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A Comparative Study of Efficacy and Safety of Intravenous Iron Sucrose *vs* Intravenous Ferric Carboxy Maltose in Correcting Iron Deficiency Anemia in Post-Partum Period

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Abstract

Introduction: Post-partum anemia needs a major concern not only to ensure healthy puerperum, better mother baby bonding, build up iron reserves in the puerperal to have a better quality of life and also to ensure minimized incidence of anemia in next pregnancy and to crucially avoid maternal and perinatal mortalities. This co-morbid condition can be effectively treated with the help of intravenous iron therapy. This study aims to compare the efficacy and safety of intravenous ferric carboxymaltose with intravenous iron sucrose in treating anemia during post-partum period.

Method: This interventional prospective study conducted in the Department of Obstetrics and Gynecology at T.M.U Moradabad, India, encompassed a total of 120 postnatal women in the 2 equal predefined study group, pertaining to- Group A who received intravenous iron sucrose and Group B who received intravenous ferric carboxymaltose. The rise in Hemoglobin and serum ferritin levels and with the evaluation of its safety and tolerance were compared primarily at 24 hr postpartum and secondarily at 3 weeks post treatment amongst the two groups.

Results: The mean rise in the hemoglobin level with ferric carboxymaltose was 2.35 gm/dl and with that of iron, sucrose was 1.51 gm/dl (pvalue<.01). The mean rise in the serum ferritin levels with ferric carboxymaltose was 53.03 ng/ml and with iron sucrose was 43.91 ng/ml. (p value<. 01). Ferric carboxymaltose was observed to be safer with less adverse events in comparison to the Iron sucrose.

Conclusion: Properties like ultra-short duration of treatment, fewer adverse reactions and better compliance makes FCM the first-line drug in the management of postpartum iron deficiency anemia.

Keywords: Hemoglobin; Intravenous ferric carboxymaltose; Intravenous iron sucrose; Serum ferritin

Background

Iron deficiency anemia is the commonest nutritional deficiency in the world. Similarly maternal anemia is a major health concern especially in pregnancy and reproductive age group and developing countries have the highest incidenc [1]. The following can be the causes of iron deficiency anemia in women during pregnancy- hookworm infestation, improper diet, nutritional deficiencies such as folic acid deficiency, vitamin B12 deficiency, vitamin A deficiency, genetic hemoglobinopathies such as sickle cell anemia and thalassemia, helicobacter pylori, malaria etc [2-4]. Anemia in pregnant women is much more prevalent in developing countries than in developed countries (52% *vs* 22.5%) [5]. The highest disease burden of anemia in pregnancy is amongst South Asia (80%), Asia (60%), and Africa (52%) [5]. There is also the difference between the prevalence rates of anemia in the country, Andhra Pradesh having 33% and Rajasthan having 90% of prevalence rate [6-8].

The factors responsible for and leading to iron deficiency anemia in pregnancy includes

- Diet poor in iron content coupled with
- Regular menstrual losses
- Increased risk of infections or infestation.
- Exacerbated by the physiological effects of pregnancy.
- Blood losses at the time of delivery.
- Multiple number pregnancies in which iron is not supplemented.
- Closed spaced pregnancies.

Since the introduction of parenteral iron therapy, there have been 3 generations of parenteral iron-

- 1 generation- high molecular weight iron dextran and iron-sorbitol-citric acid complex.
- 2 generation included- iron sucrose (IS) and low molecular weight iron dextran.
- 3 generation- ferric carboxymaltose (FCM) and ferric isomaltoside.

After the first trimester, treatment of IDA with IV iron appears superior to oral iron therapy with respect to a faster increase in the hemoglobin concentration and faster replenishment of body iron stores. The use of IV iron prior to delivery may reduce the need for blood transfusions in the postpartum period and constitutes an alternative to blood transfusion in profound IDA. Furthermore, IV iron administered as total dose infusion yields

replenishment of body iron reserves within a few days compared with oral iron therapy.

Ferric iron carboxymaltose as the studies suggests, has proven effective in the treatment of postpartum anemia. According to the manufacturer's instructions, up to 1,000 mg iron dissolved in 250 ml isotonic saline can be given as a single infusion over 15–60 min. The total-dose-infusion concept is convenient for the patient and can save resources in the health care system. In this study, we compare and evaluate the safety and efficacy of IV ferric carboxymaltose and iron sucrose in treatment of postpartum iron deficiency anemia.

Methodology

- The sample size of 120 subjects was selected from the postpartum women admitted in maternity ward of obstetrics and gynaecology department who fulfilled the selection criteria.
- Written and informed consent was taken for getting enrolled in the study.
- After history taking and clinical examination, the iron deficiency anemia was confirmed by - Complete Blood Count and Peripheral Blood Picture done after 24 hours of delivery. The baseline serum ferritin levels were also done.
- Parenteral iron dosage was calculated according to the Hb deficit formula- [2.4 x Weight of the patient in Kgs (target Hb - Hb of the patient)+500].
- All patients were given deworming therapy (Tab. Albendazole 400 mg orally single dose).

All Subjects were then divided into two groups (Group A and Group B) by envelope method of randomization, w ith 60 patients in each group:

Group A: received IV Iron Sucrose 200 mg/day in multiple doses, on alternate days, by IV injection mixed with 100 ml of normal saline (0.9%) over 15 mins, till the required dose is completed.

Group B: received injection FCM according to the calculated dose of Hb deficit by infusing 500 or 750 or 1000 mg FCM in 100 ml, 150 ml or 250 ml of norm al saline over 15 mins respectively. Additional required dose above 1000 mg was administered after 7 days of initial therapy.

- During infusion and up to 1 hour after completion of infusion, patient were kept under strict observation, patient's pulse rate, blood pressure, temperature and respiratory rate was monitored every 5 minutes during infusion and every 15 minutes after the completion of parenteral iron therapy.
- Patients were observed for any side effects like headache, nausea, diarrhea, vomiting, pain and burning at injection site, rigor, fever, hypotension and hypertension, tingling sensation, itching or any other side effects during the therapy and for 1 hour after completion of infusion.
- All women were followed up after 4 weeks of receiving last dose of parenteral iron therapy. Repeat complete blood count and Serum ferritin levels were done and outcome was measured.
- All demographic data, history, clinical findings, laboratory investigation reports, and outcome measures related to efficacy and safety was recorded in predesigned proforma.

Statistical analysis

The quantitative data was represented as their mean ± SD. Categorical and nominal data was expressed in percentage. The t-test was used for analyzing quantitative data, or else non parametric data was analyzed by Mann Whitney U test i.e. U=R-n(n+1)/2 [where R is the sum of ranks in the sample, and n is the number of items in the sample] and categorical data was analyzed by using chi-square test. The significance threshold of p-value was set at <0.05. All analysis was carried out by using SPSS software version 21.

Results

Total number of patients was 120, sixty in each group. Most of the females were between 20-29 years of age (71.7%) in both groups with no statistical difference between the groups (p-0.44). Table 1.

Table 1: Age wise distribution of cases.

Age	Group		Total
	AA	BB	
20-24	19	20	39
	31.70%	33.30%	32.50%
25-29	26	21	47
	43.30%	35.00%	39.20%
30-35	15	17	32
	25.00%	28.30%	26.70%

>35	0	22	22
	0.00%	3.30%	1.70%
Total	60	60	120
	100.00%	1 00.0%	100.00%
- value - 0.44			

A total of 52.5% case were from lower socio-economic status (SES) while 40.8% were from middle socio-economic status indicating more prevalence of anaemia in poor and uneducated patients as shown in Table 2.

Table 2: Distribution of cases according to socioeconomic status.

Socio-economic Status	**Group**		**Total**
	Group a	**Group b**	
Lower	37	26	63
	61.7%	43.3%	52.5%
Middle	20	29	49
	33.3%	48.3%	40.8%
Upper	3	5	8
	5.0%	8.3%	6.7%
Total	60	60	120
	100.0%	100.0%	100.0%
p- value - 0.13			

Table number 3 shows booking status of patient and its correl ation with average hemoglobin of that group. In group a total number of unbooked cases were 44 and their average hemoglobin was 9.06 which were lower as compared to booked 9.21. Similarly in group B, 49 cases of unbooked cases Hb was 8.75 in comparison to 11 booked cases with Hb of 9.5 indicating the importance of antenatal care.

Table 3: Effect on haemoglobin in booked versus unbooked patients.

Booking of the patient				
Booking status	**Group a**		**Group b**	
	No. of patients	**Hemoglobin pretreatment (gm/dl)**	**No. of patients**	**Hemoglobin pretreatment (gm/dl)**
Booked	16	9.21	11	9.5
Unbooked	44	9.06	49	8.75
Total	60		60	

Table 4 depicts the difference in rise of haemoglobin between two groups. Mean baseline haemoglobin in sucrose and Ferric Carboxymaltose group was 9.01 and 8.91 gm% respectively which improved to 10.52 and 11.26 gm% after intervention. The

increase in hemoglobin levels was significantly more in Ferric Carboxymaltose group (2.35 gm%) as compared to sucrose group (1.51 gm%) (p<0.01).

Table 4: Effect on haemoglobin on group A and B after treatment.

Variables	Group	N	Mean	SD	p- value (Inter-group)	p- value (Intra-group IS)	p- value (Intra-group FCM)
Pretreatment hemoglobin (gm/dl)	A	60	9.01	1.02	0.59	<0.01	<0.01
	B	60	8.91	1.11			
Post treatment hemoglobin (gm/dl)	A	60	10.52	1.26	<0.01		
	B	60	11.26	1.21			

Table 5 shows post intervention, all the RBC indices i.e. MCV, MCH, MCHC and RDW improved significantly in both groups (p<0.05); however no difference was observed between sucrose and Ferric Carboxymaltose group (p>0.05).

Table 5: Different RBC indices in both the groups post treatment.

Variables	Group	N	Mean	SD	p- value	p- value (Intra-group IS)	p- value (Intra-group FCM)
Pretreatment MCV (fl)	A	60	76.55	11.00	0.43	0.011	0.013
	B	60	74.95	11.03			
Post treatment MCV(fl)	A	60	78.03	9.05	0.90		
	B	60	78.29	13.73			
Pretreatment MCH(pg)	A	60	27.32	3.47	0.81	<0.01	<0.01
	B	60	27.10	6.12			
Post treatment MCH(pg)	A	60	28.98	3.06	0.50		
	B	60	29.73	7.96			
Pretreatment MCHC(gm/dl)	A	60	30.06	2.28	0.63	<0.01	<0.01
	B	60	29.83	2.82			
Post treatment MCHC(gm/dl)	A	60	31.55	2.26	0.60		
	B	60	31.34	2.17			
Pretreatment RDW(%)	A	60	18.66	3.54	0.67	<0.01	<0.01
	B	60	18.39	3.36			
Posttreatment RDW(%)	A	60	15.14	3.20	0.02		
	B	60	16.53	3.32			

Table 6 shows mean baseline ferritin levels in sucrose and Ferric Carboxymaltose group was 27.26 and 25.69 ng/mL which improved to 65.93 and 86.24 ng/mL respectively after intervention. The increase in ferritin levels was significantly more in Ferric Carboxymaltose group (60.55 ng/mL) as compared to sucrose group (38.67 ng/mL) (p<0.01)

Table 6: Effect on serum ferritin in both the groups post treatment.

Ferritin Levels (ng/ml)	Group	N	Mean	SD	p- value	p- value (Intra-groupS)	p- value (Intra-group FCM)
Pre treatment	A	60	27.26	30.65	0.76	<0.01	<0.01
	B	60	25.69	25.08			
Post treatment	A	60	65.93	29.32	<0.01		
	B	60	86.24	28.61			

Table 7 shows most common adverse reactions reported in sucrose and Ferric Carboxymaltose group cases were pain and swelling at injection site (6.7%) and nausea/ vomiting (4.2% each). Other side effects includes metallic taste (6.7% *vs* 0%), dirrhoea (3.3% *vs* 1.7%), muscle cramps (1.7% *vs* 0%), constipation (1.7% *vs* 0%) and headache (1.7% *vs* 0%), whichwere slightly more prevalent in group B. The difference was however not statistically significant (p>0.05).

Table 7: Side effects post treatment in both the groups.

Adverse reactions	Group		Total	p-value
	A	B		
Muscle cramps	1	0	1	0.5
	1.7%	0.0%	0.8%	
Diarrhoea	2	1	3	1.00
	3.3%	1.7%	2.5%	
Nausea/ Vomiting	2	3	5	1.00
	3.3%	5.0%	4.2%	
Metallic taste	4	0	4	0.12
	6.7%	0.0%	3.3%	
Constipation	1	0	1	0.50
	1.7%	0.0%	0.8%	
Headache	1	0	1	0.50
	1.7%	0.0%	0.8%	
Pain and swelling at site	6	2	8	0.27
	10.0%	3.3%	6.7%	

Discussion

Postpartum anemia (defined as Hb<10 gm/dl) is social health problem in the world [9]. The prevalence of postpartum anemia is 27% and a postpartum haemoglobin (Hb) level of less than 8 g/dl is observed in 10% of women [10,11].

In India early age at marriage and childbearing is very prevalent, especially in economically backward and rural areas. The high rate of illiteracy in India leads to low socio-economic status which in turn becomes the cause of poor maternal health due to its customs, beliefs, and taboos where male child is preferred over female child. Women are the biggest community

to be ignored, especially when it comes to their health, keeping need of their family's first, poor nutrition and lack of personal hygiene all these reasons breeds a vicious cycle which ultimately compromises the life of the female.

Postpartum iron deficiency is a social problem as it has been associated with maternal postpartum depression and stress thereby hampering infant care, further leading to their developmental delay [12,13].

Oral iron therapy is currently the treatment of choice for the majority of patients with iron deficiency anemia but it has disadvantages like poor absorption, poor compliance and gastro-intestinal (GI) side effects. Parenteral iron helps in restoring iron stores faster and more effectively than oral Iron. Intravenous iron sucrose is safe, effective, and economic in comparison to the repeated and painful intramuscular iron injections. By far, the largest experience in the published literature is with this formulation. In their study observed that Intravenous iron sucrose administration increases the haemoglobin level and serum ferritin levels more rapidly, without any serious adverse effect in comparison with oral ferrous sulphate in women with iron deficiency anemia in the postnatal period [15].

In Our Study most of the females were between 20-29 years of age (71.7%), pointing that most women were entering their reproductive age with insufficient iron stores. This was because of similar reasons mentioned before in addition with- increasing growth needs, chronic blood loss due to menstruation or hookworm infestation, lack of iron in the diet, vegetarian food forming the major portion of their diet, and these women were very likely to succumb to increasing iron demands of pregnancy and postpartum period thus developing anemia. A similar study by Breymann et al. [14].

Table 8: Reported the mean age in their study as 27.7 yrs.

Study	Mean age	
	IS	FCM
Naqash, et al.	27·32 ± 4·15 yrs	30·41 ± 7·99 yrs
Vitthal Hol, et al.	20-25 years	20-25 years
Joshi, et al.	1 8-25 yrs (74.7%)	18-25 yrs (71.1%)
Present study	20-29 yrs	20-29 yrs

The study by Irfan Ullah et al. states the prevalence of anemia among pregnant women to be as high as 67.6%. Also the percentage was high in illiterate 88%, lower socioeconomic condition 80%, and 30-37 age pregnant women, similarly in this study most of the females were uneducated or were educated below higher secondary, 79 patients (65.9%)] and belonged to lower socio-economic status 63 patients (52.5%)], it shows that education has an influence over anemia through knowledge on health (such as need for antenatal visit, iron requirements, better compliance to stick to medical advices), occupation and socio-economic status [21].

Table 9: Socio-economic status.

Study	Socio-economic status in is group	Socio-economic status in FCM group
Joshi, et al.	low- 68.7%	low- 67.8%
	middle - 31.3%	middle- 32.2%
Garg. R, et al.	Lower middle class	Lower middle class
Present study	lower (61.7%)	Middle (48.3%)

On comparing the response to these two drugs for replenishment of iron deficiency, we found that Ferric Carboxymaltose caused relatively rapid rise in Haemoglobin levels. Mean baseline haemoglobin in iron sucrose and Ferric Carboxymaltose group was 9.01 and 8.91 gm% which improved to 10.52 and 11.26 gm% respectively after intervention. The increase in haemoglobin levels were significantly more in Ferric Carboxymaltose group (2.35 gm%) as compared to sucrose group (1.51 gm%) ($p<0.01$).

Similar to present study, Sharma N et al. observed a mean increase in Hb (p- value <0.001, 0.001) and ferritin (p value<0.001,0.001) in both the groups. Intergroup comparison showed FCM was superior to IS (p-value <0.001) for both rise in heamoglobin as well as serum ferritin levels [17]. Keklik M et al. also observed an expected increase in haemoglobin (Hb) and median ferritin levels in both groups. Post treatment fe rritin levels increased more significantly in the FCM group than in the IS group (58.15 *vs*. 29.65 ng/mL, respectively) ($p<0.001$) [18].

Lunagariya M et al. in their study observed mean rise of Hb as 1.9 gm/dl for FCM group and 1.66 gm/dl for iron sucrose group, which was statistically significant. Serum ferritin level in ferric carboxymaltose group also raised more (83.9 ng/ml) as compared to (76.06 ng/ml) iron sucrose group [22].

In the present study, most common adverse reactions reported in Iron sucrose and Ferric Carboxymaltose group cases were pain and swelling at injection site (6.7%) and nausea/ vomiting (4.2% each). Other side effects that were noted were in comparison to groups- metallic taste (6.7% *vs* 0.0%), diarrhea (3.3% *vs* 1.7%), muscle cramp (1.7% *vs* 0.0%), constipation (1.7% *vs* 0.0%) and headache (1.7% *vs* 0.0%) others reported adverse events, which were slightly more prevalent in sucrose group. The difference was however not statistically significant (p>0.05). The incidence of drug related adverse events was low and comparable to those described for ferric carboxymaltose and iron sucrose in other studies [1,6,7,9,11,12]. Registered adverse events were all mild and quickly reversible. There were no treatment-related serious adverse events. No anaphylactic or anaphylactoid reaction was detected. No venous thrombosis was registered. None of the adverse events required further medical intervention [19,20]. In a similar study reported side effects in 40% among patients treated with iron sucrose as compared to 16.67% in case of ferric carboxymaltose group [21,22]. Aimed to compare the safety and efficacy of intravenous iron sucrose and I.V. ferric carboxymaltose in treating postpartum iron deficiency anemia [23,24].

Conclusion

The comparative study between IV Iron Sucrose and IV Ferric Carboxymaltose yielded following results-

Most of the subjects in Most of the females were between 20-29 years of age (71.7%) in both groups with no statistical difference between the groups (p-0.44).

A total of 52.5% case was from lower socio-economic status (SES) while 40.8% were from middle socio-economic status. The average heamoglobin in cases belonging to lower socio-economic strata was found to be lower (8.77 gm/dl) as compared to other two classes (middle class-9.17 gm/dl and upper class 9.63 gm/dl). No statistical difference was however observed between the groups with respect to Socio-economic status (p-0.44).

A total of 22.5% cases were booked either inside or outside our hospital while 77.5% cases were unregistered pregnancies. The average pretreatment hemoglobin in booked cases (9.21 and 9.5 gm/dl in group A and B respectively) was higher in comparison to average pretreatment hemoglobin in unbooked cases (9.06 and 8.75 gm/dl in group A and B respectively) No statistical difference was observed between the groups with respect to booking status of cases (p-0.06).

Mean baseline hemoglobin in iron sucrose and Ferric Carboxymaltose group was 9.01 and 8.91 gm% which improved to 10.52 and 11.26 gm% respectively after intervention. The increase in hemoglobin levels was significantly more in FCM group (2.35 gm%) as compared to IS group (1.51 gm%) (p<0.01).

Post intervention, all the RBC indices i.e. MCV, MCH, MCHC and RDW improved significantly in both groups (p<0.05); however, no difference was observed between iron sucrose and Ferric Carboxymaltose group (p>0.05).

Mean baseline ferritin levels in sucrose and Ferric Carboxymaltose group was 27.26 and 25.69 ng/mL which improved to 65.93 and 86.24 ng/mL respectively after intervention. The increase in ferritin levels was significantly more in Ferric Carboxymaltose group (60.55 ng/mL) as compared to iron sucrose group (38.67 ng/mL) (p<0.01).

Common adverse reactions reported in sucrose and Ferric Carboxymaltose group cases were pain & swelling at injection site (10% *vs* 3.3%) and nausea/ vomiting (3.3% *vs* 5% each). Other reported adverse events were also slightly more prevalent in iron sucrose group, the difference was however not statistically significant (p>0.05), and there were no major side effects.

We thus conclude that Intravenous ferric carboxymaltose administration increases the hemoglobin level more rapidly in comparison to iron sucrose in women suffering from with IDA in postnatal period. Ferric carboxymaltose is associated with fewer side effects as compared to iron sucrose. It has the benefits of increasing the iron content more rapidly thereby reducing the need for multiple applications and thus also increases patient comfort.

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