SINGLE DOSE INTRAVENOUS CARBOXYMALTOSE VERSUS ORAL IRON THERAPY IN THE TREATMENT OF ANAEMIA IN POSTPARTUM PATIENTS IN A RURAL AREA

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ABSTRACT

BACKGROUND
To compare the efficacy and safety of oral and intravenous administration of iron supplement (single dose of ferric carboxymaltose) for treating postpartum anaemia.

MATERIALS AND METHODS
It is a longitudinal interventional study in anaemic mother in postpartum period, which fits into inclusion criteria. It is a hospital-based randomised prospective study. Out of two groups, one had received single dose of ferric carboxymaltose of 500 mg IV infusion and second group received 200 mg of oral iron daily for four weeks.

RESULTS
Mean age in both groups was 22.3 years. 94% patients belong to rural area. Significantly, higher number of participants had achieved the target haemoglobin level in IV iron group as compared to oral iron group (24 vs. 12), which suggests poor compliance of participants in oral iron group. Adverse drug reactions- GI side effects were mostly observed in oral iron group, but treatable hypersensitivity reaction in the form of itching all over body was seen in IV iron group in a small proportion of patients.

CONCLUSION
IV ferric carboxymaltose appears to be very effective and safe option for treatment of postpartum anaemia with very good compliance, less hospital stay and rapid rise of Hb.

KEYWORDS
Ferric Carboxymaltose (FCM), Intravenous Iron, Iron Deficiency Anaemia, Postpartum Period.


BACKGROUND
Anaemia in a postpartum period is a common problem in a developing world especially in India, which contributes to maternal morbidity and mortality. Again, it causes poor breast secretion leading to poor breastfeeding and disturbances in the growth of newborn.1,2,4

According to National Family Health Survey (NHFS) of 2005-2006, the prevalence of anaemia is 55% in females aged 15-49 years, and during postnatal period, it is 26 to 30%. But, according to Somdatta et al, prevalence of postpartum anaemia is as high as 70%.1,5

Treatment options for anaemia include oral iron therapy, IV iron therapy and blood transfusion.6,7 Oral iron therapy frequently causes GI side-effects contributing to poor compliance of the patients. In addition, such oral therapy must be given for a long time. As far as blood transfusion is concerned, cost factor, availability issues and transmission of various infections, makes it an option only to be used in life-threatening emergency situations.9,10,11,12

In cases of severe iron deficiency, absorption and red blood cell production are influenced by additional pathologies such as renal disease and chronic inflammatory bowel disease in pregnancy. About blood transfusions because of the risk of infections (bacterial, viral, protozoal) and immunomodulation associated with allogeneic blood products, especially in this young and otherwise healthy population, transfusions are used only in the most severe cases and particularly in life-threatening situations. Therefore, intravenous iron, alone or in combination with Recombinant Human Erythropoietin (rHuEPO) has been considered as an alternative in the management of iron deficiency anaemia. Ferric carboxymaltose (Ferinject (R)). FCM is a complex and stable structure formulated as colloidal solution with physiological pH. Once administered
IV, FCM will be taken up by reticuloendothelial system. It will go to endogenous transport system for heme-formation in process of erythropoiesis. FCM is non-dextran-containing molecule, so hypersensitivity reactions are very less and test dose is not required. FCM increases serum iron concentration in a dose-dependent manner. It gets cleared rapidly from the circulation. FCM is more stable compound than ferric gluconate or iron sucrose as it releases very less amount of free ionic iron, which leads to controlled delivery of iron to the target tissue. Further, it gets bound to ferritin and transferrin.

Various clinical trials were done in more than 2000 patients show steady improvement in haemoglobin level. Iron stores also have been replenished. FCM is safe with very good compliance rate and very effective in postpartum anaemia and other medical disorders such as chronic kidney disease, inflammatory bowel disease and menorrhagia. Excellent toxicity profile and high effectiveness allows FCM to be administered in a single bolus infusion.

AIMS AND OBJECTIVES
This study aims at evaluating the effectiveness and safety of single dose of parenteral (ferric carboxymaltose) iron versus four weeks of oral iron in management of anaemia during postpartum period. It includes the study of prevalence of postpartum anaemia in rural populations and role of parenteral iron in improving the Hb level, quality of life, duration of hospital stay as well as patients satisfaction with parenteral iron. It also includes the effect of IV carboxymaltose iron on breastfeeding compared to oral iron in a woman with Hb <8 g%.

MATERIALS AND METHODS
Study Design- It is longitudinal interventional study in anaemic mother in postpartum period, which fits into inclusion criteria. Patients were evaluated in follow-up visit with their haematological parameters.

The study was conducted in postnatal ward (PNC ward in Department of OB-GYN, JN Medical College and AVBR Hospital, Sawangi (Meghe), Wardha, Maharashtra.

Sample Size- This study was done in 60 patients in over the duration of 6 months from February 2016 to August 2016.

Inclusion Criteria
Postpartum patients in postnatal ward with Hb <8 g after 24 hrs. of delivery and willing to give valid/informed and written as well as oral consent were included in this study.

Exclusion Criteria
1. Case of anaemia other than nutritional deficiency.
2. Immunocompromised patients.
3. Patients with severe cardiac, renal, hepatic or cerebrovascular disease like connective tissue disorders, diabetes or hypertension.
4. Patients having sepsis, history of thromboembolism, asthma.
5. Known allergy to parenteral iron.
6. Patients not willing for follow-up study.

Methodology
Considering the exclusion as well as inclusion criteria, minimal basic investigations were done to rule out any other causes of anaemia.

Two groups were made each having 30 patients.

Group A- Consist of 30 women who were given the single dose of IV 500 mg ferric carboxymaltose.

Group B- Consist of 30 women who were given oral 200 mg of iron (ferrous sulfate daily for 4 weeks).

Data analysis was done using SPSS software version 13.0 using unpaired t-test and Chi-square test.

Patients have been followed after 1 month for estimation of Hb level and overall improvement in general condition of patients.

RESULTS

Characteristic of Study Population

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients (n=60)</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Primigravida</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>Multigravida</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>Mean age in years</td>
<td>22.3</td>
<td>22.3</td>
</tr>
<tr>
<td>Mean weight in kg</td>
<td>45.8</td>
<td>46.7</td>
</tr>
</tbody>
</table>

Table 1. Variable- Group A and Group B

a. Age of patients- Mean age in both groups 22.3 years.
b. Mean weight of patients were 46 kg.

Geographic distribution of anaemia- 94% of women belong to the village (rural area), only 6% from city (urban area).5

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pretreatment Hb</td>
<td>8.3</td>
<td>8.2</td>
</tr>
<tr>
<td>Post-treatment Hb</td>
<td>10.7</td>
<td>10.2</td>
</tr>
</tbody>
</table>

Table 2. Response to Oral and Intravenous Therapy
With single dose of ferric carboxymaltose Hb rise was from 8.3 to 10.7.
In group B, Hb rise was gradual, required 4 weeks treatment, to raise the Hb from 8.2 to 10.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Hb</td>
<td>24</td>
<td>12</td>
</tr>
<tr>
<td>Failed to achieve target Hb</td>
<td>6</td>
<td>18</td>
</tr>
</tbody>
</table>

**Table 3. Achievement of Target Hb**

With group A, 24 patients achieved target Hb to 10 g.
With group B, 12 patients achieved target Hb to 10 g.
This response to therapy in B group was similar, but number of patients sticking to oral drug therapy were less (less compliance).

**Graph 3**

**Adverse Drug Reactions**

<table>
<thead>
<tr>
<th>Side Effects</th>
<th>Nausea</th>
<th>Giddiness</th>
<th>Diarrhoea or Constipation</th>
<th>Hypersensitivity Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Group B</td>
<td>12</td>
<td>8</td>
<td>11</td>
<td>0</td>
</tr>
</tbody>
</table>

**Table 4. Type and Prevalence of Adverse Reaction to Iron Therapy**

**Graph 4**
Bowel disturbances in the form of nausea, diarrhoea, constipation is more prevalent in oral group.

There were 3 cases (10%) having hypersensitivity to parental iron group in the form of itching all over body, but were managed symptomatically.

**DISCUSSION**

The aim of this study is to evaluate efficiency of single dose ferric carboxymaltose vs. oral iron for 4 weeks in a postpartum period. Participants were mostly (94%) from rural area considering their low educational status compliance with oral iron was poor. Significantly, higher number of participants had achieved the target haemoglobin level in IV iron group as compared to oral iron group (24 vs. 12)

We had given IV carboxymaltose single dose of 500 mg in 200 mL of normal saline. Hb estimation was done after 1 month. There is rise of haemoglobin to 10 gm%, which reflects good response and effective compliance of patients as compared to poor compliance of oral iron group. Only factor we observed, which limits the ferric carboxymaltose use was its cost, but when patients were counselled properly, they accepted the therapy very well.14,15

Regarding adverse drug reactions; nausea, vomiting, constipation and diarrhoea were much less in IV iron group as compared to oral iron group.16,17,18,19

As compared to other IV iron preparations (i.e. iron sucrose) ferric carboxymaltose have added advantage of less hospital stay and less overall cost of the therapy.19,20,21,22,23

**CONCLUSION**

This study was done to evaluate the efficacy of ferric carboxymaltose in postpartum patients in comparison to oral iron treatment.22,23 Prevalence of anaemia is mainly seen in rural area as compared to urban, so this study is mainly focussed on rural hospital.1,2,3,4 The aim was to treat anaemia more accurately, efficiently with only required minimal investigations. Overall, intravenous ferric carboxymaltose appears to be an effective mode of treatment especially in postpartum patients with no serious side effects.14,15,16,18,19 It does not require frequent hospital visits and overall hospital stay is also very less.17,19

So, novel molecule like intravenous ferric carboxymaltose proves to be very effective option regarding increase in Hb level in short span of time with patient’s satisfaction, less hospital stay and very minimal adverse drug reactions.23,24

**REFERENCES**


