Original Article

Comparison of Ferric Carboxymaltose Versus Iron Sucrose for Treatment of Iron Deficiency Anaemia in Pregnant Women

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Abstract

Objective: To compare the mean rise in hemoglobin with ferric carboxymaltose versus iron sucrose for treating iron deficiency anaemia in pregnant women

Methodology: This randomized controlled trial study was conducted at Department of Obstetrics & Gynaecology, Combined Military Hospital Multan from February 2024 to July 2024. Sixty pregnant women (20-45 years, 28-34 weeks gestation) with iron deficiency anemia (Hb <10 gm%, ferritin <30 ng/ml) were randomized via lottery method to intravenous ferrous carboxymaltose (FCM; 1000 mg/sitting) or iron sucrose complex (ISC; 300 mg twice weekly). Both groups received anthelminthic therapy and folic acid. Total iron dose was calculated as (2.4×weight×Hb deficit) +500 mg. Hemoglobin, ferritin, and demographics were recorded. Post-treatment outcomes were assessed at 3 weeks. Descriptive statistics were run using SPSS version 23. The mean rise in hemoglobin between the groups was compared through independent t-tests at 5% significance level.

Results: Participants' mean age was 31.4±3.9 years. Baseline Hb and ferritin were 8.8±0.5 g/dL and 31.6±12.8 ng/mL respectively. Post-treatment, FCM demonstrated higher mean Hb (10.7±0.4 vs.10.4±0.3 g/dL), ferritin (370.9±47.6 vs.261.1±34.2 ng/mL), and Hb rise (2.0±0.3 vs.1.4±0.2 g/dL) compared to ISC (p<0.001). Educational status, socioeconomic class, and baseline Hb differed significantly between groups. Stratified analysis confirmed sustained superiority of FCM across demographics (p<0.001).

Conclusion: Intravenous ferrous carboxymaltose outperformed iron sucrose in correcting haemoglobin and levels of ferritin in iron-deficient pregnant women, despite baseline disparities. FCM offers a more efficacious parenteral iron therapy option in this population.

Key Words: Ferric carboxymaltose, Iron sucrose, Iron deficiency anemia, Pregnancy.

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Introduction

An estimated 32.4 million pregnant women globally suffer from anemia, according to World Health Organization (WHO).[1] In addition, iron deficiency anemia (IDA) accounts for 50% of anemia cases.[2] It accounts for 40% of maternal fatalities in developing countries and is a global public health concern.[3] Hemoglobin level below 11 gm% is taken as anemia by the WHO. Inadequate dietary iron intake, less bioavailability of iron, poor eating habits, and a high prevalence of diseases like malaria are the causes of high incidence of anemia in Pakistan.[5] Because of the high need for iron during gestational period needed for developing fetus and placenta, it is typical for pregnant women to progress from iron deficiency to iron deficiency anemia (IDA).[6]

Preterm delivery, intrauterine growth retardation, increased susceptibility to infection, and perinatal mortality and morbidity are just a few of the pregnancy issues that can result from IDA.[7] Iron supplementation, whether taken orally or in intravenous form, is the cornerstone of treatment for IDA. This is especially true for individuals who require quick return of iron reserves in cases of moderate to severe anemias, particularly in last trimester of pregnancy, or who are intolerant to oral

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iron. Ferric carboxymaltose (FCM) and iron sucrose (IS) are dextran-free iron preparations used in parenteral treatment.[8]

One hundred pregnant women were randomly assigned to either intravenous FCM or IS by Papaniya TD et al. At 4 weeks, the mean rise in Hb (gm%) in FCM group was substantially larger than that of the IS group (1.67±0.47 vs. 1.07±0.25 gm%; p<0.0001). Other biochemical indicators, such as MCV and MCHC, increased in both groups as well.[9] Jose A et al published a comparative study on one hundred pregnant women who were split equally into two groups. The FCM group experienced a substantially greater mean rise in Hb (g/L) after 12 weeks (29.6 ± 8.2 vs. 22.1 ± 8.2 g/L; p value < 0.01).[10]

For pregnant individuals who are anemic, parenteral treatment offers a greater response. This study has been planned to compare the efficacy of intravenous FCM and IS for treating anemia in pregnant women. The results obtained from our local setting will provide evidence to practice most suitable IV iron preparation in the form of better efficacy and less frequent visits. It will lessen blood transfusions requirement antenatally as well as postnatally. We hypothesized that mean rise in hemoglobin will be higher in women undergoing treatment with iron carboxymaltose versus iron sucrose complex infusion.

Methodology

This open label, parallel group randomized controlled trial (trial reg # NCT06911034) was performed in duration of 6-months (1st February 2024 - 31st July 2024) at Obstetrics & Gynaecology department, Combined Military Hospital Multan after approval from the ethics review committee (ERC # 147/2023, dated 29th December 2023). Out of 80 pregnant women assessed for eligibility, 20 were excluded due to not meeting inclusion criteria (n=5), declining participation (n=10), or other reasons (n=5). A total of 60 participants were randomized equally into two groups: 30 received intravenous ferric carboxymaltose (FCM), and 30 received intravenous iron sucrose complex (ISC). There were no losses to follow-up or discontinued interventions in either group. All 60 participants completed the study and were included in the final analysis for the primary outcome.

A total of 60 pregnant ladies with IDA, 20-45 years of age and 28-34 weeks of gestation were consecutively enrolled after obtaining informed consent. The women with chronic infectious illnesses like hepatitis and AIDS; serum transaminase levels >1.5 times the upper limit of normal; serum creatinine level of more than 2.0 mg/dL, women with hypophosphatemia (serum phosphate level below 2.5 mg/dL), women with hemoglobinopathies (based on Haemoglobin electrophoresis), or history of allergic reaction to intravenous iron infusion were excluded from the study.

The data on age, gestation, parity, area of residence, educational status and socioeconomic status was recorded. All patients underwent venous sampling through aseptic technique and complete blood counts including hemoglobin and serum ferritin were measured from single laboratory. Iron deficiency anemia was labelled if hemoglobin is <10 gm% and serum ferritin less than 30 ng/ml. Total iron requirement was calculated by formula (2.4×body weight (in kg) × hemoglobin deficit) + 500 mg (iron reserves). Haemoglobin deficit was measured by subtracting from 11 gm%. The World Bank classification was used to evaluate socioeconomic condition, depending on monthly household income and classified as: Low (≤ 11605 PKR), lower middle (11606 - 45395 PKR), upper middle (45396 - 140461 PKR) and High (> 140461 PKR).

All pregnant ladies were administered anthelminthic treatment with tablet mebendazole 100 mg 2 times a day for 3 days and given 5 mg Folic acid once a day. Through lottery method, using sealed opaque envelopes, participants were randomly assigned to intravenous ferrous carboxymaltose and intravenous iron sucrose complex. Parenteral iron treatment was given under supervision of doctor on duty. In ferrous carboxymaltose group maximum dose per sitting was 1000 mg in dilution of 200 ml full strength normal saline and given as an intravenous infusion over 30 min. In iron sucrose group infusion was administered as 300 mg in 200 ml normal saline over 15-20 min 2 times a week till total iron requirement was achieved, not to administer 600mg/week. The pregnant mothers were then called for follow up 3 weeks after parenteral iron therapy and hemoglobin and serum ferritin levels were noted again. Increase in hemoglobin was calculated by subtracting post treatment hemoglobin from pretreatment levels.

A minimum sample size of 60 women (30 in each group) was calculated through OpenEpi online calculator assuming mean rise of Hb in carboxypolymaltose group as 1.67±0.47 gm%, mean rise in Hb in in sucrose complex group as 1.07±0.25 gm%,[9] 80% power of the study and 95% confidence level. Normality of numerical data was assessed through Shapiro-Wilk test. Mean ±

SD was calculated for numerical data and frequency percentages for categorical data. Mean rise in hemoglobin and serum ferritin between the groups were compared through independent sample t-test and p-value < 0.05 was taken as significant.

Results

The mean age of the participants was 31.4 ± 3.9 years and median parity was 3 (IQR-2). The participants belonged from urban areas in 32(53.3%) majority were having higher secondary 19(31.7%) and secondary education 12(20%). Two third of the participants came from middle socioeconomic class; 25(41.7%) upper middle and 30% (n=18) from lower middle. The mean hemoglobin (g/dl) and ferritin (ng/ml) before treatment were 8.8 ± 0.5 and 31.6 ± 12.8 respectively. Educational status, socioeconomic status and mean hemoglobin level were significantly different between pregnant women treated with iron carboxymaltose and iron sucrose complex. Table I

The mean hemoglobin (g/dl), ferritin (ng/ml) and rise in hemoglobin after treatment were 10.5 ± 0.4, 315.9 ± 68.9 and 1.7 ± 0.4 respectively. The mean hemoglobin (g/dl), ferritin (ng/ml) and rise in hemoglobin were significantly (p-value < 0.001) higher in pregnant women treated with iron carboxymaltose (10.7 ± 0.4, 370.9 ± 47.6 and 2.0 ± 0.3) compared to iron sucrose complex (10.4 ± 0.3, 261.1 ± 34.2 and 1.4 ± 0.2). Table II

After stratification on demographic characteristics the effect on mean hemoglobin (g/dl), ferritin (ng/ml) and rise in hemoglobin remained significantly high (p-value < 0.001) in iron carboxymaltose treatment compared to iron sucrose complex. Table III

Discussion

Iron deficiency anaemia, a preventable illness, affects about 50% of pregnant women, making it a major

Table I: Baseline characteristics of study groups.

		Total (n=57)	ISC (n=29)	FCM (n=28)	Mann-Whitney U	p-value
Age (years)		25.0 (7.0)	24.0 (8.0)	25.0 (5.0)	429.5	0.706*
Household income (PKR/month)		30000.0 (20000.0)	30000.0 (20000.0)	30000.0 (31000.0)	418.5	0.841*
Education status	Illiterate	07 (100.0%)	04 (57.1%)	03 (42.9%)	-	0.899**
	Primary	05 (100.0%)	03 (60.0%)	02 (40.0%)		
	Middle	08 (100.0%)	05 (62.5%)	03 (37.5%)		
	Matric	24 (100.0%)	11 (45.8%)	13 (54.2%)		
	Graduate	13 (100.0%)	06 (46.2)	07 (53.8%)		
Place of residence	Urban	49 (100.0%)	24 (49.0%)	25 (51.0%)	-	0.706**
	Rural	08 (100.0%)	05 (62.5%)	03 (37.5%)		
Employment status	Housewife	47 (100.0%)	25 (53.2%)	22 (46.8%)	-	0.504**
	Working	10 (100.0%)	04 (40.0%)	06 (60.0%)		
Gestational age (weeks)		32.0 (4.0)	31.0 (4.0)	33.0 (5.0)	522.0	0.061*
Gravida		2.0 (2.0)	3.0 (2.0)	2.0 (2.0)	354.5	0.397*
Para		1.0 (2.0)	1.0 (2.0)	1.0 (3.0)	364.5	0.491*
Miscarriage		0.0 (0.0)	0.0 (1.0)	0.0 (0.0)	381.0	0.574*

*Mann-Whitney U test; **Pearson Chi square test

Table II: Comparison of iron profiles and effective breastfeeding between study groups.

		Total (n=57)	ISC (n=29)	FCM (n=28)	Mann-Whitney U	p-value
Baseline hemoglobin level (g/dl)		8.7 (1.0)	8.8 (0.8)	8.6 (1.1)	309.5	0.122*
Baseline ferritin level (ng/ml)		12.0 (12.0)	16.0 (8.0)	10.0 (10.0)	237.0	0.007*
Iron dose calculated		910.0 (226.0)	917.0 (224.0)	857.0 (252.0)	463.0	0.362*
Iron dose administered		600.0 (100.0)	600.0 (100.0)	500.0 (0.0)	259.0	0.014*
Number of infusions		2.0 (2.0)	3.0 (1.0)	1.0 (0.0)	40.0	<0.001*
Postpartum hemoglobin level (g/dl)		9.7 (1.0)	9.5 (0.7)	10.0 (1.4)	637.5	<0.001*
Postpartum ferritin level (ng/ml)		31.0 (13.0)	33.0 (17.0)	30.0 (9.0)	296.5	0.080*
Change in hemoglobin level (g/dl)		1.1 (1.2)	0.8 (0.4)	1.9 (0.8)	725.0	<0.001*
Change in ferritin level (ng/ml)		19.0 (14.0)	19.0 (18.0)	21.5 (15.0)	388.5	0.780*
Neonatal weight gain (grams)		543.0 (664.0)	680.0 (155.0)	31.0 (14.0)	88.5	<0.001*
Breastfeeding initiation time (hours)		12.0 (16.0)	20.0 (16.0)	9.0 (12.0)	175.5	<0.001*
Lactation adequacy	Sufficient	39 (100.0%)	23 (59.0%)	16 (41.0%)	-	0.072**
	Insufficient	18 (100.0%)	06 (33.3%)	12 (66.7%)		

*Mann-Whitney U test; **Pearson Chi square test

Table III: Impact of maternal factors and iron therapy on effective breastfeeding.

	Model 1			Model 2			Model 3		
	Neonatal weight gain								
	β	**SE**	**p-value**	**β**	**SE**	**p-value**	**β**	**SE**	**p-value**
IRT (ISC/FCM)	-498.532	48.376	<0.001	-339.475	55.32	<0.001	-321.251	52.990	<0.001
Change in Hb level				-153.737	34.943	<0.001	-148.720	33.378	<0.001
Age (years)							-6.694	5.098	0.195
Gestational age (weeks)							-21.837	9.034	0.019
Para							4.728	18.699	0.801
	Breastfeeding initiation time								
	β	**SE**	**p-value**	**β**	**SE**	**p-value**	**β**	**SE**	**p-value**
IRT (ISC/FCM)	-8.637	2.031	<0.001	-8.702	2.708	0.002	-8.396	2.783	0.004
Change in Hb level				0.064	1.710	0.970	0.252	1.753	0.886
Age (years)							0.136	0.268	0.614
Gestational age (weeks)							-0.454	0.475	0.343
Para							-0.187	0.982	0.850
	Lactation adequacy (sufficient/insufficient)								
	OR	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
IRT (ISC/FCM)	2.875	0.893-9.258	0.077	6.162	1.082-35.086	0.040	5.593	0.997-31.363	0.050
Change in Hb level (≥1.0/<1.0)				3.101	0.552-17.413	0.199	2.579	0.443-14.995	0.292
Age (≤25/>25 years)							0.748	0.198-2.827	0.668
Gestational age (≤32/>32 weeks)							0.902	0.265-3.070	0.868
Para (≤2/>2)							0.643	0.128-3.226	0.592

IRT: Iron replacement therapy; ISC: Iron sucrose complex; FCM: Ferric carboxymaltose; Hb: Hemoglobin; β: Unstandardized coefficient; SE: Standard error

worldwide health concern. Intravenous iron treatment can lower the risk of morbidity and mortality during gestational period, and promptly addressing this issue can lessen the strain on the healthcare system by lowering anemia-related delivery problems.[11] When moderate to severe IDA occurs during pregnancy, iron sucrose is the usual medication used as parenteral iron treatment. Its lesser maximum dose per sitting and per week, however, is a significant drawback because it requires repeated visits to provide the necessary iron dose. Large doses of FCM can be given in a single sitting with greater safety and effectiveness.[12]

Mean age of our study participants was comparable to participants in other studies. In this study, mean age of the participants was 31.4 ± 3.9 years. According to Patel AR, 49% of the women were between the ages of 24 and 32 years.[13] According to Papaniya TD et al, most of the patients were between the ages of 20 and 30 years.[9] Most participants in this study received higher secondary education (31.7%), were from the upper middle socioeconomic class (41.7%), and came from urban areas (53.3%). Due to nutritional deficiencies, a diet high in phytate, frequent infections like intestinal worms and malaria, and shorter time between pregnancies, iron deficiency anaemia is known to be more common in low socioeconomic class and illiterate communities.[14]

We found majority population with IDA belonging to urban areas. According to reports, people who live in cities tend to eat more processed meals that are deficient in important elements like iron. This dietary pattern increases the risk of IDA during pregnancy by causing an inadequate intake of iron. Urban populations frequently consume large amounts of tea, which contains chemicals that prevent the absorption of iron. According to a study done in Hyderabad, Pakistan, pregnant women who drank more than three cups of tea a day prior to becoming pregnant had a considerably higher risk of anaemia.[15]

In our study, mean hemoglobin (g/dl), ferritin (ng/ml) and rise in hemoglobin were significantly higher in pregnant women treated with iron carboxymaltose compared to iron sucrose complex. Similar findings were described by Patel AR, who found that serum ferritin and haemoglobin levels increased significantly (p<0.001) in both groups, but that the rise was greater in the group that was administered FCM.[13] Christoph P et al found that ferric carboxymaltose was as safe and tolerable as iron sucrose, and it also showed a similar increase in haemoglobin percentage at the conclusion of the study.[16] In contrast, after three weeks, the FCM group in the current study had noticeably greater haemoglobin levels than the iron sucrose group.

According to studies by Ambily J et al and Divyani and colleagues, women who were administered IV FCM had significantly higher levels of serum ferritin and haemoglobin than those who got iron sucrose.[17,18] Our results are comparable with these findings. Like this study, a study by Sabina K et al, in 2019, found that serum ferritin rose significantly following parenteral iron therapy in both IS and FCM treatment groups, but the increase was significantly greater in the ferric carboxymaltose group.[19]

In a recent study conducted by Patel GR et al, enrolled 334 pregnant women in second or third trimester with moderate to severe iron-deficiency anemia. They compared intravenous iron sucrose and FCM, reporting significantly greater rise in hemoglobin and ferritin at both 3 and 6 weeks in the FCM group ($p < 0.0001$).[20] These results mirror our findings.

With little chance of releasing significant amounts of ionic iron into the bloodstream, ferric carboxymaltose enables the regulated transport of iron within the reticuloendothelial system's cells and then to the iron-binding proteins ferritin and transferrin.[21] When FCM is administered intravenously, serum iron, ferritin, and transferrin saturation temporarily increase. Then haemoglobin levels improve and the depleted iron stores are restored.[22]

The levels of total iron in the blood increase quickly in a dose-dependent manner following IV administration of FCM. Ferric carboxymaltose is quickly removed from the blood and is mainly deposited in the bone marrow (about 80%), as well as in the liver and spleen.[23] Frequent administration of FCM once a week, does not cause transferrin iron deposition in iron-deficient patients.[24]

Prior research comparing the therapy costs for FCM and IS treatment has shown that the FCM group incurs much lower costs.[25] The overall cost of the drugs in both groups was not evaluated in this study, nor were travel expenses or the number of lost working days resulting from travel included. These factors would have been higher in the ISC group because of the substantially larger number of hospital visits. Because the IS group required many visits to acquire the full dosage, the total treatment cost would have been increased. Another limitation of our research was that adverse effects of both intravenous iron therapies were not assessed. This restricts the evaluation of safety profiles and patient tolerance, which are important for clinical decision-making. Future studies should incorporate monitoring of side effects to provide more comprehensive comparison.

Conclusion

According to our study, ferric carboxymaltose works better than IS as a parenteral iron therapy for treating iron deficient anaemia and restoring iron stores. FCM provides several advantages over iron sucrose, including the ability to administer high dosages in a single sitting, an early rise in haemoglobin, a lower total number of doses needed, which shortens treatment times, and cost effectiveness. Because FCM treatment involves fewer visits, which lowers transportation costs, and because it eliminates the discomfort associated with repeated needle punctures, patients are more compliant.

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