7%) versus 1 patient (3.3%) respectively. Residence patterns showed rural distribution of 18 patients (60.0%) versus 15 patients (50.0%), and urban distribution of 12 patients (40.0%) versus 15 patients (50.0%) in the ferric carboxymaltose and iron sucrose groups respectively (as shown in Table I).

Table I
Patient Demographics

Demographics	IV Ferric Carboxymaltose Group (n=30)	IV Iron Sucrose Group (n=30)
Age (years)	27.83±3.39	27.63±3.73
Parity	2.73±1.31	2.63±1.45
Gestational Age (weeks)	26.50±3.43	26.27±3.66
Socioeconomic Status		

Poor n (%)	12 (40.0%)	13 (43.3%)
Middle n (%)	16 (53.3%)	16 (53.3%)
Rich n (%)	2 (6.7%)	1 (3.3%)
Residence		
Rural n (%)	18 (60.0%)	15 (50.0%)
Urban n (%)	12 (40.0%)	15 (50.0%)

Hemoglobin analysis revealed no significant difference in baseline levels between groups, with ferric carboxymaltose showing 84.13±4.14 g/L compared to iron sucrose at 84.04±3.87 g/L (p=0.934). However, post-treatment hemoglobin levels demonstrated significant superiority of ferric carboxymaltose at 113.45±4.95 g/L versus iron sucrose at 106.29±4.87 g/L (p<0.001). The change in hemoglobin from baseline was substantially greater with ferric carboxymaltose at 29.32±3.23 g/L compared to iron sucrose at 22.25±1.75 g/L (p<0.001) (as shown in Table II).

Table II

Comparison of Hemoglobin Levels Between Groups

Hemoglobin Levels	Ferric Carboxymaltose Group (n=30)	Iron Sucrose Group (n=30)	P value
Baseline Hb (g/L)	84.13±4.14	84.04±3.87	0.934
Post-Treatment Hb (g/L)	113.45±4.95	106.29±4.87	<0.001
Change in Hb (g/L)	29.32±3.23	22.25±1.75	<0.001

For age stratification, patients ≤30 years showed changes of 29.24±3.59 g/L versus 22.10±1.72 g/L (p=0.711), while those >30 years demonstrated 29.65±1.07 g/L versus 22.74±1.90 g/L (p<0.001) for ferric carboxymaltose and iron sucrose respectively. Parity analysis showed that patients with ≤3 children had hemoglobin changes of 29.21±3.66 g/L versus 22.10±1.72 g/L (p<0.001), while those with >3 children showed 29.67±0.97 g/L versus 22.74±1.90 g/L (p<0.001). Socioeconomic stratification revealed that poor patients achieved changes of 29.44±2.51 g/L versus 21.31±1.64 g/L (p<0.001), middle-class patients showed 30.21±2.55 g/L versus 23.06±1.50 g/L (p<0.001), while rich patients demonstrated identical results of 21.50±0.00 g/L versus 21.50±0.00 g/L (p=1.000). Residence-based analysis showed rural patients achieving 29.47±2.73 g/L versus 21.71±1.86 g/L (p<0.001), and urban patients demonstrating 29.10±3.99 g/L versus 22.79±1.50 g/L (p<0.001) for ferric carboxymaltose and iron sucrose groups respectively (as shown in Table III).

Table III

Stratification of Mean Change in Hemoglobin with Respect to Demographic Factors in Both Groups

Demographic Factors	Group		Mean Change in Hb (g/L) Mean ± SD	P Value
Age (years)	≤30	Ferric Carboxymaltose (n=24)	29.24±3.59	0.711
		Iron Sucrose (n=23)	22.10±1.72	
	>30	Ferric Carboxymaltose (n=6)	29.65±1.07	<0.001
		Iron Sucrose (n=7)	22.74±1.90	
Parity	≤3	Ferric Carboxymaltose (n=23)	29.21±3.66	<0.001
		Iron Sucrose (n=23)	22.10±1.72	
	>3	Ferric Carboxymaltose (n=7)	29.67±0.97	<0.001
		Iron Sucrose (n=7)	22.74±1.90	
Socioeconomic Status	Poor	Ferric Carboxymaltose (n=12)	29.44±2.51	<0.001
		Iron Sucrose (n=13)	21.31±1.64	
	Middle	Ferric Carboxymaltose (n=16)	30.21±2.55	<0.001
		Iron Sucrose (n=16)	23.06±1.50	
	Rich	Ferric Carboxymaltose (n=2)	21.50±0.00	1.000
		Iron Sucrose (n=1)	21.50±0.00	
Residence	Rural	Ferric Carboxymaltose (n=18)	29.47±2.73	<0.001
		Iron Sucrose (n=15)	21.71±1.86	
	Urban	Ferric Carboxymaltose (n=12)	29.10±3.99	<0.001
		Iron Sucrose (n=15)	22.79±1.50	

DISCUSSION

The comparable baseline demographies between groups, including age, parity, gestational age, socioeconomic status, and residence, ensure any observed differences in treatment outcomes can adequately be attributed to interventions rather than patient characteristics. Homogenous baseline hemoglobin concentrations (84.13±4.14 g/L versus 84.04±3.87 g/L, p=0.934) further support similarity in the study population and exclude selection bias as a confounding factor.

The increased rise in hemoglobin observed for ferric carboxymaltose (29.32±3.23 g/L versus 22.25±1.75 g/L, p<0.001) is a consequence of its molecular framework and pharmacokinetic features. Ferric carboxymaltose is a stable iron-carbohydrate compound with a regulated release of iron directly in iron-poor sites without transferrin saturation in order not to cause free iron-mediated peroxidative stress.[14] Such a methodology allows administration in single infusions so as to lead to increased iron utilization and an earlier production in comparison with iron sucrose whose administration in multiple smaller doses is obligatory because it is not so stable at a molecular level and is cleared so quickly from the circulating system.

The systematic superiority of ferric carboxymaltose over strata like age, parity, socioeconomic status, and residence means an independence of patient-specific variables in its action. The remarkable result seen with ferric carboxymaltose retaining its efficacy at all levels of socioeconomic status means an indifference towards nutritional status or adherence issue so commonly a property of variable economic strata. Absence of significant age-dependent variation in response towards treatment ($p=0.711$ for ≤30 years group) is most likely a result of physiologically similar iron metabolism and capability for hemoglobin synthesis within reproductive age range in pregnant women.

Our findings are strongly consistent with previous studies demonstrating the superiority of ferric carboxymaltose (FCM) over iron sucrose (ISC). Jamal et al.[15] observed rises of 3.18 ± 0.60 g/dL versus 2.14 ± 0.81 g/dL, while Saleem et al. [16] reported increases of 2.0 ± 0.3 g/dL versus 1.4 ± 0.2 g/dL in the FCM and ISC groups, respectively. The convergence of findings across multiple trials, despite differences in baseline hemoglobin levels and gestational ages, highlights the robust therapeutic advantage of FCM across diverse clinical settings.

In our study, the superiority of FCM was consistent across demographic subgroups, including age, parity, socioeconomic status, and place of residence, suggesting its benefit is independent of patient-specific variables. This observation aligns with Sharma et al. [17] who documented significantly higher hemoglobin levels with FCM (11.6 ± 0.77 g/dL vs. 10.60 ± 0.87 g/dL, $p<0.001$), and Arzoo et al. [18] who demonstrated greater rises in hemoglobin from 9.2 ± 1.1 to 11.9 ± 1.0 g/dL with FCM compared to 9.3 ± 1.2 to 11.3 ± 1.1 g/dL with ISC ($p<0.001$). Notably, the single-dose regimen of FCM eliminates compliance-related barriers associated with multi-dose ISC, which may explain its consistent performance across varying socioeconomic backgrounds.

Age-stratified analysis further revealed that while no significant differences were observed in women ≤30 years ($p=0.711$), FCM showed greater efficacy in those >30 years ($p<0.001$). This suggests that older pregnant women, who may experience reduced iron absorption and altered metabolism, derive particular benefit from the superior bioavailability and sustained release of FCM. To our knowledge, such age-related differential responses have been rarely reported, making this an important contribution to individualized therapy considerations.

An interesting anomaly was the absence of difference in the high socioeconomic group, where both treatments achieved identical hemoglobin rises (21.50 ± 0.00 g/L; $p=1.000$). This likely reflects the very small sample size (n=2 vs. n=1) or possibly better baseline nutrition and adherence to supportive therapies among wealthier patients, which may reduce the treatment gap between FCM and ISC. Similar observations by Papaniya et al. [19] who reported more modest early rises (1.67 ± 0.47 g/dL vs. 1.07 ± 0.25 g/dL, $p<0.0001$), suggest that the therapeutic advantage of FCM becomes more pronounced with longer follow-up periods, as seen in our data.

Beyond hemoglobin, FCM has also shown superior replenishment of iron stores. Chaturvedi et al. [20] reported ferritin levels of 435.2 µg/L with FCM versus 377 µg/L with ISC at 3 weeks ($p=0.02$), while Saleem et al. [16] observed ferritin rises of 370.9 ± 47.6 ng/mL compared to 261.1 ± 34.2 ng/mL. These findings, in line with our study, highlight the enhanced ability of FCM to restore iron reserves, which is critical for sustaining hemoglobin production throughout pregnancy and reducing recurrence of anemia. The molecular stability of FCM facilitates efficient iron incorporation into ferritin, ensuring ongoing availability for erythropoiesis beyond the immediate treatment window.

Collectively our findings, in keeping with a number of independently performed researches, support ferric carboxymaltose as a successful therapy for iron deficiency anemia in pregnancy. Its consistent efficacy in a large population of patients, superior response in ferritin, as well as dose-independent compliance, make it a reliable intervention in optimising maternal hematological outcomes.

There are certain limitations in this study which should be highlighted. Due to it being a single-center study, generalizability of findings might be restricted. That sample size is modest, especially in certain subgroups such as upper socioeconomic groups, might have decreased statistical power for detection of fine distinctions. Follow-up was further restricted to antenatal periods only without regard for postpartum results or neonatal parameters. To substantiate and prolong such findings, more multicenter research with greater patient groups and longer term follow-up is warranted.

CONCLUSION

Our investigation concluded that ferric carboxymaltose is superior to iron sucrose when treating iron deficiency anemia in pregnancy. It was consistently superior in an assortment of patient subgroups in verifying its therapeutic advantage irrespective of demographic or socio-economic factors. As a result of its single administration regimen with effective replenishment of stores for both hemoglobin as well as iron stores, ferric carboxymaltose is a convenient as well as a reliable option for maximizing maternal outcomes in antenatal care.

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