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Original Research Article

Comparative study of efficacy and safety of intravenous ferric carboxy maltose versus iron sucrose in treatment of postpartum iron deficiency anemia

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ABSTRACT

Background: As postpartum iron deficiency anemia is observed in about 65% of women in India, it is the major contributing factor and indirect cause of maternal death. Postpartum anemia may lead to postpartum depression, stress, anxiety and cognitive impairment. Adequate treatment of anemia in postpartum period will have improved life quality in women in child bearing age so this study was designed with the objective to compare the safety and efficacy of intravenous FCM versus iron sucrose in treatment of postpartum iron deficiency anemia.

Methods: It was a prospective observational study of postpartum women (within 10 days of delivery) with iron deficiency anemia (7-9 gm%) who delivered in LG hospital, Ahmedabad. A sample size of 215 women was estimated based on prevalence of anemia which is 65% among postpartum women in India including dropout rate of 10% which were further divided into 2 groups. Group 1: iron sucrose group, Group 2: ferric carboxy maltose group.

Results: FCM has greater rise in Hb, less side effects, and easy administration of dose as compared to iron sucrose. The rise in Hb with FCM as compared to iron sucrose is (4.6 versus 3.5 respectively).

Conclusions: FCM has more safety and efficacy as compared to iron sucrose in treatment of postpartum iron deficiency anemia.

Keywords: Ferric carboxy maltose, Hemoglobin, Iron sucrose, Iron therapy, Postpartum anemia

INTRODUCTION

Postpartum iron deficiency anemia is a common problem in India. It is observed in about 65% of women.¹ It is the major contributing factor and indirect cause of maternal death. Postpartum anemia may lead to postpartum depression, stress, anxiety and cognitive impairment.^{2,3} Adequate treatment of anemia in postpartum period will have improved life quality in women in child bearing age.⁴ Parenteral iron therapy is safe due to faster correction of Hb level with better compliance.

The objective of the study was to compare the safety and efficacy of intravenous FCM versus iron sucrose in treatment of postpartum iron deficiency anemia.

METHODS

It was a prospective observational study of postpartum women (within 10 days of delivery) with iron deficiency anemia (7-9 gm%) who delivered in LG hospital. A sample size of 215 women was estimated based on prevalence of anemia which is 65% among postpartum women in India (Ministry of Health and Family Welfare. National Iron+ Initiative: Guidelines for Control of Iron Deficiency Anaemia, Adolescent Division, Ministry of Health and Family Welfare, Government of India, New Delhi; 2013) including dropout rate of 10%.

The sample size of 215 women were divided into two groups: 1) Iron sucrose group (200 mg/day in 100 ml 0.9% normal saline over 30minutes on 0, 2, 4, 6 and 8

day). 2) Ferric carboxy maltose (FCM) group (1000 mg in 100 ml 0.9 % normal saline over 30 minutes).

Both the formulations are free of cost as they are supplied by the hospital under the JSSK (Janani shishu suraksha karyakram) program for women and child development.

Diagnosis was confirmed by CBC and peripheral smear.

Follow up will be done after 6 weeks along with 1st day of her baby’s immunization schedule on OPD basis for CBC investigation.

Any side effects (pain at injection site, itching and rash, abdominal pain, palpitation, headache, nausea, vomiting, anaphylactic shock) and compliance were be noted.

Written informed consent will be taken from all the patients enrolled in the study.

Calculation of iron requirement: $2.4 \times \text{body weight (target Hb – actual Hb) + 500 mg}$

Inclusion criteria

18-40 years old; postpartum (within 10 days of delivery) iron deficiency anemia (7-9 gm/dl); no history of significant vaginal bleeding in last 24 hours; no infection; intolerance to oral iron.

Exclusion criteria

History of parenteral iron intolerance; having thalassemia or sickle cell disease; history of bleeding disorders; non iron deficiency anemia; recent treatment with iron, blood transfusion or erythropoietin within 3 months; postpartum hemorrhage; previous blood transfusion; history of asthma or cardio vascular disease.

RESULTS

Out of the 215 patients treated for postpartum anemia 94 from iron sucrose group and 100 from FCM group completed the protocol. Those who completed protocol and came for follow up were included for study and statistical analysis.

Epidemiologically both groups were compared with age and parity.

Table 1: Distribution of subjects based on obstetric profile among two groups.

	Iron sucrose group		Ferric carboxy maltose group	
	n	%	n	%
Parity				
Multi gravida	66	70.3	70	70
Primi gravida	28	29.7	30	30
Total	94	100	100	100

Postpartum iron deficiency anemia was more common in multigravida patients than in primigravida (Table 1).

The most common age group affected with iron deficiency anemia was 18-25 years of women (Table 2).

Table 2: Age wise distribution of study subjects among two groups.

Age group	Iron sucrose group		Ferric carboxy maltose group	
	Frequency	Percent	Frequency	Percent
18-25	66	70.3	70	70
26-30	18	19.2	22	22
>30	10	10.6	08	8
Total	94	100	100	100
Mean	31.33±4.41		33.33±4.62	

Sufficient rise in Hb (4.6 versus 3.5) was seen in patients receiving FCM as compared to iron sucrose (Table 3).

Table 3: Comparison of haemoglobin level among two groups.

Hb levels	Iron sucrose group	Ferric carboxy maltose
	Mean±SD	Mean±SD
Pre treatment	7.79±0.69	8.23±0.55
Post treatment	11.36±1.17	12.84±1.04
Hb difference	3.5±1.12	4.6±0.96

Less side effects (pain at injection site, itching and rash, abdominal pain, nausea, vomiting, palpitation, anaphylactic shock) were seen with administration of FCM (only 3 patients) as compared to iron sucrose (Figure 1).

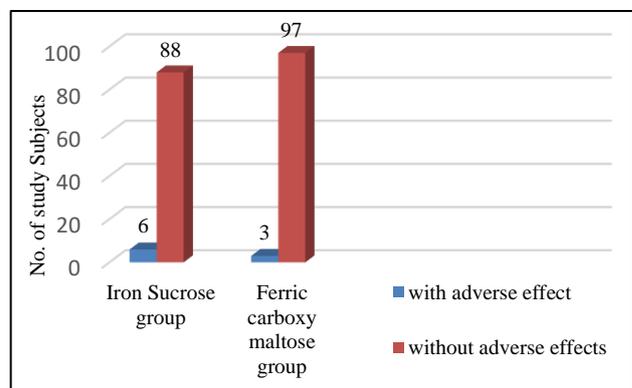


Figure 1: Distribution of the study subjects based on adverse effects among the two groups.

FCM is safer than ferric carboxy maltose as only 3% of study subjects of FCM group suffered from adverse effects as compared to 6.3% in iron sucrose group.

Since FCM is a single dose therapy as compared to iron sucrose (5 doses), hospital stay of patients receiving FCM is less as compared to patients receiving iron sucrose.

DISCUSSION

Postpartum anemia is a major public health problem and is observed in 65% of women in India. Postpartum anemia arises frequently and imposes a substantial disease burden during the critical period of maternal-infant interactions. Anemic women have a longer average length of hospital stay, are more likely to receive a blood transfusion and incur higher hospitalization costs. Hence, postpartum IDA require attention and high quality care.⁵

Traditional treatments i.e. oral iron therapy and blood transfusion involves significant drawbacks. To overcome this problem IV iron preparations were used.⁶

Our study indicates that postpartum anemia can be treated effectively by FCM (ferric carboxy maltose) as compared to iron sucrose with additional advantage of single infusion, less side effects and better patient compliance.

In our study total 215 postpartum women with iron deficiency anemia were divided randomly in two groups, iron sucrose (group 1) and ferric carboxy maltose (group 2). Both groups were given deworming therapy, baseline investigations done, follow up was done at 6 weeks and Hb level repeated.

Singh et al in their study on 200 postpartum patients with Anemia and observed that there was mean rise of Hb was 2.086 gm for FCM group and 1.766 gm for iron sucrose group and Patel et al in their study showed the mean rise of hemoglobin value in Ferric carboxy maltose injection in the treatment of postpartum iron deficiency anemia was 5.2 gm/dl for ferric carboxy maltose and 4.1 gm/dl for iron sucrose in pregnant women.^{7,8}

In our study mean rise of Hb in FCM group was 4.6 and in iron sucrose group was 3.5 which was significant.

Joshi et al in their study, most common age group affected was 18-25 years and Lunagariya et al study, most common age group was 20-25 years, in our study also most common age group is 18-25 years.^{9,10}

Joshi et al in their study, postpartum anemia was more common in multiparous women (70-75% in both the groups).⁹ In our study also postpartum anemia was more common in multiparous women which accounts for nearly 70 % in both groups.

In Joshi et al study, adverse effects were seen in 7.2% of iron sucrose group and 3.3% of FCM group whereas in our study 6.3 % of patients of iron sucrose group and 3% of patients of FCM group developed side effects.⁹

Registered adverse effects were mild and quickly reversible and mostly restricted to local reaction at the infusion site. There was no treatment related serious adverse events. No anaphylactic reaction was detected.

No venous thrombosis was registered. Most common adverse effect in iron sucrose group was urticarial.¹¹

Intra venous iron supplementation is highly effective in treating postpartum iron deficiency anemia, resulting in a much rapid resolution of iron deficiency anemia, has minimal side effects, and because it is administered intravenously, it circumvents problem of compliance.¹²

CONCLUSION

From our study we concluded that ferric carboxy maltose is safe and efficient in treatment of iron deficiency anemia in postpartum women as compared to iron sucrose, with lesser adverse effects and better patient compliance. Due to ultrashort duration of treatment i.e. ability to administer 1000mg dosage in a single sitting, fewer adverse effects, better compliance and decreased hospital stay in patients makes FCM the first line drug in management of postpartum iron deficiency anemia causing faster and higher replenishment of iron store and correction of Hb level. It increases patient compliance and decreases bed occupancy and burden on health facility in developing country like India.

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Conflict of interest: None declared

Ethical approval: Study was conducted after taking approval from institutional review board of LG hospital, Ahmedabad

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