Ferric carboxymaltose: A revolution in the treatment of postpartum anemia in Indian women

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Abstract

Objectives: The objective of the present study is to compare the safety and efficacy of ferric carboxymaltose (FCM), intravenous (IV) iron sucrose and oral iron in the treatment of post = partum anemia (PPA). **Materials and Methods:** A total of 366 women admitted to SCB Medical College, Cuttack between September 2010 and August 2012 suffering from PPA hemoglobin (Hb) <10 g/dL were randomly assigned to receive either oral iron or IV FCM or iron sucrose. FCM, IV iron sucrose, and oral iron were given as per the protocol. Changes in hemoglobin (Hb) and serum ferritin levels at 2 and 6 weeks after treatment were measured and analyzed using ANOVA. Adverse effects to drug administration were also recorded. **Results:** A statistically significant increase in Hb and serum ferritin level were observed in all three groups, but the increase in FCM group was significantly higher (P < 0.0001) than conventional iron sucrose and oral iron group. The mean increase in Hb after 2 weeks was 0.8, 2.4, and 3.2 g/dL and 2.1, 3.4, and 4.4 g/dL at 6 weeks in oral iron, iron sucrose and FCM groups, respectively. The mean increase in serum ferritin levels after 2 weeks was 2.5, 193.1, and 307.1 and 14.2, 64, and 106.7 ng/mL after 6 weeks in oral iron, iron sucrose and FCM groups, respectively. Adverse drug reactions were significantly less (P < 0.001) in FCM group when compared with other two groups. **Conclusion:** Ferric carboxymaltose elevates Hb level and restores iron stores faster than IV iron sucrose and oral iron, without any severe adverse reactions. There was better overall satisfaction reported by the patients who received FCM treatment.

Key words: Ferric carboxymaltose, iron Sucrose, oral iron, postpartum iron deficiency anemia **Submission:** 30-01-2014 **Accepted:** 30-07-2014

INTRODUCTION

World Health Organization has defined postpartum anemia (PPA) as hemoglobin (Hb) of <10 gm% during the postpartum period.^[1] The prevalence of PPA varies from 4% to 27%.^[2] In a survey from a north Indian village, about 70% women in the postpartum period were found to be anemic.^[3] About 29.8% of women who were not

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	DOI: 10.4103/2229-516X.149230		

previously anemic during pregnancy become anemic after delivery.^[4] PPA affects low income and minority women disproportionately, imposes a substantial disease burden during a critical period of maternal-infant interaction, and may give rise to lasting developmental deficits in infants of affected mothers.^[5] Iron deficiency is the most common cause of anemia worldwide. Each ml of blood loss results in loss of 0.5 mg iron. About 20% of maternal deaths worldwide can be attributed to anemia.^[6] In India, about 36% of the total maternal deaths are attributable to postpartum hemorrhage or anemia.^[7] In healthy women after normal delivery, the prevalence of anemia 1-week postpartum is 14% in iron-supplemented women and 24% in nonsupplemented women.^[8] Patients with severe PPA have a longer average length of hospital stay, are more likely to receive a blood transfusion and incur higher hospitalization costs.^[9] About 18% of women hospitalized with anemia and postpartum bleeding receive a blood transfusion.^[9] Currently, the Center for Disease Control and Prevention (CDC; Atlanta, Georgia) recommends selective anemia screening at 4-6 weeks postpartum

for women who have had "anemia continued through the third trimester," "excessive blood loss during delivery" and "multiple births."^[10] 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 (IV) iron sucrose is safe, effective, and economic in comparison to the repeated and painful intramuscular iron injections. Although the incidence of anaphylaxis and other adverse reactions with IV iron sucrose is markedly lower, multiple doses and prolonged infusion times are typically required.^[9] IV ferric carboxymaltose (FCM) has a neutral pH (5.0-7.0) and physiological osmolarity, which makes it possible to administer its higher single doses over shorter time periods (single dose up to 1000 mg over 15 min) than other parenteral preparations.^[11] Moreover, it does not contain dextran; therefore, the risk of anaphylaxis or serious hypersensitivity reactions is very low, and a test dose is also not required. FCM though reported in the literature is yet to find its place in India for routine use. In this study, we compare and evaluate the safety and efficacy of IV FCM, iron sucrose and oral iron in the treatment of postpartum iron deficiency anemia.

MATERIALS AND METHODS

This comparative study was conducted at SCB Medical College, Cuttack, Odisha between September 2010 and August 2012. Approval of institutional ethics committee was obtained before starting the study. The patients with hemoglobin (Hb) <10 g/dL, suffering from postpartum iron deficiency anemia were randomly categorized to receive IV FCM, IV iron sucrose or oral iron/ferrous ascorbate 100 mg daily. The adverse effects to drug administration in the three groups were recorded and treated if needed. Patients are having sickle cell anemia, thalassemia, aplastic anemia, megaloblastic anemia, anemia due to liver disease, kidney disease, cardiovascular disease, history of recent blood transfusion and history of allergy to parenteral iron therapy were excluded from the study. Investigations, including peripheral smear, baseline serum ferritin and Hb levels were initially measured. The doses for IV FCM and IV iron sucrose were calculated as under:

Dose calculation/total dose infusion for intravenous iron sucrose

In PPA = $2.4 \times W \times D + 500$ where W = weight in kg, D = Target - Actual Hb/Hb deficit, Target Hb in postpartum women = 12 g/dL, 500 mg for body stores in lactation. The factor 2.4 is derived from blood volume, which is 7% of body weight and iron content of Hb, which is 0.34%. $0.07 \times 0.0034 \times 100 = 2.4$ (conversion from g/dL to mg).

Iron sucrose is given by IV injection according to the iron deficit calculated and rounded up to the nearest multiple of 100 for each individual. 300 mg elemental iron diluted in 300 mL normal Saline 0.9% was the maximum dose given as slow IV infusion over 30 min in this study and was repeated on alternate days when necessary.

Dose calculation/total drug infusion for ferric carboxymaltose

The cumulative dose required for Hb restoration and repletion of iron stores is calculated by the following Ganzoni formula:

Cumulative iron deficit (mg) = body weight in kg × (Target Hb - Actual Hb g/dL) × 2.4 + iron storage depot (mg). For patients \leq 66 kg: The calculated cumulative dose is to be rounded down to the nearest 100 mg. For patients > 66 kg: The calculated cumulative dose is to be rounded up to the nearest 100 mg.

In this study, FCM was administered only by IV drip infusion. IV drip infusion - maximum single dose of 1000 mg (20 mL) diluted in 250 mL sterile 0.9% sodium chloride solution over 15 min not more than once a week and not exceeding 0.3 mL of FCM injection (15 mg of iron)/kg body weight or the calculated cumulative dose.

Statistical analysis

The changes in Hb and serum ferritin levels at 2 and 6 weeks after treatment were measured and analyzed by ANOVA (SPSS software) *IBM SPSS Statistics v19*.

Results

A total of 532 postpartum women with (CDC recommended) risk factors were screened for postpartum iron deficiency anemia out of which 366 were found to be iron deficient. They were grouped according to the treatment they received viz., oral iron, iron sucrose or FCM. Double blinding was done to decide specific modality of treatment for a patient. A total of 300 women were analyzed (100 patients belonging to each group) after loss to follow-up; 30 in oral iron group, 22 in iron sucrose group and 14 in the FCM group. The demographic data like age, (body mass index), habitat, parity, presence of the antenatal anemia, mode of delivery and type of risk factors were comparable among the three groups (P > 0.05) [Table 1]. Delivery by caesarean section, instrumental vaginal delivery, postpartum hemorrhage (PPH), hypertensive disorders of pregnancy, placenta previa and multiple gestations were among the leading risk factors. Baseline Hb levels in the three groups

was clinically insignificant. There was an overall increase in Hb and ferritin levels from baseline at 2 weeks and 6 weeks, which was significant between groups as well as within the group (P < 0.0001). The mean baseline Hb and ferritin was the lowest in the FCM group, but it showed the highest increase when compared to the other two groups [Figures I and 2]. The increase in Hb and serum ferritin levels in the FCM group was found statistically significant over both iron sucrose and oral iron group (P < 0.0001), whereas the increase with iron sucrose was found to be statistically significant over oral iron only (P < 0.0001) [Table 2]. Confidence interval (95%) was found in multiple comparisons of rise in Hb level and serum ferritin level in 3 groups above baseline [Tables 3 and 4]. Despite having the least mean baseline Hb, 66% of the patients in FCM group achieved a target Hb \geq 12 g/dL (P < 0.0001) at 6 weeks whereas it was 12% and 27% in the oral iron and iron sucrose group, respectively [Table 5]. FCM proved better than oral iron and iron sucrose in achieving target Hb levels by the end of puerperium.

We categorized anemia into mild (9.1-10 g/dL), moderate (7.1-9 g/dL) and severe (≤ 7 g/dL). There was no significant difference at baseline in the 3 study groups with respect to the grade of anemia. The mean rise in Hb ± standard deviation is depicted in Table 6. Both forms of parenteral iron were found to cause a significant increase in Hb compared with oral iron in the three grades of anemia at 2 weeks and 6 weeks. Iron sucrose showed a statistically significant increase in Hb at 2 weeks in mild anemia and the rise was found to be statistically significant (P < 0.0001) over FCM, but at 6 weeks the rise in FCM group was found to be higher (P < 0.0001). FCM showed a statistically significant rise in Hb over iron sucrose in moderate and severe anemia at 2 weeks and 6 weeks after treatment (P < 0.0001). Adverse drug reactions were seen in 51% of patients on oral iron.

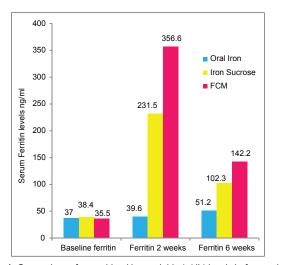


Figure 1: Comparison of mean blood hemoglobin (g/dL) levels before and after therapy

This led to poor compliance in these patients. They were treated conservatively and had an uneventful recovery. The adverse reactions were least among the parenteral iron groups (P < 0.0001). Joint pain and tingling sensation was present in six patients and three developed transient

Table 1: Demographic distribution and baseline clinical data					
Parameters	Oral iron %	Iron sucrose %	FCM %	Р	
Mean age (years)	25.4±3.05	26.0±3.66	25.9±3.57	0.837	
BMI	21.34±1.67	21.26±1.71	21.66±1.86	0.406	
Habitat rural	79	80	78	0.942	
Parity (primi/multi)	46/54	46/54	40/60	0.553	
Antenatal anemia	64	67	57	0.650	
Delivery (LSCS/VD)	94/6	90/10	88/12	0.332	
Type of risk factor					
PPH	27	21	24	0.716	
Hypertensive disorder	17	16	22		
Multiple pregnancy	8	9	4		
Placenta previa	6	11	9		
Exclusive breast feeding	81	78	73	0.394	
Baseline Hb (g/dl)	8.23±1.01	8.05±1.07	7.71±1.17	0.003	
Baseline ferritin (ng/ml)	37.01±18.06	38.39±19.79	35.52±20.22	0.579	

BMI: Body mass index; LSCS: Lower segment caesarean section; FCM: Ferric carboxymaltose; VD: Vaginal delivery; PPH: Postpartum hemorrhage; Hb: Hemoglobin

6 weeks					
Parameters	Oral iron	Iron sucrose	FCM	Р	
Hb (g/dl)					
Baseline	8.23±1.01	8.05±1.07	7.71±1.17		
2 weeks	9.04±1.27	10.41±1.30	10.87±0.83	< 0.00	
6 weeks	10.36±1.39	.40± .17	12.11±0.84	< 0.00	
Serum ferritin (ng/ml)					
Baseline	37.01±18.06	38.39±19.79	35.52±20.22		
2 weeks	39.52±19.18	231.53±97.11	356.62±203.38	<0.00	
6 weeks	51.20±21.49	102.32±48.73	142.22±58.74	< 0.00	

FCM: Ferric carboxymaltose; Hb: Hemoglobin

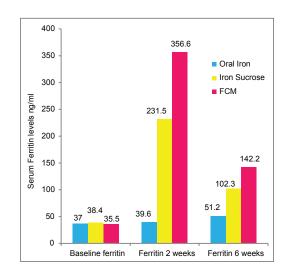


Figure 2: Comparisons of mean serum ferritin levels (ng/mL) before and after therapy

International Journal of Applied and Basic Medical Research, Jan-Apr 2015, Vol 5, Issue 1

Table 3: Mult baseline in 3		parisons of the	e rise in Hb I	evel abov	e	
Post-hoc test	Tukey HS	D				
Dependent	(I) Iron	(J) Iron	S ignificant	95% CI		
variable				Lower bound	Upper bound	
Hb baseline-2	Oral	Iron sucrose	0.000	-1.7415	-I.3825	
weeks	iron	FCM	0.000	-2.5335	-2.1745	
	Iron	Oral iron	0.000	1.3825	1.7415	
	sucrose	FCM	0.000	-0.9715	-0.6125	
	FCM	Oral iron	0.000	2.1745	2.5335	
		Iron sucrose	0.000	0.6125	0.9715	
Hb baseline-6	Oral	Iron sucrose	0.000	-1.3939	-1.0681	
weeks	iron	FCM	0.000	-2.4409	-2.1151	
	Iron	Oral iron	0.000	1.0681	1.3939	
	sucrose	FCM	0.000	-1.2099	-0.8841	
	FCM	Oral iron	0.000	2.1151	2.4409	
		Iron sucrose	0.000	0.8841	1.2099	

Cl: Confidence interval; HSD: Honestly significant difference; Hb: Hemoglobin; FCM: Ferric carboxymaltose

 Table 4: Multiple comparisons of the rise in serum ferritin levels

 above baseline in 3 groups

Post-hoc test Tukey HSD						
Dependent	(I) Iron	(J) Iron	Significant	95 %	% CI	
variable				Lower bound	Upper bound	
Tukey HSD						
Ferritin baseline-	Oral iron	lron sucrose	0.000	-224.6782	-156.5890	
2 weeks		FCM	0.000	-338.6366	-270.5474	
	lron sucrose	Oral iron	0.000	156.5890	224.6782	
		FCM	0.000	-148.0030	-79.9138	
	Ferric carboxy	Oral iron	0.000	270.5474	338.6366	
	maltose	lron sucrose	0.000	79.9138	148.0030	
Ferritin baseline-	Oral iron	lron sucrose	0.000	-62.0746	-37.4218	
6 weeks		FCM	0.000	-104.8373	-80.1845	
	lron sucrose	Oral iron	0.000	37.4218	62.0746	
		FCM	0.000	-55.0891	-30.4363	
	Ferric carboxy	Oral iron	0.000	80.1845	104.8373	
	maltose	lron sucrose	0.000	30.4363	55.0891	

CI: Confidence interval; HSD: Honestly significant difference; FCM: Ferric carboxymaltose

hypotensions after administration of iron sucrose. These patients were treated conservatively and responded well to treatment. Only one patient complained of arthralgia, tingling sensation and headache after administration of FCM. She was treated with analgesic, antihistaminic, and had an uneventful recovery. There were no serious adverse drug reactions or episodes of anaphylactic shock in any patient. Patient satisfaction and general well-being were the highest

Table 5: Percentage of patients achieving a target Hb 12 g/dl in 3 groups

Mode of	At 6 weeks Hb n (%)		
treatment	<12 g/dl	≥l2 g/dl	
Oral iron	88 (88)	12 (12)	
Iron sucrose	73 (73)	27 (27)	
FCM	34 (34)	66 (66)	

P<0.0001. FCM: Ferric carboxymaltose; Hb: Hemoglobin

Table 6: Grade of anaemia					
Hb (g/dl)	Oral iron	Iron sucrose	FCM	Р	
Mild (9.1-10) %	29	21	14	0.016	
Moderate (7.1-9) %	55	56	52		
Severe (≤7) %	16	23	34		
Mild anemia					
Baseline	9.42±0.27	9.46±0.29	9.38±0.28	0.700	
2 weeks	10.47±0.57	12.23±0.54	11.92±0.50	<0.001	
6 weeks	11.92±0.34	12.98±0.38	12.99±0.43	<0.001	
Moderate anemia					
Baseline	8.09±0.50	8.13±0.51	8.13±0.56	0.913	
2 weeks	8.84±0.71	10.36±0.73	. ±0.58	<0.001	
6 weeks	10.11±0.89	11.43±0.58	12.43±0.50	<0.001	
Severe anemia					
Baseline	6.6±0.33	6.55±0.46	6.39±0.61	0.304	
2 weeks	7.14±0.51	8.88±0.67	10.07±0.47	<0.001	
6 weeks	8.36±0.73	9.88±0.62	11.25±0.64	<0.001	

FCM: Ferric carboxymaltose; Hb: Hemoglobin

in subjects treated with IV FCM, followed by IV iron sucrose and lastly with oral iron. This difference was statistically significant [Table 7] (P < 0.0001).

DISCUSSION

The treatment of postpartum iron deficiency anemia with any form of iron therapy aims at raising serum Hb levels by 2.4-4.6 g/dL. Various studies reported increase of Hb level by 2-3 g/dL within 4-12 weeks of oral iron therapy.[9-13] In our study with oral iron therapy an increase of 2 g/dL is achieved in 6 weeks irrespective of mild, moderate, and severe anemia. Giannoulis et al.[12] reported increase of Hb by 4-6 g/dL in 4 weeks in patients receiving iron sucrose, whereas in our study, 2.4 g/dL and 3.4 g/dL increase seen in 2 weeks and 6 weeks respectively. Van Wyck et al.[13] reported increase of Hb by 2 g/dL within 7 days and 3 g/dL in 2-4 weeks in patients receiving FCM. In the study by Seid et al. FCM achieved a Hb rise of 3 g/dL or more, faster (median 15 vs. 28 days; P < 0.0001) than ferrous sulfate group. Seid et al. reported that the ferritin levels were replenished at 42 day in the patients receiving FCM, but not in the oral iron group (238 ng/mL vs. 21 ng/mL; P < 0.0001).^[9] Breymann et al. reported mean ferritin levels increased from 39.9 µg/L at baseline to 568.2 μ g/L at week I and 161.2 μ g/L at week I2.

Table 7:AEs of iron treatment					
Parameters	Oral iron %	Iron sucrose %	FCM %	Р	
Patient satisfaction<0.001					
Poor	48	8	I	<0.00	
Satisfactory	34	20	3		
Good	18	55	37		
Excellent	0	17	59		
AE	51	9	I		
Type of AEs					
Vomiting	17	0	0	<0.00	
Diarrhoea/constipation	34	0	0		
Transient hypotension	0	3	0		
Arthralgia/tingling sensation	0	6	I		

FCM: Ferric carboxymaltose; AEs: Adverse effects

In contrast, patients in the control group showed only a marginal increase of ferritin levels (32.4 µg/L to 34.8 µg/L at week 2 and 43.3 µg/L at week 12). The changes from baseline were significantly higher in the iron carboxymaltose group compared with the control group for all visits, including week 12 (P < 0.0001).^[11] In our study, we observed in FCM group, mean ferritin level increase from 35 ng/dL to 356 ng/dL at 2 weeks and 142 ng/dL at 6 weeks.

Adverse reactions do occur with various iron therapies. GI disorders are the commonest adverse effect with oral iron therapy. The incidence of adverse effects reported by various studies is between 6.8% and 24.2%.^[9,11,13] It is higher at 51% in our study group of patients. None of the patients in our study group required prolonged hospitalization. They had an uneventful recovery. This also supports our view that when there is intolerance to oral iron therapy, one should consider the use of total dose infusion therapy. Aggarwal et al.,^[14] reported fever, arthritis, dysgeusia and anaphylaxis Grade I in patients receiving iron sucrose therapy. In our study, 9% patients had adverse effects in the form of arthralgias and tingling sensation of feet (6%) and transient hypotension (3%). All patients made an uneventful recovery after receiving treatment. The reported incidence of adverse effects with FCM therapy is between 6.3% and 10.6%.^[9,11,13] In our study group, we had one patient who reported arthralgia and tingling sensation of feet 15 min after completing administration of the full dose of FCM. Patient was given treatment in the form of analgesics and made an uneventful recovery.

The prophylaxis of PPA should begin early in pregnancy in order to ensure a good iron status prior to delivery and preventing further PPA. Both iron sucrose and FCM are a safe and effective treatment option for PPA, and there is no evidence of risk to their breastfed infants, but the ability to administer 1000 mg doses in a single sitting, fewer adverse reactions and better compliance makes FCM the first-line drug in the management of postpartum iron deficiency anemia causing a faster and higher replenishment of iron stores and correction of Hb levels. Being robust, it is associated with a low risk of oxidative stress reactions when compared to iron sucrose. It is closest to the ideal parenteral iron. Finally, patients who received FCM also expressed better-overall satisfaction to administration of treatment.

CONCLUSION

We conclude that:

- Intravenously administered iron elevated serum Hb and restored iron stores better than oral iron (ferrous ascorbate).
 Out of the two different IV iron preparations used in this study, FCM proved to be statistically better than iron sucrose
- Ferric carboxymaltose elevates serum ferritin, Hb level and restores iron stores faster than iron sucrose and oral iron. It has minimal adverse reactions. The overall satisfaction reported by the patients was better as they received the drug with minimum hospital stay in a single dose (within 15 min).

Postpartum anemia is widespread in India. The total drug infusion concept with third-generation parenteral iron molecules is convenient for the patient and can save resources in the health care system, especially when compared with oral therapy and blood transfusions. Due to properties like ultra-short duration of treatment, no hospitalization required, lesser side-effects and quicker replenishing of iron stores, IV FCM may be considered early, while treating patient with postpartum iron deficiency anemia. In a few women with severe anemia and blunted erythropoietin due to infection and/or inflammation, FCM may be also considered in combination with recombinant human erythropoietin therapy. National health authorities should establish guidelines to combat iron deficiency in pregnancy and postpartum, thereby decreasing maternal mortality, morbidity, and infant morbidity in order to facilitate a prosperous future for both mothers and children in a continuing globalize world.

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How to cite this article: Rathod S, Samal SK, Mahapatra PC, Samal S. Ferric carboxymaltose: A revolution in the treatment of postpartum anemia in Indian women. Int J App Basic Med Res 2015;5:25-30.

Source of Support: Nil. Conflict of Interest: None declared.