Original Articles

Study of Effect of Ferrous Carboxymaltose on Postpartum Anemia

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ABSTRACT

Background: The incidence of post-partum anemia (PPA) is 14-24%. Treatment of PPA with injectable iron replenishes the iron store. Ferric carboxy-maltose complex (FCM) is an intravenous iron agent designed to be administered in large doses in a short period of time. This study aims to find the efficacy and safety of FCM in treating postpartum anemia. **Materials And Methods :** The present study is a Prospective interventional hospital based therapeutic trial conducted on postpartum anemic women of more than 18 years of age with HB <10gm. Intravenous ferric carboxy-maltose (FCM) was given to the anemic women who has just delivered. Total 500 mg/10 ml in 250 ml of 0.9% normal saline was given over 15-20 min. **Result :** Mean hemoglobin level before intravenous ferric carboxy maltose was 8.1+/-0.4gm% while it was 10.05+/-0.6 gm% after treatment. Hb level, Serum ferritin, MCV and MCHC improved after 2 weeks of treatment. **Conclusion :** FCM was well tolerated and effectively increased mean hemoglobin levels in postpartum women. The duration of hospital stay also shortened and their were no serious side effects noted with the use of FCM.

INTRODUCTION

Iron deficiency is the most prevalent nutritional deficiency amongst women in the reproductive age group.[1] Effects of iron deficiency during pregnancy and post-partum period include – fatigue, cardio-respiratory problems, increased chances of infection, reduced immunity, lactation failure, increased post-partum depressive episode, and post-partum hemorrhage[2] WHO estimates that, of the 5,29,000 maternal deaths occurring every year, 1,36,000 (25.7%) takes place in India, where two-thirds of maternal deaths occur postpartum, PPH being the leading cause of death.[3]

Iron therapy is the treatment of choice in treatment of postpartum anemia.it can be given by oral or i.v. route. Intravenous (IV) low-molecular-weight iron dextran has been associated with an incidence of anaphylaxis or anaphylactoid reactions as high as 1.7%.[4-5] The high incidence of these serious AEs is believed to be caused by the formation of antibodies to the dextran moiety. Newer parenteral iron products (FCM) do not contain the dextran moiety, and the incidence of anaphylaxis with these products is markedly lower.[5-6] Ferric carboxy maltose (FCM) is a Type I polynuclear iron (III)-hydroxide carbohydrate complex that produces a slow and controlled delivery of the complexed iron to endogenous iron binding sites. FCM is cost effective with other positive benefits of fewer hospital visits and improved patient compliance.[7] This study assessed the efficacy and safety of intravenous FCM in the post-natal women with iron deficiency anemia and to see rise n Hb level after 2weeks of treatment with FCM.

INCLUSION CRITERIA

Post-partum women >18yrs age with Hb <10gm/dl.

EXCLUSION CRITERIA

Women with

1. Chronic Disease
2. Immunological Reaction
3. Allergy to Iron Compounds
4. Requiring Blood Transfusion
5. Serious Medical Disease.

METHOD

This was an observational study held over a period of 3months (May2019 to July 2019) in department of obstetrics and gynecology in GMERS MEDICAL COLLEGE & CIVIL HOSPITAL, SOLA.

After explaining about the requirement of administering FCM, its adverse effects, written informed consent were obtained from all the women and attenders. Ethical guidelines were followed. Data of the questionnaire and outcome of blood tests were computerized and analyzed in Microsoft excel. Iron deficiency was diagnosed on

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parameters like complete blood count (CBC), peripheral blood smear, packed cell volume (PCV), and serum ferritin.

Intravenous ferric carboxy maltose (FCM) was administered to the anemic postpartum women. They are available as ampoules of 10 ml containing 500 mg of elemental iron.

Dose calculation/total drug infusion for ferric carboxy maltose

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 x (Target Hb - Actual Hb g/dL) × 2.4 + iron storage depot (mg).

A maximum dose of 1000 mg/10 ml in 250 ml of 0.9% normal saline infused over 15-20 min not more than once a week. Repeat hemoglobin level was done 15 days after administrating Intravenous ferric carboxy maltose (FCM). Measurement of Hemoglobin was done with Cyan-meth Hemoglobin method. Any side effects or adverse events post injection were also noted. All patient receiving FCM were given folic acid supplementation.

RESULT

A total of 120 postpartum anemic women who delivered in our department from May 2019 to July were included in the study.

Table 1: Distribution of patients according to demographic and obstetric profile

AGE	No.	%
<20	24	20
20-25	40	33.3
26-30	38	31.7
>30	18	15
PARITY		
PRIMI	40	33.3
MULTI	80	66.67
MODE OF DELIVERY		
LSCS	70	58.3
VAGINAL	50	41.67

Table 2 : Distribution based on severity of anemia

SEVERITY OF ANEMIA	No.	%
MILD (9.1-10gm/dl)	35	29.17
MODERATE (7.1-9gm/dl	68	56.67
SEVERE (<7gm/dl)	17	14.17

Table 3 : Laboratory parameters before and after FCM administration.

PARAMETERS	BASE	AT 2 WEEKS	P VALUE
HB	8.1+/-O.4	10.05+/-0.6	<0.001
S. FERRITIN (ng/dl)	17.23+/-3.6	88.67+/-10.54	<0.001
MCV (fL)	68.23+/-2.7	72.45+/-3.25	0.0014
MCH (pg/cell)	27.36+/-2.64	25.97+/-3.21	0.118
MCHC (gm/dl)	25.47+/-2.65	29.75+/-2.05	<0.001

Table 4 : Assessment of efficacy of FCM based on severity of anemia

Patient Categories	N	Baseline Hb (gm/dl)	Hb after FCM treatment (gm/dl)	Mean change in Hb from baseline (gm/dl)	'P' value Vs baseline
Mild anemia	35	9.48 ± 0.27	10.9± 0.70	1.42± 0.73	<0.001
Moderate anemia	68	8.34 ± 0.68	10.46 ± 0.76	2.12± 0.86	<0.001
Severe anemia	17	6.54 ± 0.36	9.5 ± 0.91	2.96 ± 1.05	<0.001

Table 5 : Adverse reactions of FCM

DESCRIPTION	No.
Local Reaction	40
Systemic Reaction	05
TOTAL	45

The hospital stay was also reduced with an average stay of 3.21+/-0.21 days.

DISCUSSION

In the present study, average hemoglobin level before intravenous ferric carboxy maltose was 8.1± 0.4g% while it was 10.05 ± 0.6g% after treatment. There was mean rise of 1.91 g% in two weeks. Rise in Hb level was seen in all patient irrespective of the severity of anemia but it was maximum in patient with severe anemia i.e. Hb <7 and was statistically significant after FCM administration. The treatment of iron deficiency anemia in patients who has just delivered after administrating any form of iron aims at elevating serum Hb levels by 2.4 – 4.6 g/ dl. There are various studies which suggests increase of Hb level 2-3 g/dl within 4-12 weeks of oral iron therapy.

Van Wyck et al.[8] 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 µg/L at week 1 and 161.2 µg/L at week 12. 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

In our study the total no. of cases of adverse effect noted were 45. This suggests that FCM was well tolerated and was associated with few local and mild systemic reactions but no serious life-threatening allergic reactions. Most common adverse effects noted were nausea, diarrhea, bloating, abdominal pain, headache and rashes.[10] Serious adverse reactions noted were unrelated to FCM administration.

CONCLUSION

Present study showed FCM is better and more rapid in improving Hb concentration and replenishment of iron store in PPA. Large doses were given in short period of time which not only save hospital resources but also improve patient satisfaction. No serious adverse effect was noted and it was well tolerated.

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