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Research Article

Comparison of Efficacy and Safety of IV Ferric Carboxymaltose versus IV Iron Sucrose in Pregnancy and Postpartum Anemia

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ABSTRACT:

Introduction: Ferric carboxymaltose is a safe intravenous drug that is equally effective as the iron sucrose complex, which is currently the accepted treatment for iron deficiency anemia in pregnant women. A literature search revealed that ferric carboxymaltose and iron sucrose complex are equally effective. Despite being used for many years, iron sucrose is only used at low quantities since larger concentrations can have detrimental effects both locally and systemically.
Methodology: A total of 122 individuals (61 in each group) with pregnancy or postpartum anemia presented to the Obstetrics & Gynecology department of National Hospital, Faisalabad, between the ages of 20 and 40 after receiving approval from the ethical review committee. Patients who had a history of iron intolerance or allergy, parenteral iron hypersensitivity, Thalassemia, blood transfusion indications, bleeding/clotting disorders, or chronic illnesses were not included. Using opaque envelopes and the lottery method, randomization was carried out. Sixty one patients were in Group B, or IV iron supply, and sixty-one patients were in Group A, or ferric carboxymaltose. After 12 weeks, all patients were contacted for follow-up. Repeated blood tests revealed that both groups' hemoglobin levels had changed.
Results: The baseline hemoglobin levels for ferric carboxymaltose (group A) and IV iron sucrose (group B) were 7.85 ± 1.29 g/dl and 7.61 ± 1.03 g/dl, respectively, in my investigation. After 12 weeks of treatment, the Hb for ferric carboxymaltose (group A) was 11.84 ± 1.17 g/dl, while the Hb for IV iron sucrose (group B) was 9.56 ± 1.19 g/dl (p-value = 0.0001). 52 patients (85.25%) in group A (intravenous ferric carboxymaltose) and 42 patients (68.85%) in group B (intravenous iron sucrose) demonstrated success at the conclusion of the six-week treatment period.
Conclusion: Ferric carboxymaltose is an inexpensive, easily accessible iron preparation that significantly raises hemoglobin levels with fewer adverse effects than iron sucrose.

Keywords: anemia, pregnancy, intravenous iron, iron sucrose, hemoglobin.

INTRODUCTION:

Pregnancy-related anemia is a serious public health issue since it is difficult to measure, prevent, and treat in many nations worldwide. Anaemia is believed to affect 58.1% of pregnant South Asian women, while the incidence of this condition is considered to be around 38% worldwide.[1] By 2030, all types of malnutrition, including anemia, must be eradicated, according to the Sustainable Development Goals, which emphasize the necessity of closing the gaps in inequality at the international, national, and subnational levels.[2] However, there has been limited and inconsistent progress in preventing anemia in low and middle-income countries (LMICs), which is especially attributed to complicated, poorly characterized context-specific aetiologies.[3]

Both the mother and the fetus may suffer from anemia during pregnancy. Pregnant women who are very anemic are more susceptible to unfavorable pregnancy outcomes and have a 2.36-fold increased risk of dying.[4] In addition to anemia, maternal anemia raises the baby's risk of obesity, heart disease, and issues with intellectual development.[5]

Iron deficiency has historically been the most common cause of anemia, accounting for over 50% of cases of anemia in pregnancy globally.[6] Pregnancy increases maternal erythropoiesis, which raises the need for iron. Additionally, the development of fetal tissues and iron reserves depends on iron. Iron stores in the body steadily diminish and eventually show up as iron deficiency anemia when the supply cannot keep up with the increased demand for a variety of causes, including poor diet, illnesses, or infestations.[7,8]

Parenteral therapy provides an enhanced response in these patients and can eliminate the necessity for blood transfusions during pregnancy and the postpartum period.[9] Numerous research have been published regarding the utilization of Ferric Carboxymaltose (FCM) for the treatment of postpartum anemia and other anemia-inducing conditions.[10]

Ferric carboxymaltose is a safe intravenous drug that works just as well as the iron sucrose complex, which is now the standard treatment for iron deficiency anemia during pregnancy. A search of the literature shows that iron sucrose complex and ferric carboxymaltose work just as well. Although iron sucrose has been used for many years, its usage is restricted to moderate levels since higher concentrations can cause systemic and local negative effects. Compared to intravenous iron sucrose therapy, intravenous iron carboxymaltose therapy appears to be a safer, more practical, and more successful way to treat anemia during the postpartum phase. We intend to compare the efficacy and safety with ferric carboxymaltose and intravenous iron source in anemic prenatal patients in our local community in order to obtain more local data.

METHODOLOGY:

A total of 122 individuals (61 in each group) with pregnancy or postpartum anemia—defined by the WHO as hemoglobin of less than 10 g/dL—presented to the Obstetrics & Gynecology department of National Hospital, Faisalabad, between the ages of 20 and 40 after receiving approval from the ethical review committee. With a 5% level of significance, 80% power of research, and an efficacy of 82.22% in the IV ferric carboxymaltose group and 62.22% in the iron sucrose group, the Openepi calculator yielded a sample size of n=122 (61 per group).[10] Patients who had a history of iron intolerance or allergy, parenteral iron hypersensitivity, Thalassemia, blood transfusion indications, bleeding/clotting disorders, or chronic illnesses were not included.

Patients' baseline demographic data and baseline hemoglobin levels were collected. Parents of patients were asked to give their informed consent after being informed of the study's benefits. Using opaque envelopes and the lottery method, randomization was carried out. The envelope containing the treatment mode was selected by each subsequent patient. Sixty one patients were

in Group B, or IV iron supply, and sixty-one patients were in Group A, or ferric carboxymaltose.

For three days, all women received 100 mg tablets of mebendazole (Vermox) twice a day as part of their antihelminthic treatment. They also received 5 mg of folic acid once a day.

Before the infusion began, a test dose was administered for both iron formulations. Iron sucrose complex intravenous injections: 200 mg elemental iron (2 ampoules of 5 ml) in 100 ml of 0.9% normal saline was administered as an intravenous injection over 30 minutes on alternate days for a maximum of 5 doses. The highest single dose for carboxymaltose preparation was 1000 mg diluted in 250 ml of sterile normal saline 0.9%, administered as a gradual infusion over 45 minutes. The remaining doses will be administered on the eighth and fifteenth days, if necessary. After 12 weeks, all patients were contacted for follow-up. Repeated blood tests revealed that both groups' hemoglobin levels had changed. All of this information was recorded on a specially created proforma.

The statistical software SPSS version 25.0 was utilized. The mean ± SD or median (IQR) were calculated for quantitative parameters, including age, height, weight, BMI, and hemoglobin levels before and after treatment. Frequency and percentage were calculated for qualitative criteria such safety, efficacy (yes/no), mode of delivery (CS/SVD), parity, gravidity, and housing location (rural/urban). The Chi Square/fisher exact test was used to assess the performance of the two research groups; a p-value of ≤0.05 was considered significant. Age, BMI, parity, gravidity, residence (rural/urban), mode of delivery (CS/SVD), and baseline hemoglobin levels were among the effect modifiers that were managed through stratifications. The post-stratification chi square/fisher exact test was used to determine their impact on the outcome.

RESULTS:

With a mean age of 27.79 ± 4.93 years, the study's participants ranged in age from 20 to 40. The average age of patients in group A was 27.69 ± 5.01 years, whereas the average age of patients in group B was 27.84 ± 4.91 years. The mean BMI was 21.92 ± 1.55 kg/m2 in group A and 21.84 ± 1.42 kg/m2 in group B. The distribution of patients by various variables is shown in Table I.

The baseline hemoglobin levels for ferric carboxymaltose (group A) and IV iron sucrose (group B) were 7.85 ± 1.29 g/dl and 7.61 ± 1.03 g/dl, respectively, in my investigation. After 12 weeks of treatment, the Hb for ferric carboxymaltose (group A) was 11.84 ± 1.17 g/dl, while the Hb for IV iron sucrose (group B) was 9.56 ± 1.19 g/dl (p-value = 0.0001). Table II shows that at 12 weeks, the mean decrease in hemoglobin was 4.03 ± 1.88 g/dl for ferric carboxymaltose (group A) and 1.97 ± 0.78 g/dl for IV iron sucrose (group B) (p-value = 0.0001). 52 patients (85.25%) in group A (intravenous ferric carboxymaltose) and 42 patients (68.85%) in group B (intravenous iron sucrose) demonstrated success at the conclusion of the six-week treatment period, as shown by a rise in hemoglobin >2 g/dl and serum ferritin ≥15 µg/L. The statistically significant p-value is 0.031. (Table III). Table IV displays the stratification of efficacy by age, BMI, parity, gravidity, place of residence, mode of delivery, and baseline hemoglobin levels.

Table-I: Distribution of different variables (n=122).

	Group A (n=61)	Group B (n=61)

		Number (%)	Number (%)
Age (years)	**20-30**	40 (65.57%)	39 (63.93%)
	31-40	21 (34.43%)	22 (36.07%)
Gravidity	**Primi**	22 (36.07%)	21 (34.43%)
	Multi	39 (63.93%)	40 (65.57%)
Parity	**Primi**	24 (39.34%)	25 (40.98%)
	Multi	37 (60.66%)	36 (59.02%)
BMI (kg/m^2)	**≤25**	36 (59.02%)	40 (65.57%)
	>25	25 (40.98%)	21 (34.43%)
Residence	**Rural**	37 (60.66%)	34 (55.74%)
	Urban	24 (39.34%)	27 (44.26%)
Baseline Hb	**≤7**	42 (68.85%)	34 (55.74%)
	7.1-9.9	19 (31.15%)	27 (44.26%)
Mode of delivery	**SVD**	34 (55.74%)	33 (54.10%)
	CS	27 (44.26%)	28 (45.90%)

Table-II: Comparison of mean change in Hb with ferric carboxymaltose and IV iron source in anemic antenatal patients.

Hb (g/dl)	**Group A (n=61)**	**Group B (n=61)**	**p-value**
	Mean ± SD	Mean ± SD	
Baseline	7.85 ± 1.29	7.61 ± 1.03	**0.429**
At 12 weeks	11.84 ± 1.17	9.56 ± 1.19	**0.0001**
Change	4.03 ± 1.88	1.97 ± 0.78	**0.0001**

Table-III: Comparison of efficacy (n=122).

	Group A (n=61)		**Group B (n=61)**		**P-value**
	Yes	No	Yes	No	

EFFICACY	52 (85.25%)	09 (14.75%)	42 (68.85%)	19 (31.15%)	**0.031**
SAFETY	54 (88.52%)	07 (11.48%)	49 (80.33%)	12 (19.67%)	**0.212**

Table-IV: Stratification of efficacy with respect to age, BMI, parity, gravidity, place of living, mode of delivery and haemoglobin levels at baseline.

		Group A (n=61)		Group B (n=61)		P-value
		Efficacy		Efficacy		
		Yes	No	Yes	No	
Age (years)	**20-30**	36 (90.0%)	04 (10.0%)	34 (87.18%)	05 (12.82%)	**0.693**
	31-40	16 (76.19%)	05 (23.81%)	08 (36.36%)	14 (63.64%)	**0.008**
Gravidity	**Primi**	19 (86.36%)	03 (13.64%)	11 (52.38%)	10 (47.62%)	**0.015**
	Multi	33 (84.62%)	06 (15.38%)	31 (77.50%)	09 (22.50%)	**0.420**
Parity	**Primi**	22 (91.67%)	02 (8.33%)	14 (56.0%)	11 (44.0%)	**0.005**
	Multi	30 (81.08%)	07 (18.92%)	28 (77.78%)	08 (22.22%)	**0.727**
BMI (kg/m^2)	**≤25**	31 (86.11%)	05 (13.89%)	22 (64.71%)	12 (35.29%)	**0.037**
	>25	21 (84.0%)	04 (16.0%)	14 (66.67%)	07 (33.33%)	**0.169**
Residence	**Rural**	33 (89.19%)	04 (10.81%)	26 (76.47%)	08 (23.53%)	**0.153**
	Urban	19 (79.17%)	05 (20.83%)	16 (59.26%)	11 (40.74%)	**0.126**
Baseline Hb	**≤7**	34 (80.95%)	08 (19.05%)	22 (64.71%)	12 (35.29%)	**0.109**
	7.1-9.9	18 (94.74%)	01 (5.26%)	20 (74.07%)	07 (25.93%)	**0.069**
Mode of delivery	**SVD**	27 (79.41%)	07 (20.59%)	19 (57.58%)	14 (42.42%)	**0.054**
	CS	25 (92.59%)	02 (7.41%)	23 (82.14%)	05 (17.86%)	**0.245**

DISCUSSION:

To avoid less than ideal pregnancy outcomes, iron deficiency anemia in pregnancy must be identified early and treated appropriately. Ferric carboxymaltose is somewhat less expensive than other intravenous iron preparations, and because of its effectiveness and convenience of use, patients with iron deficiency anemia have been shown to prefer it over oral therapy, even if it is more expensive than oral forms.[11] Although this formulation's success in treating iron

deficiency anemia caused by dietary deficiencies, chronic renal disease, and ischemic heart disease is well documented, its effectiveness and tolerance during pregnancy are less well recognized, which is why this study was conducted.[12-14]

Participants in our study sample were 27.79 ± 4.93 years old on average. In a 2018 study, Adnan et al. discovered that women who presented with anemia during pregnancy had a mean age of 26.8 ± 3.4 years, which was comparable to our findings. Jose et al. similarly observed that the mean age was 26.2 ± 3.6 years.[15,16] Zeisler et al., on the other hand, found that the majority of pregnant women who had iron insufficiency were in their third decade of life.[17] Early marriages and pregnancies in emerging nations compared to industrialized ones are the reasons for this discrepancy in outcomes.

We discovered that the majority of IDA patients lived in rural areas. Village dwellers are reported to consume more processed foods that are low in essential nutrients like iron. Due to insufficient iron consumption, this eating pattern raises the risk of IDA during pregnancy. Tea, which includes compounds that inhibit iron absorption, is often consumed in considerable quantities by rural populations. A study conducted in Hyderabad, Pakistan, found that pregnant women who drank more than three cups of tea per day before getting pregnant were significantly more likely to suffer from anemia.[18]

The baseline hemoglobin levels for ferric carboxymaltose (group A) and IV iron sucrose (group B) were 7.85 ± 1.29 g/dl and 7.61 ± 1.03 g/dl, respectively, in my investigation. After 12 weeks of treatment, the Hb for ferric carboxymaltose (group A) was 11.84 ± 1.17 g/dl, while the Hb for IV iron sucrose (group B) was 9.56 ± 1.19 g/dl (p-value = 0.0001). At 12 weeks, the mean Hb change for ferric carboxymaltose (group A) was 4.03 ± 1.88 g/dl, while the mean change for IV iron sucrose (group B) was 1.97 ± 0.78 g/dl (p-value = 0.0001). After twelve weeks of initial treatment, Jose et al. demonstrated comparable results, with a mean hemoglobin level of 11.5 ± 4.6 g/dL for FCM and 10.9 ± 4.4 g/dL for iron sucrose.[16]

In a related study, Rathod et al. discovered that ferric carboymaltose increased hemoglobin levels more than iron sucrose did: 12.1 ± 0.8 g/dL versus 11.4 ± 1.2 g/dL, respectively, following a follow-up of twelve weeks ($p<0.001$).[19] Singh et al. looked into how well iron sucrose and ferric carboxymaltose worked for women at the end of their pregnancies. They found that the first one raised hemoglobin levels to 10.1 ± 0.6 g/dL while the second one raised hemoglobin levels to 9.8 ± 0.6 g/dL ($p<0.001$).[20] This study's lower increases in hemoglobin in both arms compared to our findings are probably due to Singh et al.'s birth, which can result in blood loss of up to 500 mL, depending on the method of delivery.[20]

Studies by Divyani and associates[21] and Ambily J et al.[16] found that women who received IV FCM had significantly greater serum ferritin and hemoglobin levels than those who received iron sucrose. These findings are consistent with our results. Similar to this investigation, a 2019 study by Sabina K et al.[22] discovered that serum ferritin increased significantly after parenteral iron therapy in both the IS and FCM treatment groups; however, the ferric carboxymaltose group experienced a significantly larger increase.

In a recent study by Patel GR et al.[23] intravenous iron sucrose and FCM were compared, the FCM group showed a noticeably higher increase in hemoglobin and ferritin at 3 and 6 weeks ($p < 0.0001$).[23] These outcomes are consistent with our research. The increase in Hb was nearly same in the Iron Sucrose and FCM groups[24], according to a different study by Dillon et al. A similar rise in Hb values following treatment with iron sucrose and FCM[25], according to the study by Christoph et al.[25] In these investigations, there was no proof that any of the two treatments was better. Parekh et al. measured Hb levels at 4 weeks and 90 days of treatment; however, at 90 days, the FCM group had greater Hb concentrations, whereas at 4 weeks, there was no discernible difference in Hb rise.[26]

Compared to iron sucrose, which was thought to be a sign of success, a greater proportion of patients in our study resulted in a rise in hemoglobin levels of >2g/dL from baseline with FCM

(85.25% versus 68.85%, respectively). Additionally, Rathod et al. observed that ferric carboxymaltose was more effective than iron sucrose, with 66.0% versus 27.0% ($p<0.001$).[19] In a related investigation, Chaudhry et al. found an even larger difference between ferric carboxymaltose (63.3%) and iron sucrose (0%), with a p-value of less than 0.001.[27] Similarly, Singh et al. found that FCM had an effectiveness rate of 88.0% compared to 24.0% for iron sucrose ($p<0.001$).[20] There was still a lot of variation even though these studies all agreed that FCM is more effective than iron sucrose. This is probably because different research had different definitions of efficacy.

Finally, in our study, 88.52% of participants said there was no incidence of negative effects with FCM, compared to 80.33% with iron sucrose. Comparable studies like Chaudhary et al. (93.3% with FCM against 50.0% with iron sucrose) and Singh et al. (100.0% with FCM versus 93.0% with iron sucrose) showed similar safety outcomes.[20,27] We found that both groups in our study experienced very little adverse effects. Compared to iron sucrose, FCM is linked to less adverse effects. We discovered that injection site discomfort or burning was the most frequent side effect, followed by headache and nausea. Rathodet al.[19] discovered that the FCM group experienced considerably fewer adverse medication reactions. Breymann et al.[28] discovered that FCM caused less negative effects than ferrous sulfate. FCM did not cause any negative reactions, according to Khalafallah et al.[29] The rate of adverse effects was 32% for the iron sucrose group and 24% for the ferric carboxymaltose group, according to Lunagariya et al.[30] who also reported that adverse reactions were milder in both groups and primarily caused by local reactions. Adverse medication reactions were extremely rare in both groups, according to Sharma et al.[31] Additionally, Sudha and Bulusu observed hospital visits for patients in both groups and discovered that the FCM group had noticeably fewer visits.[32]

Numerous issues hindered our investigation, including the lack of blinding resulting from the varying quantity of injections given in each research arm and the avoidance of using a placebo in the study arm due to the patients' sensitive conditions, such as pregnancy. Second, it was unclear if the patient's dietary consumption of iron varied, which could have affected the results. Finally, gastrointestinal issues, nausea, vomiting, and anorexia are common during pregnancy and could have impacted the outcomes.

CONCLUSION:

Ferric carboxymaltose is an inexpensive, easily accessible iron preparation that significantly raises hemoglobin levels with fewer adverse effects than iron sucrose. Additionally, the preparation is used as a single dose, which is more convenient for the patient than the need for numerous doses with iron sucrose. Given the foregoing, pregnant individuals with iron deficiency anemia in the second and third trimesters may benefit from the preparation as a first-line treatment. Establishing safety throughout the first trimester of pregnancy should be the main goal of future studies.

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