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Efficacy of Intravenous Ferric Carboxymaltose Versus Iron Sucrose in the Treatment of Iron Deficiency Anemia of Pregnancy

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ABSTRACT

Iron deficiency anemia (IDA) during pregnancy is a widespread disease associated with adverse effects on both the mother and fetus. **Objectives:** To determine the effectiveness of intravenous ferric carboxymaltose (FCM) versus iron sucrose (IS) for improving hematological parameters in pregnancy-related iron deficiency anemia. **Methods:** This Quais experimental study was conducted over six months from January 2024 to June 2024 at Rai Medical College Sargodha. A total number of participants was n=120 pregnant IDA women (Hb<10.5 g/dL), gestational age (GA) 16 to 34 weeks), were seen and randomly assigned to either group A or group B. Iron sucrose was given as 200 mg intravenously in 200 ml of normal saline over 15-20 minutes on alternate days, with a maximum dose of 1000 mg per week. Ferric Carboxymaltose was given in a single dose, diluted in normal saline over 15-20 minutes, with a maximum of 1000 mg per day or per week. Assessment of Serum Ferritin and Hemoglobin levels at Baseline, 4th Weeks, and 8th Weeks Post-treatment, and adverse events. **Results:** There was a significant difference in mean Hb values between Group 1 and Group 2 in 4th week ($p<0.05$). Serum ferritin also improved significantly in the FCM group. When comparing FCM with IS, FCM was safer, with fewer adverse events. Patients in the FCM group also had higher rates of satisfaction and adherence and had fewer missed doses. **Conclusions:** It was concluded that FCM has quickly restored iron levels in pregnant women, significantly increasing Hb and ferritin levels over the 8th week with minor side effects.

INTRODUCTION

According to estimates from the World Health Organization (WHO), almost two billion individuals, or 25% of the global population are anemic with around half of them having iron deficiency anemia (IDA). Additionally, there is at least one patient with iron deficiency who does not have anemia for every IDA patient. Thus, iron deficiency with or without anemia affects over two billion people worldwide, the majority of whom live in nations with limited resources. Iron deficiency anemia (IDA) during pregnancy is a critical public health problem. Intravenous (IV) iron therapies, including ferric carboxymaltose (FCM) and iron sucrose (IS), are often used by pregnant women with IDA [1, 2]. Both mothers and their children may experience negative health consequences from anemia and IDA, including infections, early membrane rupture, fetal development restriction, fetal hypoxia, early birth, low birth weight, and fetal death. Maternal anemia is responsible for 18% of perinatal deaths, 19% of preterm deliveries, and 12% of low birth weights in low- and middle-income nations [3]. In general, IV iron therapy is preferred, after some wide practice showing its

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better repletion of iron stores quicker and more efficiently in cases of severe anemia or low response to oral therapy [4]. Intravenous iron therapy has a notable benefit over oral iron supplements for treating moderate-to-severe iron deficiency anemia (IDA), most importantly when prompt iron level correction is needed or when oral therapy has failed because of gastrointestinal (GI) side effects, non-compliance, or mal-absorption issues [5, 6]. Intravenous iron bypasses the digestive system, because of which rendered effective and direct, increasing the rate of hemoglobin restoration and the rate of iron storage restoration [5]. Among the various IV iron formulations available, iron sucrose (IS) and ferric carboxymaltose (FCM) are the most widely studied. FCM allows to administer substantially larger doses via a single infusion to decrease the follow-up visits and improve patient and convenience [7, 8]. It is also associated with a lower risk of adverse infusion-related events [9]. In contrast, IS is administered in smaller doses over multiple sessions, and it often takes 5–10 infusions to achieve the same total FCM dose [10]. While FCM and IS are both effective treatments for IDA, the choice is often dependent on patient preference, clinical circumstances and elements of the healthcare system [6, 11]. Ferric carboxymaltose and iron sucrose differ in pharmacokinetics, effect on patient adherence and dosing schedule, suggesting that both treatments could be compared. As indicated earlier that IS requires multiple small doses within several sessions, which has medical adherence implications, FCM allows high, single-session, rapid administration with the convenience advantages of shortening treatment duration. Limited studies are conducted in Pakistan regarding the alleviation of anemia among pregnant women using FCM and IS in dose-dependent manner.

This study aims to determine the effectiveness of intravenous ferric carboxymaltose (FCM) versus iron sucrose (IS) for improving hematological parameters in pregnancy-related iron deficiency anemia in hospitals.

METHODS

This Quasi experimental study was conducted over six months from January 2024 to June 2024 at Rai Medical College Sargodha. The study was approved by the Institutional Review Board number (RMCS/ERC/26/23), ensuring adherence to ethical standards. Informed consent was obtained from all participants before their involvement in the research. Inclusion criteria were pregnant women with (IDA) and Hb <10.5 g/dl, aged between 16 and 34 weeks of gestation were included in the study. Exclusion criteria included hypersensitivity to IV iron, causes of anemia other than IDA, and renal or hepatic impairment. The sample size formula was calculated by expected mean improvement in hB in ferric carboxymaltose11.6 ± 0.77 g/dl and iron sucrose 10.60 ± 0.87g/dl) by taking 80% power of test and 95% confidence interval as 22 which is too small to perform god statistical test with good efficiency so we increase sample size upto 120 (60 in each group) [12]. The sample size was calculated based on 80% power and at a significance level of 5% to detect a significant difference in hemoglobin (Hb) between the two groups, targeting 60 participants per group [13]. Participants were equally distributed in two groups, using block randomization. Iron sucrose was given as 200 mg intravenously in 200 ml of normal saline over 15-20 minutes on alternate days, with a maximum dose of 1000 mg per week. Ferric Carboxymaltose was given in a single dose, diluted in normal saline over 15-20 minutes, with a maximum of 1000 mg per day or per week. All patients were monitored for adverse reactions during and for 1-hour post-infusion in the ward. Patients were discharged from the ward after completion of the regimen, and each of them was followed up in the 4th week and 8th week after completion, to assess the increase in peripheral hemoglobin, serum ferritin and smear. Data were analyzed by SPSS version 22.0 and involved both descriptive and comparative analyses. Paired samples t-test for comparison of pre-treatment with post-treatment values (4th and 8th week) within each group (FCM and IS). Independent samples t-test for comparison between FCM and IS groups at 8th week post-treatment. The chi-square test was applied for the comparison of categorical data (side effects) between groups. A p-value<0.05 was considered statistically significant.

RESULTS

In our study, the number of subjects in the study was 120 (60 per group, FCM and IS). Demography including age, gestational age, BMI, parity and gravidity was similar between groups (p>0.05 for all). There was no significant difference in spans or means between pregnancies. For continuous variables presented as mean ± SD including age, gestational age, and inter-pregnancy interval, we used the independent t-test. For ordinal variables presented as medians with interquartile ranges which include parity and gravidity, the Mann-Whitney U test was applied. Categorical variables, including pre-treatment anemia type, iron supplementation use, and inter-pregnancy interval categories, were analyzed using the chi-square test. Additionally, Fisher's exact test was used when the expected frequencies in any cell were less than five (Table 1).

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Table 1: Demographic Characteristics of Participants

Characteristics	FCM Group (n=60)	IS Group (n=60)	p-Value
Age (Years) Mean ± SD	28.5 ± 4.8	29.3 ± 5.1	0.45
Gestational Age (Weeks) Mean ± SD	26.2 ± 3.6	25.8 ± 3.4	0.62
Parity	Median=2 (IQR: 1-3)	Median=2 (IQR: 1-3)	0.73
Gravidity	Median=3 (IQR: 2-4)	Median=3 (IQR: 2-4)	0.68
Pre-treatment Anemia Type (% Age)			
Microcytic Hypochromic	35%	36%	0.55
Normocytic Normochromic	40%	38%	0.55
Normocytic Hypochromic	25%	26%	0.55
Inter-Pregnancy Interval (Years)			
<1 Year	20 (33.3%)	25 (41.7%)	0.42
1-2 Years	25 (41.7%)	22 (36.7%)	0.42
>2 Years	15 (25.0%)	13 (21.6%)	0.42
Mean ± SD	1.8 ± 0.9	1.7 ± 0.8	0.56

The study compared changes in blood levels between Ferric Carboxymaltose (FCM) and Iron Sucrose (IS) from before treatment to the 4th and 8th weeks. In the FCM group, hemoglobin, serum ferritin, and iron levels, all increased significantly, with hemoglobin rising from 9.2 to 11.9 g/dL and ferritin from 20 to 85ng/mL by the 8th week. In the IS group, the improvements in these levels were smaller and not statistically significant. This shows that FCM works better than IS for improving iron levels and related blood markers (Table 2).

Table 2: Comparison of Hematological Changes Pre-Treatment (4th Week And 8th Week) Between FCM and IS Groups. p-value is Calculated Using an Independent T-Test

Parameters	Time Point	FCM (mean ± SD)	IS (mean ± SD)	p-Value
Hemoglobin (g/dL)	Pre-Treatment	9.2 ± 1.1	9.3 ± 1.2	<0.001
	4th Week	11.2 ± 1.0	11.1 ± 1.0	
	8th Week	11.9 ± 1.0	11.3 ± 1.1	
Serum Ferritin (ng/mL)	Pre-Treatment	20.0 ± 6.5	18.0 ± 5.9	<0.001
	4th Week	80.0 ± 8.3	70.0 ± 7.2	
	8th Week	85.0 ± 8.0	75.0 ± 7.5	
Iron (µg/dL)	Pre-Treatment	30 ± 8	28 ± 9	<0.001
	4th Week	90 ± 12	88 ± 11	
	8th Week	95 ± 11	92 ± 10	

The percentage of microcytic hypo-chromic, normocytic normochromic and normocytic hypo-chromic cells throughout the various time points was not different between the two treatments. p-value is Calculated Using the Chi-Square Test (Table 3).

Table 3: Comparison of Peripheral Blood Smear Pre vs Post-Treatment (4th Week and 8th Week) Between FCM and IS Groups Shown as Count and % Age

Anemia Type	Time Point	FCM Count (% Age)	IS Count (% Age)	p-Value
Microcytic Hypo-chromic	Pre-Treatment	21 (35.0%)	22 (36.7%)	0.771
	Post-Treatment (4th Week)	10 (16.7%)	13 (21.7%)	0.671
	Post-Treatment (8th Week)	5 (8.3%)	7 (11.7%)	0.770
Normocytic Normochromic	Pre-Treatment	24 (40.0%)	23 (38.3%)	0.221
	Post-Treatment (4th Week)	35 (58.3%)	32 (53.3%)	0.221
	Post-Treatment (8th Week)	45 (75.0%)	42 (70.0%)	0.667
Normocytic Hypo-chromic	Pre-Treatment	15 (25.0%)	15 (25.0%)	0.687
	Post-Treatment (4th Week)	15 (25.0%)	15 (25.0%)	0.687
	Post-Treatment (8th Week)	10 (16.7%)	11 (18.3%)	0.117

There were no significant differences in the incidences of GI issues, headache, dizziness, local pain, allergy, or fatigue between both groups based on FCM versus other IS groups by using Chi-square tests, p>0.005. P-values are calculated using Chi-square tests (Table 4).

Table 4: Adverse Effect in FCM vs IS Groups

Adverse Effect	FCM (mean ± SD)	IS (mean ± SD)	p-Value
Gastrointestinal Issues	25%	30%	0.541
Headache	15%	12%	0.617
Dizziness	18%	20%	0.792
Injection Site Pain	10%	8%	0.752
Allergic Reactions	5%	3%	0.651
Fatigue	20%	18%	0.812

Adverse effects of gastrointestinal issues, headache, dizziness, local pain, allergy, or fatigue between both groups based on FCM versus other IS group were analyzed (Figure 1).

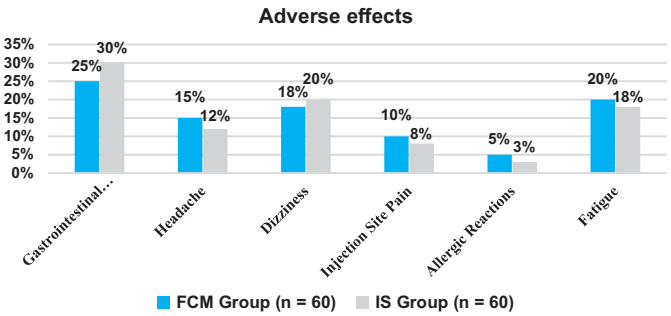

Figure 1: Bar Graph Represent the Comparison of Adverse Effects Between FCM and IS Groups

DISCUSSION

Iron supplements are commonly given for iron deficiency anemia, particularly during pregnancy because it is associated with low birth weight, preterm birth, and maternal morbidity [14]. Several studies have been

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conducted which have used FSM to treat iron deficiency and evaluated the efficacy of FCM during pregnancy. One such study has shown that FSM was safe and effective within 6 weeks of pregnancy, based on the Hb, RBC and serum ferritin levels [15]. Another study has evaluated the effectiveness and Safety of FCM in comparison to IS for treating iron deficiency anemia during pregnancy. They have found that FCM helped better in replenishing iron among pregnant women in comparison to IS [16]. One study reported that in FCM treated group, hemoglobin level was 9.87 ± 0.77 in iron sucrose group it was 9.39 ± 0.72 (p=0.001), 3 week post treatment, Whereas hemoglobin level in the FCM group was 11.51 ± 0.76 and in iron sucrose group it was 10.78 ± 0.61 (p=0.001), 6 week post treatment, which suggested that change in hemoglobin level was higher among patients of FCM compared to Iron sucrose group [17]. The results of the current study revealed that in the FCM group, overall (from baseline to 8th week) increase in hematological was significant 9.2 ± 1.1 to 11.9 ± 1.0 along with serum ferritin rising from 20 ± 6.5 ng/mL to 85 ± 8.0 ng/mL and serum iron levels from 30 ± 8 µg/dL to 95 ± 11 µg/dL while the IS group showed less pronounced increases, hemoglobin levels 9.3 ± 1.2 g/dL to 11.3 ± 1.1 g/dL, ferritin levels rising from 18 ± 5.9 ng/mL to 75 ± 7.5 ng/mL and serum iron level from 28 ± 9 µg/dL to 92 ± 10 µg/dL Hence this study advocates the high efficacy of FCM over IS (with p value<0.001 for all the three iron deficiency markers) in replenishing iron stores and thus treating iron deficiency. One study has reported 2.9 ± 0.2 g/dl Increase in Hb in the treated group versus 1.4 g/dl in IS treated group during 4 weeks, with a significant p-value of 0.004. They have also reported an increase of 63.1 ng/mL ferritin in the treated group versus 26.1 in the IS-treated group, with a significant p-value of 0.001 [18], which is more pronounced than our study. Although, in the reported study, change has been seen in both groups, however, FCM group has shown more robust changes [18]. Such results are in line with others that have demonstrated a higher effect of FCM compared to IS on the immediate increase of Hb and ferritin. Bharadwaj et al., suggested that FCM turns out to be better than IS due to a higher rise of hemoglobin and ferritin levels with lesser side effects [19]. Another study reports a randomized controlled trial for pregnancy-related IDA, comparing a single IV infusion of 1000mg of FCM over 15 minutes, a single IV infusion of 1000mg of IPM, over 2 hours and 325mg daily oral ferrous sulphate until delivery. They have found that usage of IV FCM during pregnancy was safe and showed better efficacy than IV IPM or oral iron [20]. This indeed correlates well with our data showing the superior effect of FCM on serum ferritin levels. In our study, we did not see any significant difference between the two groups regarding microcytic hypochromic, normocytic normochromic and normocytic hypochromic cells checked at the 4th and 8th week after implantation. These findings imply that both treatment modalities have a comparable impact on peripheral blood smear, even though there appeared to be greater improvements in iron status with FCM. Additionally, we did not find significant adverse effects in both groups, which indicates that FCM and IS have not caused any harm to the treatment groups. Moreover, the existing data coming from observational studies [18, 7] as well as in randomized controlled trials [10], suggests that intravenous iron carboxymaltose administration in pregnancy is likely to be safe and effective. IS has been proven but requires multiple doses while FCM is advantageous as higher doses can be given in a single sitting which reduces hospital visits. To optimize both maternal and fetal outcomes, comparative effectiveness, Safety, and adherence studies are needed.

CONCLUSIONS

It was concluded that FCM was an effective treatment for pregnant women suffering from iron-deficient anemia. While therapeutic effects were comparable for both FCM and IS, FCM achieved much faster serum ferritin increases, even improving it up to the normal range, though hematological parameters improved with both FCM and IS.

Authors Contribution

Conceptualization: KA
Methodology: SJ, RA[1], RA[2]
Formal analysis: SJ, AM
Writing review and editing: RA[2], AM, MAUR

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

The authors declare no conflict of interest.

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