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Comparative study on intravenous iron sucrose versus intravenous ferric carboxymaltose in the management of iron deficiency anaemia in pregnancy in a tertiary care hospital, Bengaluru

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Abstract
Background: Iron deficiency is the most common nutritional deficiency worldwide; it affects 1.6 billion people Iron deficiency (ID) and iron deficiency anemia (IDA) are often encountered in the general population, particularly among children and women with abnormal uterine bleeding (AUB) and during pregnancy as well as postpartum period Intravenous (IV) iron replacement can deliver the total amount of required iron over a short period. Currently, the most commonly used IV iron formulations are iron sucrose (IS) and ferric carboxymaltose (FCM) [4-6]. Iron sucrose does not require test dose and is safe. Ferric carboxymaltose (FCM) is the latest I.V. iron formulation which can be used at high doses and allows rapid administration (up to 1000 mg in a single dose infused in 15 minutes) The present study was a comparative study of parenteral iron therapy (intravenous iron sucrose versus intravenous ferric carboxymaltose in the management of iron deficiency anaemia in pregnancy.
Methods: In the present study, 50 pregnant women with IDA were randomly distributed into two groups of 25 each. Group - A: 25 receiving intravenous iron sucrose therapy; Group - B: 25 receiving intravenous ferric carboxymaltose therapy.
Results: Majority of the study participants in Group A had gestational age between 20–25 weeks (48%). The mean age of the study participants in Group A was found to be 22.86±4.42 weeks. Majority of the study participants in Group B had gestational age between 20-25 weeks (36%). The mean age of the study participants was found to be 23.01±3.01 weeks. Majority of the study participants in Group A had nil parity (40%). 36% of the study participants in Group B had nil parity. 60% of the study participants in group A had Mild degree of anaemia with 52% in group B having mild degree of anaemia. 40% and 44% of the study participants in group A and group B had Moderate degree of anaemia respectively. The association was found to be statistically significant between the mean Hb and Ferritin values pre-treatment, 3rd and 6th week follow-up post treatment and the 2 groups of study participants. The adverse effects were comparatively lower among Group B (IV ferric carboxymaltose) than Group A (IV iron sucrose) of the study participants.
Conclusions: IV ferric carboxymaltose administration increases the hemoglobin level more rapidly as compared to iron sucrose in women with iron deficiency anemia in the pregnancy. It also stores iron more rapidly. No serious adverse effects were recorded. Ferric carboxymaltose is well tolerated, safe and effective alternative to iron sucrose in iron deficiency anemia of pregnancy. FCM has the advantage of a large dose administration per sitting and early rise in hemoglobin level.

Keywords: Iron deficiency anaemia, Pregnancy, iron sucrose therapy, Ferric carboxymaltose

Introduction
Iron deficiency is the most common nutritional deficiency worldwide; it affects 1.6 billion people [1]. Iron deficiency (ID) and iron deficiency anemia (IDA) are often encountered in the general population, particularly among children and women with abnormal uterine bleeding (AUB) [2] and during pregnancy as well as postpartum period [3]. Traditionally, oral iron replacement is used as the first-line therapy in patients with IDA due to its ease of administration, and early initiation of this treatment can correct anemia However, oral iron has some disadvantages such as side-effects, poor compliance, and limited gastrointestinal absorption [4]. Sometimes, oral iron replacement even after prolonged treatment may fail to adequately correct anemia and iron reserves, before delivery in pregnant women [5, 6]. This situation can be easily and efficiently remedied by the use of intravenous (IV) iron replacement,

which can deliver the total amount of required iron over a short period. Currently, the most commonly used IV iron formulations are iron sucrose (IS) and ferric carboxymaltose (FCM) [7–9]. The present study was a comparative study of parenteral iron therapy (intravenous iron sucrose versus intravenous ferric carboxymaltose in the management of iron deficiency anaemia in pregnancy

Objective of the study

- To compare mean haemoglobin values and adverse effects between intravenous ferric carboxymaltose and intravenous iron sucrose in pregnant women with IDA.

Methodology

- **Study Design:** Prospective study
- **Study Duration:** 6 months (January 2022 - June 2022)
- **Study Area:** MVJ Medical College and Research Hospital, Bangalore.
- **Study Participants:** Pregnant women with iron deficiency anaemia attending MVJ Medical College and Research Hospital, Bangalore.

Inclusion Criteria

1. Pregnant women with iron deficiency anemia with hemoglobin values between 7-10 gm%
2. Gestational age 16-34 weeks
3. Single viable fetus with no anomalies

Exclusion criteria

1. Pregnant women with anemia due to causes other than iron deficiency,
2. History of blood transfusion and erythropoietin treatment in present pregnancy
3. Other medical disorders complicating pregnancy or history of hematological diseases, specific allergy to iron derivatives.

Estimation of sample size

On the basis of statistics obtained from Department of Obstretics & Gynaecology, M.V.J. Medical College and Research Hospital, an average of 8 cases per month fitting the criteria of the study with study duration of 6 months, we can expect to have N=48. Based on this population size, using YAMANE equation, for a known population size, sample size (n) equal to

n =N/1+Ne2

n=sample size

N=population size

e= margin of error (for 95% of confidence level, margin error =0.05)

n=48/1+48*0.05*0.05 = 48/1.12 = 42.85

Therefore after approximating, the sample size of the study participants was fixed at 50. 50 pregnant women with IDA were randomly distributed into two groups of 25 each.

Group - A: 25 receiving intravenous iron sucrose therapy;

Group - B: 25 receiving intravenous ferric carboxymaltose therapy.

Results

Table 1: Distribution of the study participants according to their gestational age

Gestational age	Group – A		Group - B	
	Frequency N	Percentage %	Frequency N	Percentage %
16 - 20 weeks	7	28	8	32
20 – 25 weeks	12	48	9	36
26 – 30 weeks	5	20	6	24
30 – 34 weeks	1	4	2	8
MEAN + SD	22.86 + 4.42		23.01 + 3.01	

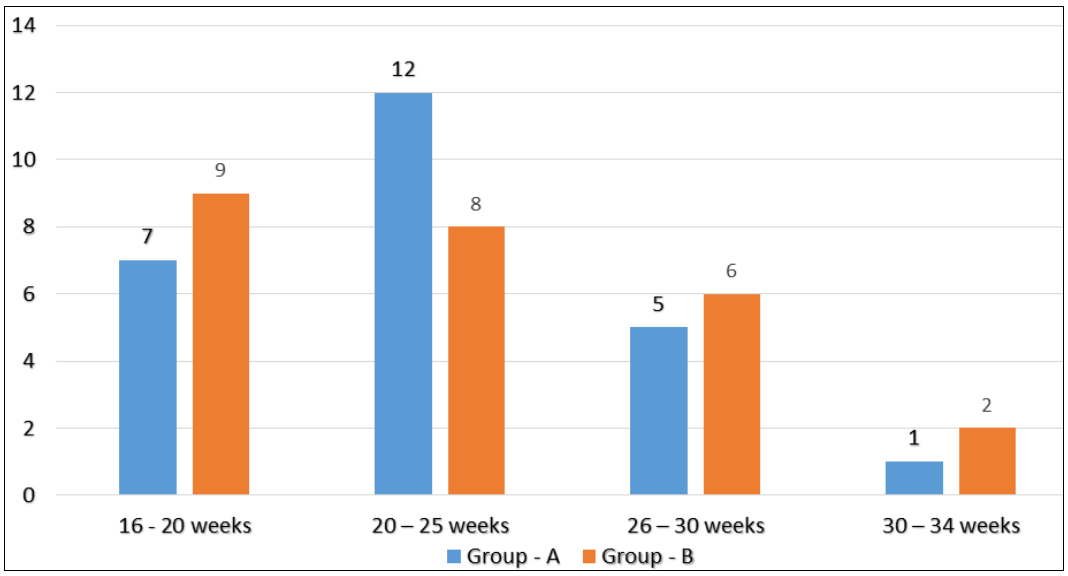

Fig 1: Distribution of 2 groups of study participants according to their gestational age

Majority of the study participants in Group A had gestational age between 20–25 weeks (48%). The mean age of the study participants in Group A was found to be 22.86 ± 4.42 weeks.

Majority of the study participants in Group B had gestational age between 20-25 weeks (36%). The mean age of the study participants was found to be 23.01 ± 3.01 weeks.

Table 2: Distribution of 2 groups of study participants according to their parity

Parity	Group – A		Group - B	
	Frequency N	Percentage %	Frequency N	Percentage %
Nil	10	40	9	36
1	8	32	6	24
2	4	16	5	20
≥ 3	3	12	5	20

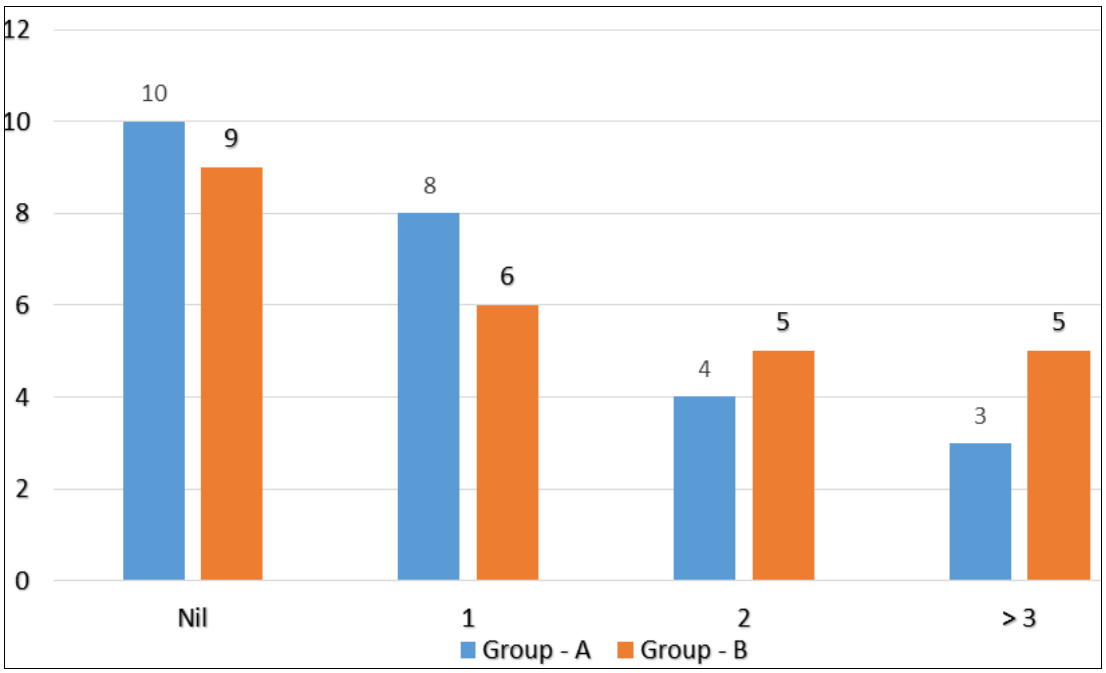

Fig 2: Distribution of 2 groups of study participants according to their gestational age

Majority of the study participants in Group A had nil parity (40%). 36% of the study participants in Group B had nil parity.

Table 3: Degree of anaemia between 2 groups of study participants

Degree of anaemia	Group A		Group B	
	Frequency N	Percentage %	Frequency N	Percentage %
Mild	15	60	13	52
Moderate	10	40	11	44
Severe	0	0	1	4

60% of the study participants in group A had Mild degree of anaemia with 52% in group B having mild degree of anaemia. 40% and 44% of the study participants in group A and group B had Moderate degree of anaemia respectively.

Table 4: Mean haemoglobin values across time period between 2 groups of study participants

Time period	Group A		Group B		P value
	Mean	SD	Mean	SD	
Pre-treatment	8.52	0.91	8.01	0.32	0.001
3 weeks post-treatment	9.50	1.02	9.82	0.93	
6 weeks post-treatment	10.62	0.72	11.30	1.07	

The mean Hb values in Group B (IV ferric carboxymaltose) were higher during 3rd and 6th week follow-up post treatment when compared with Group A (IV iron sucrose) of the study participants. The association was found to be statistically significant between the mean Hb values pre-treatment, 3rd and 6th week follow-up post treatment and the 2 groups of study participants.

Table 5: Mean Ferritin values across time period between 2 groups of study participants

Time period	Group - A		Group – B		P value
	Mean	SD	Mean	SD	
Pre-treatment	11.83	1.26	11.07	1.21	0.001
3 weeks post-treatment	56.55	12.07	80.12	6.05	
6 weeks post-treatment	80.72	13.96	98.21	7.82	

The mean Ferritin values in Group B (IV ferric carboxymaltose) were higher during 3rd and 6th week follow-up post treatment when compared with Group A (IV iron sucrose) of the study participants. The association was found to be statistically significant between the mean Ferritin values pre-treatment, 3rd and 6th week follow-up post treatment and the 2 groups of study participants.

Table 6: Adverse effects between 2 groups of study participants

Adverse effects	Group A		Group B	
	Frequency N	Percentage %	Frequency N	Percentage %
Injection site swelling	5	20	2	8
Injection site pain	6	24	3	12
Nausea, vomiting	3	12	2	4
Gastritis	1	4	2	4
Guidiness	1	4	0	0
Muscle cramp	1	4	0	0

24% and 12% of the study participants in Group A and Group B had injection site pain respectively. The adverse effects were comparatively lower among Group B (IV ferric carboxymaltose) than Group A (IV iron sucrose) of the study participants.

Discussion

In the present study, Majority of the study participants in Group A had gestational age between 20–25 weeks (48%). The mean age of the study participants in Group A was found to be 22.86 ± 4.42 weeks. Majority of the study participants in Group B had gestational age between 20-25 weeks (36%). The mean age of the study participants was found to be 23.01 ± 3.01 weeks. In a study done by Khatun F *et al*. [10], More than one third of patients of both FCM (40%) and iron sucrose (40%) had gestational age 26-30 weeks. The mean gestational age of patients of FCM and Iron sucrose was 24.86±4.48 and 23.92±4.65 weeks respectively. These findings are comparable with the findings of the present study. In the present study, Majority of the study participants in Group A had nil parity (40%) and 36% of the study participants in Group B had nil parity. In a study done by Khatun F *et al*. [10], 22.2% patients in the FCM group and 32.2% in Iron sucrose group were found to be nulliparous.

In the present study, 60% of the study participants in group A had Mild degree of anaemia with 52% in group B having mild degree of anaemia. 40% and 44% of the study participants in group A and group B had Moderate degree of anaemia respectively. In a study done by Parikh A *et al*. [11], 32% patients in the FCM group and 62% in Iron sucrose group had mild degree of anaemia.

In the present study, The mean Hb values in Group B (IV ferric carboxymaltose) group were higher during 3rd and 6th week follow-up post treatment when compared with Group A (IV iron sucrose) of the study participants. The association was found to be statistically significant between the mean Hb values pre-treatment, 3rd and 6th week follow-up post treatment and the 2 groups of study participants. In the present study, The mean Ferritin values in Group B (IV ferric carboxymaltose) group were higher during 3rd and 6th week follow-up post treatment when compared with Group A (IV iron sucrose) of the study participants. The association was found to be statistically significant between the mean Ferritin values pre-treatment, 3rd and 6th week follow-up post treatment and the 2 groups of study participants. In a study done by Parikh A *et al*. [11], they found that increment in the mean haemoglobin values were slightly more in the patients treated with FCM as compared to iron sucrose. Also, Serum ferritin level increased in both treatment modalities but was more in patient treated with FCM. In a study done by Khatun F *et al*. [10], they found that there was significant (p=0.001) difference in Hb level as well as serum ferritin levels between the groups at post treatment 3 and 6 weeks. These findings are comparable with the findings of the present study.

In the present study, 24% and 12% of the study participants in Group A and Group B had injection site pain respectively. The adverse effects were comparatively lower among Group B (IV ferric carboxymaltose) than Group A (IV iron sucrose) of the study participants. In a study done by Khatun F *et al*. [10], they found that the adverse reactions was lower among patients of FCM than iron sucrose. In a study done by Parikh A *et al*. [11], the adverse events were all mild and quickly reversible and mostly restricted to local reaction at the infusion site in both the treatment groups. These findings are comparable with the findings of the present study.

Conclusion

IV ferric carboxymaltose administration increases the haemoglobin level more rapidly as compared to iron sucrose in women with iron deficiency anemia in the pregnancy. It also stores iron more rapidly. No serious adverse effects were recorded. Ferric carboxymaltose is well tolerated, safe and effective alternative to iron sucrose in iron deficiency anemia of pregnancy. FCM has the advantage of a large dose administration per sitting and early rise in hemoglobin level.

Conflict of Interest

Not available

Financial Support

Not available

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