



Original Research Article

Study of management of postpartum anemia with inj ferric carboxymaltose

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ABSTRACT

Introduction: Women of reproductive age are more prone to iron deficiency anemia (IDA) due to blood loss or increased iron demand due to menstruation, pregnancy and lactation. With this background, the study aims to find the safety and efficacy of intravenous ferric carboxymaltose in the treatment of iron deficiency anemia in women who has just delivered.

Materials and Methods: The present study was a Prospective interventional hospital based therapeutic trial conducted on postpartum anemic women of more than 18 years of age with HB <10gm/dl during the study period. Intravenous ferric carboxymaltose (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.

Results: Mean hemoglobin level before intravenous ferric carboxymaltose was 8.42 ± 0.61 gm% while it was 10.03 ± 0.74 gm% after treatment. Before treatment, 17(28.3) women had Hb between 7.1 to 8 gm% which was decreased to 3(5) after giving intravenous ferric carboxymaltose. There was significant rise in Hb level, Serum ferritin, MCV and MCHC after 2 weeks of treatment. ($p < 0.001$)

Conclusion: We conclude from our study that Intravenous ferric carboxymaltose increases Hb levels and restores iron stores better in a shorter period of time. It also elevates serum ferritin levels. No serious adverse effects were noted and it was well tolerated by the patients. Patient compliance was better due to shorter hospital stay and single dose infusion.

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1. Introduction

Woman of reproductive age are particularly at risk owing to blood loss or increased iron demand attributed to menstruation, pregnancy and lactation.¹ Iron deficiency anemia (IDA) is associated with adverse cognitive function, physical activity, immune response and pregnancy outcome.² The properties of iv ferric carboxymaltose (FCM) like neutral PH(5.0-7.0) and physiological osmolarity, which permits it to administer it in larger doses as compared to other iron preparations (single dose up to 1000 mg over 15 mins). Moreover, it does not contain dextran, the chances of serious hypersensitivity reaction is low, its safe and it does not require a test dose.³

Ferric Carboxymaltose though reported in the literature is yet a newer intervention for Indian set up. In a study

by Van Wyck et al,⁴ the results shows increase of Hb by 2g/dl within 7 days and 3 g/dl in 4 weeks in patient receiving ferric carboxymaltose. Patel J et al.⁵ studied anemic women after administrating ferric carboxymaltose on day 8 and day 15 and reported changes in hemoglobin and serum ferritin levels on day 8 and day 15. The average increase in hemoglobin value was 5.2 g/dl for ferric carboxymaltose.” With this background, the study aims to find the safety and efficacy of intravenous ferric carboxymaltose in the treatment of iron deficiency anemia who has just delivered.

2. Materials and Methods

The study was a Prospective interventional hospital based therapeutic trial conducted from July 2016 to September 2018 in the department of Obstetrics and Gynecology of Padmashree Dr. D. Y Patil Medical College and Hospital, Pune, Maharashtra. All the postpartum anemic women

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of more than 18 years of age with HB <10gm/dl during the study period were included in the study. The patients who are suffering from chronic disease, or immunological disorders, allergic to injectable iron compounds, severe anemia who requires blood transfusion, any other serious medical illness are not taken in this study.

Intravenous ferric carboxymaltose (FCM) was administered to the anemic postpartum women. They are available as ampoules of 10 ml containing 500 mg of elemental iron. Total 500 mg/10 ml in 250 ml of 0.9% normal saline infused over 15-20 min. Repeat hemoglobin level was done 15 days after administering Intravenous ferric carboxymaltose (FCM). Measurement of Hemoglobin was done with Cyanmeth Hemoglobin method. Any side effects or adverse events post injection were also noted.

A voluntary written informed consent was taken from the patient taking part in trial after giving information about all aspects of the study including potential risk. Data of the questionnaire and outcome of blood tests were computerized and analysed in Microsoft excel. Statistics were calculated using Epi Info software. Baseline characteristics, data like hemoglobin level, ferritin level values and adverse reaction or effects were reported in percentages. PAIRED T Test is used to compare data between pre and post Groups. P value < 0.05 was taken as statistically significant.

3. Result

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

Age	No.	%
<20	12	20.0
20-25	20	33.3
26-30	19	31.7
>30	9	15.0
Parity		
Primigravida	25	41.7
Multigravida	35	58.3
Mode of Delivery		
LSCS	19	31.7
Vaginal	41	68.3
Total	60	100

Among 60 cases, 20(33.3%) were in 20-25 years age group, 19(31.7%) were in 26-30 years, 35(58.3) cases were multigravida and 41(68.3) cases were delivered vaginally Table 1 The average age of study participants was 25.6 ± 3.38 years. The commonest risk factor was hypertensive disorder and PPH which does not require blood transfusion Table 2

Mean hemoglobin level before intravenous ferric carboxymaltose was 8.42 ± 0.61 gm% while it was 10.03 ± 0.74 gm% after treatment. Before treatment,

Table 2: Distribution of patients according to risk factors

Risk factor	No.	%
PPH not requiring blood transfusion	8	13.3
Hypertensive disorder	13	21.7
Multiple pregnancy	1	1.7
Placenta previa	3	5.0

Table 3: Comparison of patients according to changes in hemoglobin level at 2 weeks

Hb Level(gm%)	Base Line		At 2 week	
	No.	Percentage	No.	Percentage
7.1-8	17	28.3	3	5.0
8.1-9	33	55.0	14	23.3
9.1-10	10	16.7	26	43.3
>10	0	0.0	17	28.3
Total	60	100	60	100

17(28.3) women had Hb between 7.1 to 8 gm% which was decreased to 3(5) after treatment with intravenous ferric carboxymaltose.

Table 4: Comparison of patients according to changes in haematological parameters

Parameters	Base Line	At 2 week	P value
Hb	8.42 ± 0.61	10.03 ± 0.74	<0.001
Serum ferritin(ng/ml)	14.43 ± 3.77	91.32 ± 15.82	<0.001
MCV(fL)	67.63 ± 5.95	71.23 ± 6.01	0.0013
MCH(pg/cell)	28.32 ± 2.27	27.64 ± 2.48	0.119
MCHC(gm/dl)	26.99 ± 3.07	30.01 ± 1.89	<0.001

There was statistically significant rise in Hb level, Serum ferritin, MCV and MCHC after 2 weeks of treatment.(p < 0.001)

Table 5: Distribution of cases according to adverse effects after intravenous ferric carboxymaltose

Adverse effects	No.	Percentage
Pain at injection site	5	8.3
Itching and rash	2	3.3
Abdominal pain, palpitation	0	0.0
Headache	3	5.0
Nausea, vomiting	2	3.3
Anaphylactic reaction with hypotension	0	0.0
Total	12	20.0

Among 60 patients, 5(8.3) patients complained of pain at injection site, 3(5.0) had headache, itching and rash was seen in 2(3.3) cases while nausea and vomiting was experienced by 2(3.3) cases. Abdominal pain, palpitation and anaphylactic reaction with hypotension was not seen in

any of the cases. The average hospital stay after intravenous ferric carboxymaltose treatment was 3.12 ± 0.39 days.

4. Discussion

In the present study, average hemoglobin level before intravenous ferric carboxymaltose was 8.42 ± 0.61 g% while it was 10.03 ± 0.74 g% after treatment. There was mean rise of 1.61 g% in two weeks. The treatment of iron deficiency anemia in patients who has just delivered after administering 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. Giannoulis et al. suggested rise in Hb by 4-6 g/dl in 4 weeks in patients receiving iron sucrose.⁶ Verma U et al. after administering iron preparations followed up iron deficiency anemia patient on 2, 4, 6 and 12 weeks and suggested that in group A of 50 patients (iron sucrose) average increase of haemoglobin level was 3.95 g/dl and in groups of 50 patients (ferric carboxymaltose) it was 3.32 g/dl at 4 weeks of treatment.⁷

Van Wyck et al.⁴ suggested rise of Hb by 2g/dl after treatment with ferric carboxymaltose within 7 days and 3 g/dl in 2 to 4 weeks. Seid et al.⁸ suggested Hb rise of 3 g/dl or more in ferric carboxymaltose group, faster (median 15 vs. 28 days; P value <0.0001) than ferrous sulfate group. Seid et al. described that the ferritin levels were replenished at day 42 in the patients getting ferric carboxymaltose, but not in oral iron group (238 ng/ml vs 21 ng/ml; p value < 0.0001).⁸

In our study 12(20) cases reported adverse effects like pain at injection site, itching over the body and mild rash over the back and limbs, headache, nausea and vomiting. In a study done by Patel J et al. adverse effects were reported in 26.67% cases which is comparable to our study.⁵ All the adverse effects of injection ferric carboxymaltose were mild and typically confined to local reactions.

5. Conclusion

We conclude from our study that Intravenous ferric carboxymaltose increases Hb levels and improves iron stores better in a shorter period of time. It also elevates serum ferritin levels. No serious adverse effects were noted and it was well tolerated by the patients. Patient compliance was

better due to shorter hospital stay and single dose infusion.

6. Funding

None

Conflicts of interest

The authors declare no conflicts of interest

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