

To study efficacy of Inj. Ferric Carboxymaltose in the treatment of Post-partum Anaemia

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ABSTRACT

Objective: The present study was conducted to compare the safety and efficacy of Injection Ferric Carboxymaltose (FCM) to that of oral iron the treatment of post-partum anemia. **Materials and Methods:** 100 postpartum women with moderate iron deficiency anemia (Hb - 7-10g/dl) were enrolled from May 2019 to June 2020 and were randomly allocated into two groups (50 each) and were given inj. FCM in one group and oral iron in the other group. Hematological parameters (Hb, PCV, MCH, MCHC and Serum Ferritin) at the beginning of study were compared with those at 3 weeks and 6 weeks later. Adverse effects in both groups were compared. **Results:** It was found there was a significant mean rise in FCM group as compared to oral iron group i.e. Hb (1.51g/dl Versus1.04g/dl), PCV(3.21% versus 1.82%), MCH(1.82pg versus0.6pg), MCHC (1.96g/dl versus 0.62g/dl) and serum ferritin (98.78ng/ml versus10.15g/dl) at 3 weeks with P value<0.0001 . Similarly, significant mean rise was seen at 6 weeks i.e. Hb (4.37g/dl versus 2.37g/dl), PCV (8.68% versus 3.98%), MCH (4.31pg versus 1.73pg), MCHC (3.62g/dl versus 1.55g/dl) and serum ferritin (67.85ng/ml versus 21.92 ng/ml) in FCM group as compared to that of oral iron respectively with P value <0.0001.**Conclusion:** The study concluded that both therapies are effective in increasing hematological parameters as well as iron stores. However, the increase is more in FCM group than that of oral iron. Less adverse effects with use of injection FCM make it safe and superior to oral iron. So, injection FCM should be considered in patients with moderate iron deficiency anemia.

Keywords: efficacy, Ferric, Carboxymaltose, treatment & Partumanaemia.

INTRODUCTION

The word anemia originated from Greek anaimia: an (without) and haimia (blood).[1] Anemia is a medical condition in which there is decrease in capacity of the blood to carry oxygen due to reduction in total amount of red blood cells or hemoglobin in blood.[2].WHO defined anemia during pregnancy as Hb<11g/dl and a hematocrit of <33%.[3] It is one of the leading causes of disability and is a major global public health problem.[4] The Centre for Disease Control and Prevention (CDC) (1998) defined anemia in iron supplemented pregnant women using a cut-off of the 5th percentile–11 g/dl in the first and third trimesters, and 10.5 g/dl in the second trimester.[5]Anemia in postpartum period is defined as

hemoglobin (Hb) level of <11gm% at1week postpartum and < 12gm% at 8 weeks postpartum.[6]

In pregnancy, total demand of iron is about 900mg (700-1400mg), out of which about 500-600mgis forfoetus andplacenta, about 150-200mgis lost in blood at delivery and approximately 500mg is used for increased hemoglobin mass, however, 225mg of iron is saved due to amenorrohea throughout the pregnancy. So, net deficiency is of about 600 -700mg. therefore, the daily requirement is approximately, 4-6mg/day in second trimester and 6-8 mg/day in third trimester.[7]

Its metabolism is maintained mainly by absorption instead of excretion. When iron stores are depleted, its absorption is increased and when iron gets adequately stored, its absorption is decreased. This is called as

mucosal block theory of absorption of iron. It gets absorbed in duodenum and jejunum in the form of ferrous form (Fe²⁺) and not ferric form (Fe³⁺). Ascorbic acid (Vit.C) and gastric HCL enhances iron absorption by reducing ferric to ferrous form by ferric reductase. That's why taking iron with Vit. C enhances its absorption whereas tannins in tea, phytates in bran and calcium in dairy products reduces iron absorption. Absorption of iron increases from 7.2% in first trimester to 66.1% in third trimester [13]

The most common cause of anemia in postpartum period is iron deficiency anemia. It is mostly due to anemia during antenatal period and acute blood loss. In developing countries, the prevalence of Postpartum anemia varies from 50-80% [14]. It is of major concern because 20% of maternal deaths in the world and 36% in India is due to anemia during pregnancy which is further aggravated by blood loss during delivery or postpartum period [14,15]. Normal blood loss during delivery is usually 300ml but may be more than 500ml in 5-6% of women [16]. Nutrition surveillance system observed that 29.8% of women who were not anemic during pregnancy became anemic in postpartum period [17]. It was found that the prevalence of postpartum anemia was 24% in women who were not supplemented with iron and 14% in women who were supplemented with iron [14].

MATERIALS AND METHODS

It was a prospective one year (May 2019 to April 2020) interventional study carried out in the department of Obstetrics and Gynecology, Government Medical College and Rajindra Hospital, Patiala on 100 postpartum patients after taking their informed consent. The approval of institutional ethical committee was also obtained.

INCLUSION CRITERIA

Post-partum women with Hb 7-10g/dl were included in the study. The patients with postpartum iron deficiency anemia (7-10 gm/dl) were randomly categorized to receive one single dose of 1000mg IV FCM within 7 days of postpartum women, or ferrous sulfate 100mg elemental iron BD daily till 6 weeks which was available in our institution free of cost by government.

EXCLUSION CRITERIA

- Patients with known case of thalassemia and hemolytic anemia.
- Anemia due to medical disorders (renal, thyroid etc.)
- History of recent blood transfusion.
- History of allergy to parenteral iron therapy.

Investigations including CBC which included Hb, PCV, MCH and MCHC and serum ferritin was measured. Day of therapy (oral or parenteral) was taken as 0 day and these were followed up at 3 weeks and 6 weeks respectively.

The demographic data like age, BMI, education status, socioeconomic status parity and habitat, presence of antenatal anemia were also recorded.

SAMPLE SIZE

For sample size calculation assuming that most of the females who are anemic in pregnancy just before delivery will be anemic immediately in postpartum when they will be recruited in the study.

Number of pregnant females who were anemic were 33%-89% from various studies. Hence in our study taking upper limit of 89% (p₀). Among these, proportion of patients who have moderate anemia is 40-65% from various studies. Hence in our study taking upper limit of 65% (p₁).

Two-sided significance level (α) = 0.05 at 95% of confidence level. Power (1- β) was 80% of confidence level.

Ratio of subjects in each group is 1:1 that is r=1

Using KELSEY Formula [47]

$$N1 = (Z\alpha/2 + z1 - \beta)^2 * p * (1-p) * (r+1) / r * (p0 - p1)^2$$

*represents multiplication in above equation $Z\alpha/2 = 1.96$ where $Z1 - \beta = 0.84$

$$\text{Hence } p = (p0 + rp1) / r + 1 = (0.89 + (1) * (0.65)) / (1 + 1) = 0.77$$

$$\text{therefore } n1 = (1.96 + 0.84)^2 * 0.77 * (1 - 0.77) * (1 + 1) / (1) * (0.89 - 0.65)^2$$

$$n1 = 7.84 * 0.77 * 0.23^2 / 0.058$$

$$n1 = 5$$

$$5\% \text{ is expected to be lost to follow up due to procedure issues} = 48 * 5 / 100 = 2.4$$

$$\text{Hence sample size is } 48 + 2 = 50 \text{ Hence } n1 = r * n2 \text{ (r=1) } n1 = n2 = 50$$

Hence, each group has sample of 50.

Statistical Analysis

Data were entered and analyzed using appropriate statistical methods. Continuous variables were expressed as mean $\pm$ standard deviation (SD), while categorical variables were expressed as frequencies and percentages. The changes in hematological parameters, including hemoglobin (Hb), packed cell volume (PCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), and serum ferritin, were compared between the ferric carboxymaltose (FCM) and oral iron groups at baseline, 3 weeks, and 6 weeks after intervention. A P-value < 0.05 was considered statistically significant.

RESULTS

Table 1. Age Distribution of the Patients

	Obs	Total	Mean	Var	Std Dev	Min	25%	Median	75%	Max	Mode
Age	100	2504	25.04	16.7	4.1	18	22	24	28	34	22

Age Groups	Frequency	Percent	Cum. Percent	Exact 95% LCL	Exact 95% UCL
< 25 years	54	54.00%	54.00%	43.74%	64.02%
25-29 years	27	27.00%	81.00%	18.61%	36.80%
30 years & above	19	19.00%	100.00%	11.84%	28.07%
TOTAL	100	100.00%	100.00%		

In this study, age of the patients ranged from 18-34 yrs with mean age and standard deviation of 25.04 ± 4.1 years. This also shows that the maximum number of patients i.e. 54% were below 25 years followed by 27% between 25-29 years and 19% were of above 30 years of age

Table 2. Mean Corpuscular Hemoglobin Concentration (MCHC-g/dl) AT0DAY

MCHC (0 day) * Group	Obs	Total	Mean	Var	Std Dev	Min	25%	Median	75%	Max	Mode
FCM	50	1384	27.68	8.39	2.90	21.8	24.9	28.35	30.1	32.3	23.8
Oral Iron	50	1429.3	28.59	10.33	3.21	21.8	26.4	29	31.2	33.3	31.7

Time Frame	0 day
Test	Mann-Whitney Test for Two Independent Samples
z-score	1.617013193
p-value	0.105875433
Significance	No

The above tables show that MCHC values ranged from 21.8g/dl to 32.3g/dl with mean and standard deviation of 27.68 ± 2.90 g/dl in the patients who were treated with FCM at 0 day whereas MCHC values ranged from 21.8 g/dl to 33.3g/dl with mean and standard deviation of 28.59 ± 3.21 g/dl in the patients treated with oral iron at 0 day. There was no significant difference in the two groups.

Table 3. Mean Corpuscular Hemoglobin Concentration (MCHC; g/dL) at 3 Weeks

MCHC (3wks) * Group	Obs	Total	Mean	Var	Std Dev	Min	25%	Median	75%	Max	Mode
FCM	50	1482	29.64	10.90	3.30	22.9	26.3	29.85	32.6	35.1	25.5
Oral Iron	50	1460.1	29.20	9.97	3.16	22	27.3	29.55	31.6	34.4	31.6

Time Frame	3 weeks
Test	Mann-Whitney Test for Two Independent Samples
z-score	0.658523807
p-value	0.511949021
Significance	No

The above tables show that MCHC values ranged from 22.9g/dl to 35.1g/dl with mean and standard deviation of 29.64 ± 3.30 g/dl in the patients treated with FCM while MCHC values ranged from 22g/dl to 34.4g/dl with mean and standard deviation of 29.20 ± 3.16 g/dl in the patients who were treated with oral iron at 3 weeks. There was no significant difference in both the two groups.

Table 4. Mean Corpuscular Hemoglobin Concentration (MCHC; g/dL) at 6 Weeks

MCHC (6wks) * Group	Obs	Total	Mean	Var	Std Dev	Min	25%	Median	75%	Max	Mode
FCM	50	1564.8	31.30	12.12	3.48	23.9	28.1	31.4	34.1	37.1	31.4
Oral Iron	50	1506.9	30.14	10.55	3.25	22.4	28.4	30.55	32.5	35.6	31.6
Time Frame						6 weeks					
Test						Mann-Whitney Test for Two Independent Samples					
z-score						1.330762793					
p-value						0.183033126					
Significance						No					

The above tables show that MCHC values ranged from 23.9g/dl to 37.1g/dl with mean and standard deviation of 31.30 ± 3.48 g/dl in the patients who were treated with FCM while values ranged from 22.4g/dl to 35.6g/dl with mean and standard deviation of 30.14 ± 3.25 g/dl in the patients who were treated with Oral iron at 6 weeks. There was no significant difference in both of the two groups at 6 weeks.

Table 5. Difference in the Rise of MCHC Values in Both Groups (3–6 Weeks)

Diff. MCHC (3 to 6wks)	Obs	Total	Mean	Var	Std Dev	Min	25%	Median	75%	Max	Mode
FCM	50	82.8	1.66	0.39	0.62	0.7	1.2	1.55	2.1	3.1	1.2
Oral Iron	50	46.8	0.94	0.51	0.71	0.2	0.4	0.6	1.4	2.9	0.5
Time Frame						3 weeks to 6 weeks					
Test						Mann-Whitney Test for Two Independent Samples					
z score						5.189343543					
p-value						<0.0001					
Significance						Yes					

DISCUSSION

Table 6. Comparison of Hb Levels at 6 Weeks Post-Intervention (ORAL IRON GROUP)

Author and year of Publication	Baseline Hb (g/dl) i.e. 0 day	6 weeks (g/dl)	Difference (g/dl)
Rathod et al ^[11] , 2015	8.23	10.36	2.13
S.C. Damineni et al ^[12] , 2016	8.907	11.156	2.249
Bhramita Roy et al ^[13] 2018	7.831	10.712	2.88
Present study	8.204	10.57	2.336

In our study, in oral iron group, the mean rise in Hb levels is 2.336g/dl (P value <0.0001) which is comparable to the studies of Rathod et al, S.C. Damineni et al and Bhramita Roy et al which showed the rise of 2.13g/dl, 2.249g/dl and 2.88g/dl respectively

Table 7. Comparison of Hb levels at 6 weeks post intervention (FCM GROUP)

Author and year of publication	Baseline i.e. 0 day (g/dl)	6 weeks (g/dl)	Mean rise (g/dl)
Rathod et al ^[11] , 2015	8.203	12.11	3.9
S.C. Damineni et al ^[14] , 2016	8.907	11.938	3
Roy Bhramita et al ^[15] 2018	7.831	12.217	4.3
Present Study	8.08	12.45	4.37

In our study, the mean rise in Hb levels at 6 weeks post intervention in FCM group is 4.37g/dl (P value <0.0001-significant) which is comparable to the studies of Rathod et al, S.C. Damineni, Roy Bhramita et al which showed the mean rise of 3.9g/dl, 3g/dl and 4.3g/dl respectively.

In our study, the mean rise in PCV in FCM group at 3 weeks post intervention is 3.21% (P value <0.0001) which is significant which is comparable to the study of Singh S et al^[37] which showed the rise of 6.57%. However, the mean rise in PCV in oral iron group in our study is 1.82% which showed the rise of PCV is also more in FCM group than that of oral iron group.

Table 8. Comparison of MCH Levels (FCM GROUP)

Name and year of publication	Mean rise in MCH (pg) at 3 weeks	Mean rise in MCH (pg) at 6 weeks	Mean rise in MCHC (g/dl) at 3 weeks	Mean rise in MCHC (g/dl) at 6 weeks
Kriplani A et al 2019 ^[16]	3.1	4.6	2	3.2
Present Study	1.82	4.31	1.96	3.62

In our study, the mean rise in MCH values in FCM group shown is significant with P value <0.0001 i.e. 1.82 pg and 4.31 pg at 3 weeks and 6 weeks respectively and is comparable to study of Kriplani A et al which showed the rise of 3.1 pg and 4.6 pg respectively. Similarly, the significant mean rise in MCHC values are shown in our study i.e. 1.96 g/dl and 3.62 g/dl at 3 weeks and 6 weeks respectively and is comparable to the study of Kriplani A et al which showed the rise of 2 g/dl and 3.2 g/dl at 3 weeks and 6 weeks respectively.

Strengths of the Study

The major strength of the present study was its prospective interventional design with random allocation of postpartum women into ferric carboxymaltose and oral iron treatment groups. The study included a relatively adequate sample size of 100 participants, with 50 patients in each treatment group, allowing a direct comparison between the two treatment modalities. Multiple hematological parameters, including hemoglobin, packed cell volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, and serum ferritin, were assessed at baseline and during follow-up. The inclusion of both hematological response and iron-store assessment provided a broader evaluation of treatment efficacy. In addition, patients were followed for six weeks, allowing assessment of both early and sustained hematological improvement. The study also evaluated adverse effects, providing information regarding the tolerability and safety of ferric carboxymaltose compared with oral iron therapy.

Limitations of the Study

The present study has certain limitations that should be considered while interpreting the findings. First, the study was conducted at a single institution, which may limit the generalizability of the results to other healthcare settings and populations. Second, the sample size was relatively small, with 100 participants divided equally between the two treatment groups. Third, the follow-up period was limited to six weeks; therefore, the long-term sustainability of hematological improvement and replenishment of iron stores could not be assessed. Fourth, the study included postpartum women with moderate anemia and therefore the findings may not be directly applicable to women with mild or severe

postpartum anemia. Additionally, adherence to oral iron therapy may vary among patients and could influence the comparative treatment response. Finally, although adverse effects were assessed, the study was not designed to evaluate uncommon or long-term adverse events associated with either treatment.

Future Implications and Future Research

The findings of the present study suggest that ferric carboxymaltose may be a useful alternative to oral iron therapy for the management of moderate postpartum iron deficiency anemia, particularly when a rapid correction of anemia and replenishment of iron stores is desired. Future studies should include larger, multicentric populations to improve the generalizability of the findings. Longer follow-up periods are also recommended to evaluate the sustainability of hematological improvement, restoration of iron stores, and recurrence of anemia. Further research should compare different dosing regimens of ferric carboxymaltose with other intravenous iron preparations and oral iron formulations. Studies incorporating patient-centered outcomes, such as fatigue, quality of life, breastfeeding-related outcomes, treatment adherence, and patient satisfaction, would provide additional evidence regarding the clinical benefits of intravenous iron therapy. Cost-effectiveness analyses may also help determine the feasibility of using ferric carboxymaltose routinely in postpartum women, particularly in resource-limited healthcare settings.

CONCLUSION

The study concluded that both therapies are effective in increasing hematological parameters as well as iron stores. However, the increase is more in FCM group than that of oral iron. Less adverse effects with use of

injection FCM make it safe and superior to oral iron. So, injection FCM should be considered in patients with moderate iron deficiency anemia.

DECLARATIONS

Ethics Approval and Consent to Participate

The study was conducted after obtaining approval from the Institutional Ethics Committee of Government Medical College and Rajindra Hospital, Patiala. Written informed consent was obtained from all participants before their enrollment in the study.

Consent for Publication

Not applicable. No individually identifiable participant information or images are presented in this manuscript.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Authors' Contributions

All authors contributed to the conception and design of the study, data collection, analysis and interpretation of the findings, and preparation and critical revision of the manuscript. All authors approved the final version of the manuscript.

Data Availability Statement

The data generated and/or analyzed during the present study are available from the corresponding author on reasonable request, subject to appropriate ethical and institutional requirements.

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REFERENCES

1. Anaemia. Dictionaory.com. archived from original on 14th July 2014. Retrieved on 7 July 2014
2. Stedman's medical dictionary (28th edition). Philadelphia: Lippincott Williams & Wilkins. 2006. p. Anemia. ISBN 978-0-7817-3390-8.
3. World Health Organization. Iron Deficiency Anemia: Assessment, Prevention and Control: A guide for Programme Managers. Geneva, Switzerland: World Health Organization; 2001.

4. World Health Organization. Anaemia prevention and control. Geneva, Switzerland: World Health Organization; 2011
5. Haematological Disorders. In: Williams textbook of obstetrics. 56th Chapter, 24th edition, pp. 1000.
6. Milman N. Postpartum anemia II: prevention and treatment. Ann Hematol. 2012 Feb;91(2):143-54. doi: 10.1007/s00277-011-1381-2. Epub 2011 Dec 9. PMID: 22160256.
7. Sharma JB. Nutritional anemia during pregnancy in non-industrialised countries. In: Studd J (Ed). Progress in Obstetrics and Gynaecology. New Delhi: Churchill Livingstone; 2003. pp. 103-22
8. Online reference www.nrhmtn.gov.in/guideline/RGPMA.pdf Guidelines for the prevention of maternal anaemia, 1989.
9. WHO. Haemoglobin concentrations for the diagnosis of anemia and assessment of severity. Vitamin and Mineral Nutrition Information System. Geneva, Switzerland: WHO (2011)
10. Ministry Of Health and Family Welfare, Govt. Of India. NHFS-IV, 2015- 2016: India. New Delhi: MOHFW; 2017
11. Rathod S, Samal SK, Mahapatra PC, Samal S. Ferric carboxymaltose: A revolution in the treatment of postpartum anaemia in Indian women. International Journal of Applied and Basic Medical Research. 2015 Jan;5(1):
12. Sherret D, Cussick S, Grosse S et al. Iron Deficiency Anemia among pregnant women, screening and preventive measures. mw.education, 2011
13. Kelsey J.L., Whittemore A.S., Evans A.S., and Thompson W.D. Methods in Observational Epidemiology. Oxford University Press, 1996. Print.
14. Damineni SC, Thunga S. IV Ferric Carboxymaltose Vs Oral Iron in the Treatment of Post-partum Iron Deficiency Anaemia. J Clin Diagn Res. 2016;10(11): QC08-QC10.
15. Bhamita R, Afshan SN, Nishat A. Intravenous Iron Sucrose and Ferric Carboxymaltose (FCM) Versus Oral Iron in the Treatment of Postpartum Iron Deficiency Anaemia. 2018;7(3):1558-62.
16. Damineni SC, Thunga S. IV Ferric Carboxymaltose Vs Oral Iron in the Treatment of Post-partum Iron Deficiency Anaemia. J Clin Diagn Res. 2016;10(11): QC08-QC10.