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COMPARATIVE STUDY OF EFFICACY AND SAFETY OF INTRAVENOUS FERRIC CARBOXYMALTOSE AND INTRAVENOUS IRON SUCROSE THERAPY IN POSTPARTUM WOMEN OF IRON DEFICIENCY ANEMIA AT JLNMCH

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ABSTRACT **Objective-** The aim of the study is to evaluate the efficacy and safety of Ferric Carboxymaltose injection in improving the Haemoglobin level in postpartum anemia, and to compare it with intravenous iron sucrose. **Method-** Study was carried out in the Department of Obstetrics and Gynaecology, of Jawaharlal Nehru Medical College and Hospital from January 2021 to December 2022. Patients with mild and moderate anemia (Hb 7-10 gm%), well compensated and stable, were included in this study after screening with inclusion and exclusion criteria. The patients were selected from those delivered in our hospital having either vaginal delivery or caesarean section.200 patients were included in the study, and they were split into two groups of 100 instances each at random.Group A will undergo intravenous Iron Sucrose therapy for 100 instances. In Group B, 100 cases will be given ferric carboxymaltose intravenously **Result-** In the iron sucrose group, the average haemoglobin increase is about 10.22 at two weeks and 10.92 at six weeks from the baseline value of 8.57g, while in the FCM group, the average haemoglobin increase is around 10.58 at two weeks and11.37 at six weeks from the baseline value of 8.54. Among iron sucrose group serum ferritin increases from baseline (37.2 to 199.97 at 2weeks; 113.62 at 6 weeks). But the improvement is greater among FCM group (31.5 to 261.03 at 2 weeks; 130.86 at 6 weeks). Following iron sucrose 12% developed side effects whereas in FCM group it was only 6%. **Conclusion-** Though our results showed improvement in hemoglobin, serum ferritin in both iron sucrose and FCM group but it was faster and greater with ferric caboxymaltose when compared with iron sucrose. Other advantages are more dose can be administered at a single visit and the hospitalization duration of the patients are reduced greater. The quality of life is also better with FCM group. FCM lacks dextran and less immunogenic so adverse reactions are also low. So out of two intravenous iron FCM seems to be clinically and statistically significant than iron sucrose in treatment of postnatal iron deficiency anemia.

KEYWORDS : Iron Sucrose, Ferric Caboxymaltose

INTRODUCTION

Anaemia is defined as decrease in oxygen carrying capacity of the red blood cell. According to the WHO, anaemia is defined as haemoglobin less than 12 g% in women and 13 g% in males. 1.62 billion individuals, or 24.8% of the world's population, are affected with anaemia globally. Anemia prevalence in reproductive age group is 29.9%.

In affluent nations, the prevalence of anaemia among women of reproductive age ranges from 10-12% and up to 87.2% in under developed country.[1]

The most common cause of anemia is nutritional deficiency anaemia. Of all the nutritional deficiencies, Iron deficiency anemia (IDA) is the most predominant cause. A large percentage (41.8%) of pregnant women are affected by Iron deficiency anemia.

Several variables, including geography, ethnicity, dietary condition, prior iron status, and prenatal iron supplementation, affect the causes and frequency of anaemia in pregnancy. In pregnancy there is physiological hemodilution that cause natural decrease in hemoglobin but the majority of pregnant women also have low iron reserves in our part.

One of the main causes of maternal mortality and morbidity is anaemia. The WHO estimates that it causes 20% of maternal fatalities. It is the main cause of prematurity, infection, and poor neurological and cognitive skills in the infant.

In the mother, it is the greatest cause of preterm labour, infections, poorly tolerated postpartum haemorrhage, and cardiac failure.

Not only during pregnancy but after childbirth also the prevalence of anemia is unacceptably high in both developed (22-50%) and developing (50-80%) countries.[2] It is primarily a continuation of antepartum iron deficiency or anaemia, or it may be triggered by postpartum hemorrhage.

Postpartum anaemia, once it manifests, causes extended hospital admissions, sepsis, secondary haemorrhage, postpartum depression, anxiety, and easy fatigue, failure of lactation, and the persistence of poor maternal health that also affects the growth and development of newborns.

Therefore, depending on the severity of the anaemia, postpartum anaemia requires prevention and treatment not just for that specific time but also to maintain excellent health and enough iron saved for the beginning of the future pregnancy.

AIM AND OBJECTIVES

The aim of the study is to evaluate the efficacy and safety of Ferric Carboxymaltose injection in improving the Haemoglobin level in postpartum anemia, and to compare it with intravenous iron sucrose.

OBJECTIVES

- To compare the rate of rise in haemoglobin % and to compare the total rise in haemoglobin % after the fixed period i.e after2 and 6 weeks of therapy.
- To compare the total rise in Serum Ferritin after 2 and 6 weeks.
- To study and evaluate the safety of drugs regarding anaphylactic reaction, nausea, vomiting, dizziness, myalgia etc.
- To compare the no. of doses required to achieve the target haemoglobin.

MATERIALS AND METHODS

Study was carried out in the Department of Obstetrics and Gynaecology, of Jawaharlal Nehru Medical College and Hospital from January 2021 to December 2022. Patients with mild and moderate anemia (Hb 7-10 gm%), well compensated and stable, were included in this study. The patients were selected from those delivered in our hospital having either vaginal delivery or caesarean section.200 patients were included in the study, and they were split into two groups of 100 instances each at random.

Group A undergo intravenous Iron Sucrose therapy for 100 instances. In Group B, 100 cases were given ferric carboxymaltose intravenously.

Study Design: A Prospective Comparative study.

Inclusion Criteria

1) Postpartum patients with Hb between 7-10 gm/dl at 24-48 hours after delivery and willing to give consent.
2) Patients with Iron Deficiency Anemia only (peripheral smear showing microcytic hypochromic picture and decreased serum ferritin levels).

Exclusion Criteria

1) Any hematological disorder other than iron deficiency anemia.
2) Patients suffering from chronic illness like renal, cardiac, hepatic

or immunological disorders.
3) Known hypersensitivity and resistance to injectable iron compounds.
4) Patients with severe anemia in decompensated state requiring blood transfusion.
5) Patients suffering from anemia due to acute blood loss e.g., Postpartum haemorrhage.
6) Any other serious medical illness like patients with history of asthma, thromboembolism, and signs of infection.

Study was started after clearance from Institutional Ethical Committee. Informed consent was taken after counselling. All the consequences & benefits of the therapy were explained to the patient. After inclusion in study detailed history of each patient was taken including age, parity, medical history, obstetric history, menstrual history & family history. Detailed physical examination was carried out along with investigations like complete hemogram, peripheral blood smear and Serum ferritin.

Dose Calculation

Required iron dose is calculated using the formula below.
2.4 X W x D + 500 where W- weight in Kg, D= Target- actual Hb (Target Hb=11 gm/dl), 500 mg for stores and lactation

Study Group A

Intravenous Iron Sucrose was given as 300mg elemental iron in 100ml of 0.9% normal saline infusion, over a period of 20 minutes period alternate days, till the required dose, up to a maximum of 600mg in a week.

Study Group B

Intravenous Ferric Carboxymaltose, single dose of Ferric Carboxymaltose was given by infusion (500 /1000mg) in 250ml of 0.9% normal saline over 20-minute period.

Patients were monitored for any side effects, including rigour, fever, nausea, vomiting, diarrhoea, burning pain at the injection site, hypotension, hypertension, tingling, itching, and other symptoms.

All the oral iron preparations were suspended during and after the therapy. All patients were given anthelminthic therapy (6 tablets of mebendazole). After completion of the regimen patients was discharged from ward and followed up on the OPD basis after 2 weeks and 6 weeks from the day of completion of therapy. Each patient was followed up for Haemoglobin rise and Serum Ferritin at 2 weeks and 6 weeks after completion of therapy; the results was noted in preformed proforma for each patient and tested statistically at the end of study.

Any adverse drug reactions during infusion and in follow up period was recorded.

RESULT

TABLE 1 Association between 'Group' and 'Sr.Ferritin (µg/L) (2 Weeks)'

Sr.Ferritin (µg/L) (2 Weeks)	Group		Wilcoxon-Mann-Whitney U Test	
	A	B	W	p value
Mean (SD)	199.97 (50.67)	261.03 (69.91)	2828.000	<0.001
Median (IQR)	209.76 (159.6-230.52)	268.13 (195.85-317)		
Min – Max	102.6 - 313.74	166 - 391.6		

The variable Sr.Ferritin (µg/L) (2 Weeks) was not normally distributed in the 2 subgroups of the variable Group. Thus, non-parametric tests (Wilcoxon-Mann-Whitney U Test) were used to make group comparisons.

The mean (SD) of Sr.Ferritin (µg/L) (2 Weeks) in the Group: A group was 199.97 (50.67). The mean (SD) of Sr.Ferritin (µg/L) (2 Weeks) in the Group: B group was 261.03 (69.91). The median (IQR) of Sr.Ferritin (µg/L) (2 Weeks) in the Group: A group was 209.76 (159.6-230.52). The median (IQR) of Sr.Ferritin (µg/L) (2 Weeks) in the Group: B group was 268.13 (195.85-317). The Sr.Ferritin (µg/L) (2 Weeks) in the Group: A ranged from 102.6 - 313.74. The Sr.Ferritin (µg/L) (2 Weeks) in the Group: B ranged from 166 - 391.6.

There was a significant difference between the 2 groups in terms of Sr.Ferritin (µg/L) (2 Weeks) (W = 2828.000, p = <0.001), with the median Sr.Ferritin (µg/L) (2 Weeks) being highest in the Group: B group.

TABLE 2 Association between 'Group' and 'Sr.Ferritin (µg/L) (6 Weeks)'

Sr.Ferritin (µg/L) (6 Weeks)	Group		Wilcoxon-Mann-Whitney U Test	
	A	B	W	p value
Mean (SD)	113.62 (21.36)	130.86 (22.28)	2848.000	<0.001
Median (IQR)	109.5 (102-132)	135.55 (112.8-147)		
Min – Max	68.9 - 151.2	85.75 – 189		

The variable Sr.Ferritin (µg/L) (6 Weeks) was not normally distributed in the 2 subgroups of the variable Group. Thus, non-parametric tests (Wilcoxon-Mann-Whitney U Test) were used to make group comparisons.

The mean (SD) of Sr.Ferritin (µg/L) (6 Weeks) in the Group: A group was 113.62 (21.36). The mean (SD) of Sr.Ferritin (µg/L) (6 Weeks) in the Group: B group was 130.86 (22.28). The median (IQR) of Sr.Ferritin (µg/L) (6 Weeks) in the Group: A group was 109.5 (102-132). The median (IQR) of Sr.Ferritin (µg/L) (6 Weeks) in the Group: B group was 135.55 (112.8-147). The Sr.Ferritin (µg/L) (6 Weeks) in the Group: A ranged from 68.9 - 151.2. The Sr.Ferritin (µg/L) (6 Weeks) in the Group: B ranged from 85.75 - 189.

There was a significant difference between the 2 groups in terms of Sr.Ferritin (µg/L) (6 Weeks) (W = 2848.000, p = <0.001), with the median Sr.Ferritin (µg/L) (6 Weeks) being highest in the Group: B group.

TABLE 3 Association between 'Group' and 'Hemoglobin (g/dL) (2 Weeks)'

Hemoglobin (g/dL) (2 Weeks)	Group		Wilcoxon-Mann-Whitney U Test	
	A	B	W	p value
Mean (SD)	10.22 (0.54)	10.58 (0.45)	3236.000	<0.001
Median (IQR)	10.3 (9.9-10.5)	10.6 (10.3-10.8)		
Min – Max	9.1 - 11.1	9.8 - 11.7		

The variable Hemoglobin (g/dL) (2 Weeks) was not normally distributed in the 2 subgroups of the variable Group. Thus, non-parametric tests (Wilcoxon-Mann-Whitney U Test) were used to make group comparisons.

The mean (SD) of Hemoglobin (g/dL) (2 Weeks) in the Group: A group was 10.22 (0.54). The mean (SD) of Hemoglobin (g/dL) (2 Weeks) in the Group: B group was 10.58 (0.45). The median (IQR) of Hemoglobin (g/dL) (2 Weeks) in the Group: A group was 10.3 (9.9-10.5). The median (IQR) of Hemoglobin (g/dL) (2 Weeks) in the Group: B group was 10.6 (10.3-10.8). The Hemoglobin (g/dL) (2 Weeks) in the Group: A ranged from 9.1 - 11.1. The Hemoglobin (g/dL) (2 Weeks) in the Group: B ranged from 9.8 - 11.7.

There was a significant difference between the 2 groups in terms of Hemoglobin (g/dL) (2 Weeks) (W = 3236.000, p = <0.001), with the median Hemoglobin (g/dL) (2 Weeks) being highest in the Group: B group.

TABLE 4 Association between 'Group' and 'Hemoglobin (g/dL) (6 Weeks)'

Hemoglobin (g/dL) (6 Weeks)	Group		Wilcoxon-Mann-Whitney U Test	
	A	B	W	p value
Mean (SD)	10.92 (0.60)	11.37 (0.61)	3336.000	<0.001
Median (IQR)	11 (10.5-11.3)	11.2 (11-12)		
Min – Max	9.5 - 12.1	10.4 - 12.5		

The variable Hemoglobin (g/dL) (6 Weeks) was not normally distributed in the 2 subgroups of the variable Group. Thus, non-parametric tests (Wilcoxon-Mann-Whitney U Test) were used to make group comparisons.

The mean (SD) of Hemoglobin (g/dL) (6 Weeks) in the Group: A group was 10.92 (0.60). The mean (SD) of Hemoglobin (g/dL) (6 Weeks) in the Group: B group was 11.37 (0.61). The median (IQR) of Hemoglobin (g/dL) (6 Weeks) in the Group: A group was 11 (10.5-11.3). The median (IQR) of Hemoglobin (g/dL) (6 Weeks) in the Group: B group was 11.2 (11-12). The Hemoglobin (g/dL) (6 Weeks) in the Group: A ranged from 9.5 - 12.1. The Hemoglobin (g/dL) (6 Weeks) in the Group: B ranged from 10.4 - 12.5.

There was a significant difference between the 2 groups in terms of Hemoglobin (g/dL) (6 Weeks) (W = 3336.000, p = <0.001), with the median Hemoglobin (g/dL) (6 Weeks) being highest in the Group: B group.

TABLE 5 Association Between 'Group' and 'Number of Doses'

Number of Doses	Group			Chi-Squared Test	
	A	B	Total	$\chi2$	P Value
1 Dose	0 (0.0%)	100 (100.0%)	100 (50.0%)	200.000	<0.001
3 Doses	34 (34.0%)	0 (0.0%)	34 (17.0%)		
4 Doses	66 (66.0%)	0 (0.0%)	66 (33.0%)		
Total	100 (100.0%)	100 (100.0%)	200 (100.0%)		

Number of Doses	Adjusted P Values
1 Dose vs. 3 Doses	<0.001
1 Dose vs. 4 Doses	<0.001
3 Doses vs. 4 Doses	1.000

Chi-squared test was used to explore the association between 'Group' and 'Number of Doses'.

There was a significant difference between the various groups in terms of distribution of Number of Doses ($\chi2$ = 200.000, p = <0.001).

0.0% of the participants in the group [Group: A] had [Number of Doses: 1 Dose]. 34.0% of the participants in the group [Group: A] had [Number of Doses: 3 Doses]. 66.0% of the participants in the group [Group: A] had [Number of Doses: 4 Doses]. 100.0% of the participants in the group [Group: B] had [Number of Doses: 1 Dose]. 0.0% of the participants in the group [Group: B] had [Number of Doses: 3 Doses]. 0.0% of the participants in the group [Group: B] had [Number of Doses: 4 Doses].

Participants in the group Group: B had the larger proportion of Number of Doses: 1 Dose. Participants in the group Group: A had the larger proportion of Number of Doses: 3 Doses. Participants in the group Group: A had the larger proportion of Number of Doses: 4 Doses.

TABLE 6 Association Between 'Group' and 'Adverse Effects'

Adverse Effects	Group			Chi-Squared Test	
	A	B	Total	$\chi2$	P Value
Present	12 (12.0%)	6 (6.0%)	18 (9.0%)	2.198	0.138
Absent	88 (88.0%)	94 (94.0%)	182 (91.0%)		
Total	100 (100.0%)	100 (100.0%)	200 (100.0%)		

Chi-squared test was used to explore the association between 'Group' and 'Adverse Effects'.

There was no significant difference between the various groups in terms of distribution of Adverse Effects ($\chi2$ = 2.198, p = 0.138).

12.0% of the participants in the group [Group: A] had [Adverse Effects: Present]. 88.0% of the participants in the group [Group: A] had [Adverse Effects: Absent]. 6.0% of the participants in the group [Group: B] had [Adverse Effects: Present]. 94.0% of the participants in the group [Group: B] had [Adverse Effects: Absent].

Odds Ratios and Relative Risks (Use whichever is applicable):

Predictor/Risk Factor	Outcome	Odds Ratio (95% CI)	Relative Risk (95% CI)
Adverse Effects: Present	Group: A	2.14 (0.77-5.94)	1.38 (0.89-1.84)
Adverse Effects: Present	Group: B	0.47 (0.17-1.3)	0.65 (0.31-1.12)
Adverse Effects: Absent	Group: A	0.47 (0.17-1.3)	0.73 (0.54-1.13)
Adverse Effects: Absent	Group: B	2.14 (0.77-5.94)	1.55 (0.9-3.21)
Group: A	Adverse Effects: Present	2.14 (0.77-5.94)	2 (0.81-4.99)
Group: A	Adverse Effects: Absent	0.47 (0.17-1.3)	0.94 (0.85-1.02)
Group: B	Adverse Effects: Present	0.47 (0.17-1.3)	0.5 (0.2-1.23)
Group: B	Adverse Effects: Absent	2.14 (0.77-5.94)	1.07 (0.98-1.18)

DISCUSSION

Table 1,2 show There was a significant difference between the 2 groups in terms of Sr.Ferritin (µg/L) (2 Weeks) (W = 2828.000, p = <0.001), with the median Sr.Ferritin (µg/L) (2 Weeks) being highest in the Group: B group. There was a significant difference between the 2 groups in terms of Sr.Ferritin (µg/L) (6 Weeks) (W = 2848.000, p = <0.001), with the median Sr.Ferritin (µg/L) (6 Weeks) being highest in the Group: B group.

Table 3,4 show There was a significant difference between the 2 groups in terms of Hemoglobin (g/dL) (2 Weeks) (W = 3236.000, p = <0.001), with the median Hemoglobin (g/dL) (2 Weeks) being highest in the Group: B group. There was a significant difference between the 2 groups in terms of Hemoglobin (g/dL) (6 Weeks) (W = 3336.000, p = <0.001), with the median Hemoglobin (g/dL) (6 Weeks) being highest in the Group: B group

Table 5 show 34.0% of the participants in the group [Group: A] had [Number of Doses: 3 Doses]. 66.0% of the participants in the group [Group: A] had [Number of Doses: 4 Doses]. 100.0% of the participants in the group [Group: B] had [Number of Doses: 1 Dose].

Table 6 show 12.0% of the participants in the group [Group: A] had [Adverse Effects: Present]. 6.0% of the participants in the group [Group: B] had [Adverse Effects: Present].

Our study found that the adverse reactions was lower among patients of FCM than Iron sucrose The overall change in Sr.Ferritin (µg/L) over time was compared in the two groups using the Generalized Estimating Equations method. There was a significant difference in the trend of Sr.Ferritin (µg/L) over time between the two groups (p = <0.001).

The overall change in Hemoglobin (g/dL) over time was compared in the two groups using the Generalized Estimating Equations method. There was a significant difference in the trend of Hemoglobin (g/dL) over time between the two groups (p = <0.001).

VanWyck et al reported increase of hemoglobin by 2 gm/dl in 1st week and 4 gm/dl by 2-4 weeks of therapy in those receiving FCM.[8] Jose et al, showed that the mean rise in Hb at 12 weeks was significantly higher in FCM group than iron sucrose group (29 gm/l versus 22 gm/l).[15] Study done by Khan et al, showed statistically significant rise in Hb in FCM group as compared to that of iron sucrose (1.79 versus 1.06 gm/dl).[14] In study of Sumathy et al, increase in level of hemoglobin among iron sucrose group was observed by 1.65 gm/dl and 2.35 gm/dl after 2 and 4 weeks of treatment.[10]

Similarly in case of FCM groups they observed the increase by 2.04 and 2.83 gm/dl at 2 and 4 weeks of treatment. According to Giannoulis et al, the mean rise of hemoglobin by 4-6 gm/dl in patients who received iron sucrose.[20] Patel et al estimated Hb level in pregnant women pre and post iron therapy.[12] They observed that in females receiving iron sucrose hemoglobin levels increased by 4.1 gm/dl while in those receiving FCM the mean rise was 5.2 gm/dl. Similar pattern of increment was also observed in our study.

Summary

200 postnatal women with iron deficiency anaemia and haemoglobin levels between 7 and 10 gm were randomly chosen for this study.With a desired haemoglobin level of 11 grammes, the iron deficit is calculated using a formula.100 women received iron sucrose and 100 women received FCM after obtaining consent and after being informed of the hazards and benefits.Both groups need approximately 1000 mg of the required amount.Patients in the iron sucrose group needed at least four visits to receive the necessary amount because only 300mg of iron sucrose may be delivered in one sitting.While in the FCM group, a single dose of 1000 mg can be administered.Using the paired T test and the independence T test, the results are compared and analysed.Haemoglobin, serum ferritin, and peripheral smear tests are performed both before and after treatment.The outcomes are listed above in brief form.

In the FCM group, haemoglobin increases on average faster and higher. In the iron sucrose group, the average haemoglobin increase is about 10.22 at two weeks and 10.92 at six weeks from the baseline value of 8.57g, while in the FCM group, the average haemoglobin increase is around 10.58 at two weeks and11.37 at six weeks from the baseline value of 8.54. Among iron sucrose group serum ferritin increases from baseline (37.2 to 199.97 at 2weeks; 113.62 at 6 weeks).

But the improvement is greater among FCM group (31.5 to 261.03 at 2 weeks; 130.86 at 6 weeks). The ferritin fall at 6th week is due to iron redistribution in haemoglobin formation.

Adverse reactions following both groups were milder. Following iron sucrose 12% developed side effects like nausea, vomiting, urticaria whereas in FCM group only 6% developed giddiness, nausea and arthralgia.

CONCLUSION

This study compared the efficacy of ferric carboxymaltose over iron sucrose in the management of postnatal iron deficiency anemia. Though our results showed improvement in hemoglobin, serum ferritin in both iron sucrose and FCM group but it was faster and greater with ferric caboxymaltose when compared with iron sucrose. Other advantages are more dose can be administered at a single visit and the hospitalization duration of the patients are reduced greater. The quality of life is also better with FCM group. FCM lacks dextran and less immunogenic so adverse reactions are also low. So out of two intravenous iron FCM seems to be clinically and statistically significant than iron sucrose in treatment of postnatal iron deficiency anemia.

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