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Comparison of Efficacy of Ferric Carboxymaltose versus Iron Sucrose Complex for the Treatment of Iron Deficiency Anemia in Pregnancy

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ABSTRACT

During pregnancy, iron deficiency anemia (IDA) is a common complication that exposes both the mother and fetus to a lot of risks. **Objectives:** To compare intravenous ferric carboxymaltose (FCM) versus iron sucrose in the treatment of moderate to severe anemia in pregnant women. **Methods:** This quasi-experimental study was conducted in a tertiary care hospital in Lahore, which registered 62 pregnant women having 16-34 weeks of gestation and hemoglobin levels of 7-9 g/dl. The participants were randomly divided into two groups, with intravenous FCM in one of them and the other without. The level of base hemoglobin and post-treatment were taken three weeks after the completion. There was also the evaluation of effectiveness and adverse impacts. **Results:** The average basal hemoglobin was 7.88 ± 0.42 g/dl. The levels after treatment were significantly higher in the FCM group (10.93 ± 0.63 g/dl) compared to the IS group (9.98 ± 0.51 g/dl), with an increase in statistically significant HB ($p<0.001$). The efficacy was reported in 87.1% of patients treated with FCM versus 38.7% in the SI group. The adverse effects were remarkably lower in the FCM group (19.4%) compared to IS (61.3%) ($p=0.001$). Although multiparous women had significantly lower basal HB, both parity groups showed similar responses to treatment. **Conclusions:** Ferric carboxymaltose demonstrated superior efficacy and tolerability compared to iron sucrose in the first leg during pregnancy. Its ability to achieve rapid HB correction with fewer side effects supports its consideration as preferred intravenous iron therapy.

INTRODUCTION

Iron deficiency anemia (IDA) remains the most frequent hematological disorder that complicates pregnancy, affects millions worldwide, and raises important risks to maternal and fetal health [1]. During pregnancy, physiological changes, including the increase in plasma volume and the highest iron requirements for fetal growth and placental development, predispose women to iron exhaustion [2]. Worldwide, the highest load falls on low and middle-income countries, particularly in southern Asia and sub -Saharan Africa, where iron intake in the diet is inadequate, infections are common, and access to timely prenatal care is often limited [3]. A recent meta-analysis of 27 studies found a pooled prevalence of 70.4% for anemia in pregnant women, with even higher rates in Punjab at 77.4% [4]. Globally, IDA is regarded as one of the most common medical complications of pregnancy and is linked

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to poor maternal and neonatal outcomes (such as fatigue, predisposition to infection, preterm birth, and low birth weight) [5, 6]. Although oral iron supplementation is recommended as a first-line management, it is often insufficient because of gastrointestinal intolerance and lack of adherence as well as hematological response in women with moderate to severe anemia or advanced gestation [7]. In turn, intravenous iron therapy (IVI) has now been proven as a safe and reliable alternative to accelerate and guarantee successful iron replacement in pregnancy, especially when an embolism needs to be treated in time [8]. However, all preparations are not alike in terms of pharmacokinetics, dosing patterns, and infusion needs, which can affect the effectiveness of the treatment, compliance of the patient, and use of the health-care resources [9, 10].

Despite the existing data, the significant knowledge gaps persist with respect to the optimal choice of IVI in various populations, particularly in low -income environments, based on the community, where the logistics of treatment often dictate the clinical decisions and where both the load and the consequences of anemia are disproportionately high. Studies with adequate power and local contextualization are essential to inform the guidelines. This study aimed to compare the ferric carboxymaltose and the iron sucrose complex in the treatment of IDA, aiming to rigorously evaluate their relative effectiveness, safety, tolerability, and practical implications in the local context.

METHODS

This was a quasi-experimental study conducted from August to November 2025 in the Department of Obstetrics and Gynecology at Arif Memorial Hospital, affiliated with Rashid Latif Khan University (RLKU) Medical College, Lahore, Pakistan. The research was carried out following ethical approval given by the institutional review board of Hameed Latif Hospital, Lahore; the teaching institute of RLKU Medical College (HLH/ADM/IRB/2025-027). Informed consent was obtained from research participants before conducting this research, and confidentiality was maintained. A total of 62 pregnant women who were between 16 and 34 gestation weeks were recruited using non-probability consecutive sampling. The eligible study subjects were 18 to 40 years old; their hemoglobin was between 7.0 and 9.0 g/dl with serum ferritin below 30 ng/ml. The inclusion criteria were pregnant women found to have IDA through laboratory data. The exclusion criteria were a history of allergy to iron preparations, multiple pregnancy, chronic systemic disease (e.g., diabetes mellitus), renal or cardiac disease, hemoglobinopathies, non-iron deficiency anemia (i.e., antepartum bleeding), or intravenous iron or blood transfusion within the last three months. Group A was given FCM intravenously, and Group B was given intravenously as iron SEC. Basic demographic features such as age, parity, and gestational age were taken. Each subject was given albendazole 400 mg in a single oral dose before being administered iron therapy. In Group A, FCM would be diluted in 0.9% normal saline and infused intravenously within 15 to 30 minutes according to the dosage. The dosage of 100-500 mg was given in 100mL in a period of 15 minutes, whereas the 500-1000mg dosage was given in 200 mL in a period of 30 minutes. The highest single dose was 1000 mg with added doses on day 7 or 14 in case of need. Group B had iron sucrose, which was used in the form of 200 mg in 100 mL of 0.9% normal saline that was infused over 30 minutes on alternate days with a maximum dose of 600 mg per week. Total iron requirement was calculated using the formula: Total iron dose (mg) = 2.4 × body weight (kg) × (target Hb – actual Hb) + 500, with a target hemoglobin of 11 g/dL. The participants were carefully monitored throughout the infusion, when pulse, blood pressure, and fetal heart rate were monitored. All the negative experiences, like infusion reactions, were reported in detail. The main product was the hemoglobin concentration three weeks after therapy was completed, and this was measured with the help of an automated hematology analyzer. The secondary outcomes were treatment efficacy (successful increase of hemoglobin levels to 11g/dl or more or marked increase in comparison with baseline) and adverse effects. The Statistical Package for the Social Sciences (SPSS) version 29.0 was used to analyze the data. Quantitative variables were represented as mean standard deviation (SD). An independent samples t-test was employed in testing the difference in mean hemoglobin increase across groups. To evaluate the relationship between treatment groups and outcomes of efficacy and side effects, chi-square tests were used. Age, parity, and baseline hemoglobin stratification were done in order to control the potential confounders. The p-value below 0.05 was regarded as significant.

RESULTS

Sixty-two pregnant women with iron-deficient anemia were involved in the study. With a range of 6.65 to 8.61 g/dL, the mean baseline hemoglobin (Hb) level was 7.88 ± 0.42 g/dL. The mean post-treatment Hb level was 10.46 ± 0.75 g/dL, with a range of 8.99 to 12.31 g/dL. 39 (62.9%) were multiparous, and 23 (37.1%) were primiparous with respect to parity. 39 (62.9%) responded favorably (efficacy "Yes") to treatment efficacy, whereas 23 (37.1%) did not (efficacy "No"). Out of the subjects, adverse effects were evident in 25 (40.3%) and absent in 37 (59.7%). These results confirm that, in comparison to the control, the experimental intervention was linked to a statistically significant rise in hemoglobin and fewer negative side effects (Table 1).

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Table 1: Baseline and Post-Treatment Hemoglobin Levels, Parity Distribution, Treatment Efficacy, and Adverse Effects Among Pregnant Women with Iron Deficiency Anemia (n=62)

Variables	Category	Frequency (%)	Mean ± SD	Range
Baseline Hb (g/dL)	–	62 (100%)	7.88 ± 0.42	6.65 – 8.61
Post Hb (g/dL)	–	62 (100%)	10.46 ± 0.75	8.99 – 12.31
Parity	Multiparous	39 (62.9%)	–	–
	Primiparous	23 (37.1%)	–	–
Efficacy	Yes	39 (62.9%)	–	–
	No	23 (37.1%)	–	–
Adverse Effects	No	37 (59.7%)	–	–
	Yes	25 (40.3%)	–	–

The mean baseline hemoglobin (Hb) in the control group was 7.84 ± 0.37 g/dL, but in the experimental group it was marginally higher at 7.92 ± 0.46 g/dL. After therapy, the experimental group's mean post-treatment Hb improved significantly more than the control groups, rising to 9.98 ± 0.51 g/dL and 10.93 ± 0.63 g/dL. A better hemoglobin response to the experimental intervention was thus shown by the mean Hb rise, which was 3.01 ± 0.53 g/dL in the experimental group and 2.14 ± 0.37 g/dL in the control group. Regarding parity, multiparous women's baseline hemoglobin levels were lower at 7.70 ± 0.40 g/dL than those of primiparous women, who had 8.19 ± 0.21 g/dL. Following treatment, the mean hemoglobin levels in primiparous and multiparous women were 10.77 ± 0.63 g/dL and 10.27 ± 0.75 g/dL, respectively. Remarkably, the mean Hb rise was 2.57 ± 0.65 g/dL for multiparous women and 2.57 ± 0.61 g/dL for primiparous women (Table 2).

Table 2: Comparison of Baseline Hemoglobin, Post-Treatment Hemoglobin, and Mean Hemoglobin Rise Between Control (Iron Sucrose) and Experimental (Ferric Carboxymaltose) Groups

Variables	Group	n	Mean ± SD
Baseline Hb	Control	31	7.84 ± 0.37
	Experimental	31	7.92 ± 0.46
Post Hb	Control	31	9.98 ± 0.51
	Experimental	31	10.93 ± 0.63
Hb Rise	Control	31	2.14 ± 0.37
	Experimental	31	3.01 ± 0.53
Baseline Hb	Multiparous	39	7.70 ± 0.40
	Primiparous	23	8.19 ± 0.21
Post Hb	Multiparous	39	10.27 ± 0.75
	Primiparous	23	10.77 ± 0.63
Hb Rise	Multiparous	39	2.57 ± 0.65
	Primiparous	23	2.57 ± 0.61

With a mean difference of -0.493 g/dL (95% CI: -0.673 to -0.312), multiparous women's baseline hemoglobin (Hb) was substantially lower than that of primiparous women (t = -5.464, df = 60, p<0.001). Similarly, the post-treatment hemoglobin levels among multiparous women were significantly lower (t = -2.631, df=60, p=0.011), and the difference in hemoglobin levels between the two groups was -0.492 g/dL (95% CI: -0.867 to -0.118). However, no such significant differences were found in the Hb increase with parity groups (t=0.003, df=60, p=0.997), indicating that the reaction to treatment did not differ depending on parity. There was no significant difference in the baseline hemoglobin of the control group and experimental group when they were compared to the treatment groups (t = -0.744, df = 60, p=0.460). The post-treatment hemoglobin of the experimental group was significantly greater (t = -6.488, df = 60, p<0.001) with a mean of -0.950 g/dL (95% CI: -1.242 to -0.657). Also, since the mean difference between the experimental and control groups was -0.871 g/dL (95% CI: -1.104-0.637), the Hb increase was significantly greater in the experimental group (t = -7.470, df=60, p=0.001), which supported the better effect of the experimental treatment (Table 3).

Table 3: Comparison of Baseline Hemoglobin, Post-Treatment Hemoglobin, and Mean Hemoglobin Rise Between Multiparous and Primiparous Women

Variables	t	df	p-value	Mean Difference	95% CI (Lower–Upper)
Baseline Hb*Parity	-5.464	60	<0.001	-0.493	-0.673 to -0.312
Post Hb*Parity	-2.631	60	0.011	-0.492	-0.867 to -0.118
Hb Rise*Parity	0.003	60	0.997	0.0005	-0.335 to 0.336
Baseline Hb*Group	-0.744	60	0.460	-0.079	-0.291 to 0.133
Post Hb*Group	-6.488	60	<0.001	-0.950	-1.242 to -0.657
Hb Rise*Group	-7.470	60	<0.001	-0.871	-1.104 to -0.637

Efficacy and treatment group were shown to be significantly correlated (χ^2 = 15.552, df = 1, p<0.001). Total of 12 individuals in the control group and 19 in the experimental group demonstrated treatment efficacy. Likewise, there was a statistically significant correlation between the therapy group and negative outcomes (χ^2 = 11.328, df = 1, p=0.001). Six participants in the experimental group and 19 in the control group reported adverse effects, while 25 and 12 participants, respectively, were lost to follow-up. These results imply that the experimental medication was better tolerated with fewer side effects (Table 4).

Table 4: Association Between Treatment Group and Outcomes of Efficacy and Adverse Effects Using the Chi-Square Test

Variables	Group	Category	n	Pearson χ^2	df	p-value
Efficacy	Control	Yes	12	15.552	1	<0.001
		No	19			
	Experimental	Yes	27			
		No	4			
Adverse Effects	Control	Yes	19	11.328	1	0.001
		No	12			
	Experimental	Yes	6			
		No	25			

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DISCUSSION

Iron deficiency anemia (IDA) during pregnancy is a significant issue in health care worldwide, and the result of the study under consideration contributes to the existing number of studies that argue in favor of ferric carboxymaltose (FCM) over iron sucrose (IS) as intravenous iron replacement therapy. The mean increase in hemoglobin in FCM was 3.01 g/dL, which was statistically significant (p=0.001) when compared to the IS group, which had a mean increase in hemoglobin of 2.14 g/dL. This is in line with the results of Khan *et al.* who found a 2.9 g/dL hemoglobin increase with FCM and a 2.2 g/dL hemoglobin increase with IS at 12 weeks, and once again, a strong benefit of FCM [11]. The same findings were obtained by Alwan *et al.* who observed greater hemoglobin increase in the FCM group (3.96 ± 4.19 g/dL) compared to the iron sucrose group (2.11 ± 1.72 g/dL; p<0.05), but the standard deviations were greater, which is likely due to the higher heterogeneity of populations [12]. These studies suggest that the possibility of FCM to administer a bigger single dose is transferred into faster and more dependable hematological recovery in the course of pregnancy. In addition to the hemoglobin improvement, this study also established a much greater treatment efficacy with FCM since 87.1% of the patients met the therapeutic targets in contrast to 38.7% of those in the iron sucrose group. These results are also highly similar to those of Gupte *et al.* who found the efficacy rates of FCM and iron sucrose were 85.3% and 41.2% (p=0.001), respectively [13]. Equally, a phase IV trial by Saleem *et al.* had a larger percentage of pregnant women who were treated with FCM than the iron sucrose group, with more than 80% attaining target hemoglobin levels in under six weeks [14]. These variations are especially clinically relevant in late pregnancy, when the correction of anemia is required at a fast rate to prevent the threat of blood transfusion and adverse neonatal outcomes [13, 14]. The safety outcome is also vital in introducing the therapies during pregnancy. This research found that of women who got FCM, 19.4% of them had adverse effects, whereas 61.3% of the women who got iron sucrose had adverse effects (p=0.001). Bharadwaj *et al.* ratified such a difference, as they reported worse outcomes like infusion-site pain, nausea, and hypotension in 17% of patients who received FCM compared to 42% of those receiving iron sucrose [15]. Likewise, Lusingu and Maisonet established many fewer adverse effects of minor cases in the FCM group, as well as no severe cases of hypersensitivity in both groups [16]. These results show that the high tolerability of FCM is similar in various populations and study designs. Another secondary factor that was considered was parity. Baseline hemoglobin levels. Multiparous women had significantly lower (7.70 ± 0.40 g/ dL) hemoglobin levels compared to primiparous women (8.19 ± 0.21 g/dL; p<0.001). Nevertheless, the extent of hemoglobin elevation after the intervention was almost the same in the two groups (2.57 ± 0.65 g/dl vs. 2.57 ± 0.61 g/dl; p=0.997). Such a tendency is in line with the results of Singh *et al.* who proved that the higher parity, the lower the baseline iron stores, but has no impact on the responsiveness to intravenous iron therapy [17]. Similar findings to these were also made by Basha *et al.* Jin *et al.* and Xing *et al.* who stated that even though multiparous women start the treatment with a more severe iron deficiency, the hematologic response to intravenous iron in them is no worse than in primiparous women [18-20].

This research has also some limitations that must be acknowledged. As it was carried out in one tertiary care facility, and the sample consisted of non-probability consecutive, the findings cannot be closely applied to other clinical environments, such as primary or rural healthcare centers and other population groups. Also, the short-term follow-up of three weeks limited the assessment of long-term hematological sustainability, iron stores replenishment, and tardy adverse consequences. Future studies should include diverse healthcare settings with longer follow-up to evaluate sustained hematological outcomes and delayed complications.

CONCLUSIONS

The intravenous ferric carboxymaltose demonstrated greater improvement in hemoglobin levels, higher treatment efficacy, and better tolerability compared with iron sucrose among pregnant women with moderate to severe iron deficiency anemia. Although multiparous women presented with lower baseline hemoglobin levels, parity did not influence the hematological response to either intervention. Integrating FCM into the normal maternity anemia care practice can enhance the quality of care and minimize the anemia -related pregnancy complications.

Authors' Contribution

Conceptualization: SK
Methodology: AAK, AAB, HMZR
Formal analysis: AAK, MOQ
Writing and Drafting: FPJ, MR
Review and Editing: FPJ, SK, AAK, AAB, MR, MOQ, HMZR, MIA

All authors approved the final manuscript and take responsibility for the integrity of the work.

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Conflicts of Interest

All the authors declare no conflict of interest.

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