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Original Research Article

Ferric carboxymaltose: choice of treatment in postpartum anaemia in multispeciality zonal hospital of armed forces medical services

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ABSTRACT

Background: World Health Organization has defined postpartum anemia (PPA) as hemoglobin (Hb) of < 10 gm% during the postpartum period. The objective of the present study was to compare the safety and efficacy of ferric carboxymaltose (FCM) in the treatment of post-partum anaemia (PPA).
Methods: A total of 214 patients were identified in a zonal hospital of Armed Forces Medical Services, between Jan 2019 and August 2019 who found to have PPA. Patients having hemoglobin (Hb) <10 g/dl were assigned to receive Intravenous FCM, as per the calculated dose. Changes in hemoglobin (Hb) and serum ferritin levels at 2 and 6 weeks after treatment were recorded and analyzed. Adverse effects to FCM administration were also recorded.
Results: Significant rises in Hb and serum ferritin levels were observed. The mean increase in Hb after 2 weeks was 3.1±0.50 g/dl and 4.0±70 g/dl at 6 weeks. The mean increase in serum ferritin levels after 2 weeks was 210.40±38.50 and 270.25±14.60 ng/ml after 6 weeks. Adverse drug reactions were significantly less ($p<0.001$).
Conclusions: Ferric carboxymaltose increases Hb level and restores iron stores faster without any severe adverse drug reactions. Patient tolerance was good after FCM injection.

Keywords: Ferric carboxymaltose, Postpartum iron deficiency anemia

INTRODUCTION

World Health Organization has defined postpartum anemia (PPA) as hemoglobin (Hb) of < 10 gm% during the postpartum period.[1] Anaemia is an important public health problem worldwide, particularly among women of reproductive age. A substantial portion of this anaemia burden is assumed to be due to iron deficiency. The consequences of anaemia resulting from iron deficiency during the postpartum period (six weeks after childbirth) can be serious and have long-term health implications for the mother and her child.

The prevalence of PPA is 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 previously anemic during pregnancy become anemic after delivery.[4] In India, about 36% of the total maternal deaths are attributable to postpartum hemorrhage or anemia.[5] In healthy women after normal delivery, the prevalence of anemia 1-week postpartum is 14% in iron-supplemented women and 24% in non-supplemented women. Oral iron therapy is presently the treatment of choice for the iron deficiency anemia but it has disadvantages like poor absorption, poor compliance and gastro-intestinal (GI) side effects like gastritis, constipation, diarrhea, nausea, and vomiting. Parenteral iron helps in restoring iron stores faster than oral iron. Multiple doses and prolonged infusion time is required for intravenous (IV) iron sucrose.[6] IV ferric carboxymaltose (FCM) has a neutral pH (5.0-7.0) and physiological osmolarity, which makes

it possible to administer its higher single dose over shorter time (single dose up to 1000 mg over 15 min) than other parenteral preparations.[7] Moreover, risk of hypersensitivity reactions is very low, and a test dose is also not required as it does not contain dextran. In this study, we compare and evaluate the safety and efficacy of IV FCM.

METHODS

This retrospective study was conducted at a multispeciality zonal hospital of Armed forces Medical Services, between Jan 2019 and August 2019. Approval of institutional ethics committee was obtained before starting the study. Informed consent was obtained from each patient prior to participation. A total of 214 patients with haemoglobin (Hb) <10 g/dl, suffering from postpartum iron deficiency anaemia were assigned to receive IV FCM. The adverse drug reactions after inj FCM were recorded and treated if needed. History of anaemia other than IDA like sickle cell anaemia, thalassemia, megaloblastic anaemia, and anaemia due to liver 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 measured and repeated after 2 weeks and 6 weeks. The dose for IV FCM was calculated as under:

Dose calculation for ferric carboxymaltose

The dose of inj FCM is calculated by the Ganzoni formula for Hb restoration and replenishment of iron stores:

Cumulative iron deficit (mg) = body weight in kg x (Target Hb - Actual Hb g/dl) × 2.4 + iron storage depot (mg).

In this study, FCM was administered only by IV drip infusion. Maximum single dose of 1000 mg (20 ml) diluted in 250 ml of 0.9% normal saline over 15 min. Maximum of 1000 mg injection FCM was given in a week. Sitting pulse and blood pressure were monitored before, immediately after, and at 30 and 60 minutes after administration of IV iron.

The changes in Hb and serum ferritin levels at 2 and 6 weeks after treatment were measured and analyzed.

Statistical analysis

Continuous variables like age, birth weight and haemoglobin were presented in mean±SD, categorical variables were expressed in percentage, and continuous variables were compared between groups by performing paired t-test. Categorical variables were compared by Chi-square statistics. $P < 0.05$ was taken as statistical significance.

RESULTS

A total of 200 women were analyzed after loss to follow-up of 14 patients. The demographic parameters like age, weight, parity, mode of delivery was taken into consideration (Table 1).

Table 1: Demographic parameters.

Parameters	Value
Total number of patients (n)	200
Age (years, mean±SD)	26±5.28
Weight (kg; mean±SD)	55.32±17.56
Type of delivery (n; Vaginal versus cesarean)	140 (70%), 60 (30%)
Parity (primi/multi)	(40%), 120 (60)

Table 2: Classification of anaemia (n = 200).

Anaemia type	No. of patients	Percentage
Mild anaemia	84	42%
Moderate anaemia	86	43%
Severe anaemia	30	15%

Table 3: Mean values of hemoglobin (g/dl) before and after FCM.

Parameter	Base line	2 weeks After FCM therapy	6 weeks After FCM therapy	p-value
Level of Hb	7.87±2.20	3.1±0.50	4±0.70	< 0.001

Table 4: Mean values of serum ferritin (ng/ml) before and after FCM.

Parameter	Base line	2 weeks after FCM therapy	6 weeks after FCM therapy	P-value
Level of ferritin	35.52±20.22	210.40±38.50	270.25±14.60	< 0.001

Delivery by caesarean section, instrumental vaginal delivery, postpartum haemorrhage (PPH), hypertensive disorders of pregnancy, placenta previa and multiple gestations were among the leading risk factors. We categorized anaemia into mild (9.1-10 g/dl), moderate (7.1-9 g/dl) and severe (≤7 g/dl) (Table 2). There was an overall increase in Hb and. ferritin levels from baseline at 2 weeks and 6 weeks, which was significant ($P < 0.0001$). FCM proved better in achieving target Hb levels by the end of puerperium (Table 3 and 4).

FCM found to cause a significant increase in Hb compared in three grades of anaemia at 2 weeks and 6 weeks. Two patients had adverse drug reaction and 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 in IV FCM.

DISCUSSION

The treatment of postpartum iron deficiency anaemia with any form of iron therapy aims at raising serum Hb levels by 2.4-4.6 g/dl. Wyck V et al, reported increase of Hb by 2 g/dl within 7 days and 3 g/dl in 2-4 weeks in patients receiving FCM.[8] In the study by Seid et al. FCM achieved a Hb rise of 3 g/dl or more, faster (median 15 versus 28 days; $P < 0.0001$. reported that the ferritin levels were replenished at 42 day in the patients receiving FCM.[6] 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. The changes from baseline were significantly higher in the iron carboxymaltose ($P < 0.0001$).[7] In this study, we observed mean ferritin level increased 210.40±38.50 ng/dl at 2 weeks and 270.25±14.60 ng/dl at 6 weeks. The mean increase in Hb after 2 weeks was 3.1±0.50 g/dl and 4.0±70 g/dl at 6 weeks.

Adverse reactions do occur with FCM. The reported incidence of adverse effects with FCM therapy is between 6.3% and 10.6%.[6-8] In our study group, we had two patients who reported arthralgia and tingling sensation of feet and headache 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.

FCM is 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 in a single dose, fewer adverse reactions and better compliance makes FCM the first-line drug in the management of postpartum iron deficiency anaemia causing a faster and higher replenishment of iron stores and correction of Hb levels. Finally, patients who received FCM also expressed better-overall satisfaction to administration of treatment.

CONCLUSION

Ferric carboxymaltose elevates serum ferritin, Hb level and restores iron stores faster. It has minimal adverse reactions. As patients received the drug with minimum hospital stay in a single dose (within 15 min), the overall satisfaction reported by the patients was better.

The total drug infusion concept with FCM is convenient option for the PPA patient and can save resources in the health care system, due to properties like short duration of treatment, no hospitalization required, lesser chances of adverse reactions and quicker replenishment of iron stores, IV FCM may be considered early, while treating patient with postpartum iron deficiency anaemia.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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