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RESEARCH ARTICLE

Ferric carboxymaltose in treating moderate iron deficiency anaemia in pregnancy

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ABSTRACT

Background: Anaemia is most common abnormality seen during pregnancy accounts for 20% of all maternal deaths. Most common cause is iron deficiency anaemia in pregnancy. Since compliance to oral iron therapy is poor and results unpredictable, parenteral iron is better option. **Objective:** To find out the role of ferric carboxymaltose in moderate iron deficiency anaemia in pregnancy. **Method:** It is a cross-sectional analytical study of 40 pregnant women in gestational age 14-28 week with moderate anaemia in Department of Obstetrics and Gynaecology, Assam Medical College and Hospital, Dibrugarh. **Results:** Within short span of 4 weeks, IV FCM increased haemoglobin by 1.56gm/dl**,** serum iron by 48.77µgm/dl and MCV by 12.10fl ($p<0.05$ in all). **Conclusion:** In a resource limitted setting, single dose administration, rapid improvement of haematological parameters makes FCM as the best option for management of IDA in pregnancy.

Keywords: Iron deficiency anaemia (IDA), ferric carboxymaltose (FCM).

Anaemia according to WHO during pregnancy defined as haemoglobin concentration less than 11 g/dl and a haematocrit of less than 33%. Anaemia is categorised into 3 levels of severity.[1]

- Mild– 10-10.9 g/dl
- Moderate –7-9.9 g/dl
- Severe–less than 7 g/dl

Iron deficiency anaemia (IDA) is the most prevalent nutritional deficiency among pregnant women. According to National Family Health Survey (NFHS) data from NFHS-2, NFHS-3, NFHS-4, approximately 50% of pregnant women in India were anaemic, India having highest prevalence among South Asian countries.[2] Prophylactic oral iron is recommended during pregnancy to meet the increased demand of iron. However compliance with oral iron therapy is problematic. Parenteral therapy offers better response.[3] Most commonly used iron preparation in pregnancy for anaemia is iron sucrose complex. Primary disadvantage of iron sucrose is limited dose per session, requiring multiple visits and increasing overall cost of therapy. Ferric carboxymaltose (FCM), a recent addition to intravenous iron preparation, is dextran free complex. The safety and effectiveness of FCM during the second and third trimesters of pregnancy were highlighted in a 2022 paper by nearby 250 obstetrics and gynaecology experts.[4] However, there are only a limited number of prospective studies on the use of FCM in pregnancy. This study was conducted to evaluate the efficacy, safety and cost effectiveness of FCM in treating moderate iron deficiency anaemia in pregnancy.

Methodology

The study is cross sectional analytical comparative study. Study period was 1 year and was carried out in department of obstetrics and gynaecology at Assam Medical College, Dibrugarh. The study comprised of 40 cases of pregnant women with moderate iron deficiency anaemia who was attending obstetrics and gynaecology department of AMCH.

Inclusion criteria

1. All pregnant women of age 18-45 year who were

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able to give informed consent.

2. Gestational age 14 week -28 week.
3. Hb level <9.9 g/dl and >7g/dl.
4. Singleton pregnancy with no anomalies.

Exclusion criteria

1. Anemia due to causes other than iron deficiency.
2. Multiple pregnancy.
3. History of blood transfusion.
4. Allergy to iron derivatives.
5. Medical or surgical disorders like bleeding disorders, DM, haemorrhoids, CVS or any haematological disorders

Total iron doses were calculated by Ganzoni's formula. Total iron doses required (mg) = 2.4×Body weight (kg) × (Target Hb -Actual Hb in g/dl) + 500mg

Statistical methods: Categorical data were expressed as frequency (percentages) and continuous data were presented as mean ± standard deviation. Difference between the two groups was tested using Chi square test/ Fisher's exact test for categorical data and t test for continuous data. A p-value of less than 0.05 was considered as statistically significant. Analysis was done using Microsoft Excel.

Results

The table 1 shows the mean baseline haemoglobin were 8.39 ± 0.62 gm/dl, mean serum iron were 30.55 ± 7.46 µgm/dl and initial MCV were 74.33 ± 4.67 fl.

Table 1: Baseline Hb, serum iron and MCH

Parameters	Mean	SD
Baseline Hb	8.39	0.62
S.Iron	30.55	7.46
Initial MCV	74.33	4.67

Table 2: Mean haemoglobin, serum iron and MCV after 4 weeks

Parameters	Mean	SD
Hb After 4 week	9.95	0.78
S. Iron after 4 week	79.25	19.83
MCV after 4 week	86.43	6.91

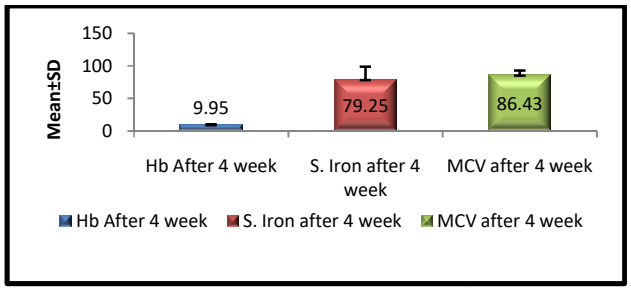

Figure 1: Mean haemoglobin, serum iron and MCV after 4 weeks

As shown in the table 2 and figure 1, mean haemoglobin after 4 weeks of FCM therapy was 9.95 ± 0.78 gm/dl, serum iron after 4 week was 79.25 ± 19.23 µgm/dl and MCV after 4 week was 86.43 ± 6.91 fl. Hence mean rise in hemoglobin was 1.56 ± 0.16 gm/dl, serum iron was 48.70 ± 11.77 µgm/dl and MCV was 12.10 ± 2.24fl after 4 weeks of therapy.

Table 3: Difference between baseline and after 4 weeks

Parameters	Baseline		After 4 weeks		P - value
	Mean	SD	Mean	SD	
Hb%	8.39	0.62	9.95	0.78	0.001
S. Iron	30.55	7.46	79.25	19.83	0.001
Initial MCV	74.33	4.67	86.43	6.91	0.001

Out of total 40 pregnant women who received FCM only 7 i.e. 17.5% women had minor adverse reactions which included nausea, vomiting in 2, epigastric pain in 1, constipation in 1, myalgia in 2, fever in 1 women (table 4). No major adverse reaction noted in any women.

Table 4: Adverse reactions

Adverse reactions	Number	Percentage
Nausea vomiting	2	5.00
Epigastric pain	1	2.50
Constipation	1	2.50
Myalgia	2	5.00
Fever	1	2.50

Discussion

In the present study mean rise in haemoglobin was 1.56 gm/dl, serum iron was 48.70µgm/dl and MCV was 12.10 after 4 weeks of therapy. Ambily Jose et al[5] found the mean rise haemoglobin after 12 weeks was significantly higher 29g/Lin FCM group. He found mean rise in serum iron after 3 weeks were 149.5µgm/dl, after 6 weeks were 127.5µgm/dl and after 12 weeks were 83.5µgm/dl from baseline in FCM group. He found the baseline MCV in FCM was 75.5 ± 6.0fl, after 3 weeks was 82.2 ± 5.5fl, after 6 weeks was 82.2 ± 5.5fl and after 12 weeks was 88.9 ± 2.1 fl.

Aneri Parikh et al[6] found mean rise of haemoglobin after 4 weeks as 1.76 gm/dl in FCM group and 1.69 gm/dl in Iron sucrose group and after 90 days as 2.81 gm/dl in FCM group and 2.07 gm/dl in Iron sucrose group from baseline.

Conclusion

Ferric carboxymaltose (FCM) is a safe intravenous treatment option during pregnancy, comparable in effectiveness to the standard iron sucrose complex for managing iron deficiency anemia in pregnant women. FCM offers notable benefits, such as the ability to deliver a larger dose in a single session, faster improvement in haemoglobin levels, and a reduced need for multiple doses. This leads to fewer hospital visits, lower overall transportation and infusion equipment costs, and less discomfort for the patient due to fewer needle pricks. In resource-limited settings, FCM's single-dose administration, rapid improvement in haematological parameters, and favourable tolerability make

it the most suitable choice for treating moderate iron deficiency anemia during pregnancy.

Conflict of interest: None. **Disclaimer:** Nil.

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