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Original Research

Role Of Injectable Iron (Comparison Between Old FCM And Orofer) In Iron Deficiency Anemia In Pregnancy And Its Safety And Efficacy

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Abstract:

Background: According to the World Health Organization (WHO), prevalence of anemia in developed and developing countries in pregnant women is 14% and 51%, respectively. IDA can cause various complications during pregnancy like increase susceptibility towards infection, reduce physical and mental functions, increase need of blood transfusion during delivery, cardiovascular complications, intra uterine growth retardation, preterm delivery, and perinatal mortality and morbidity.Iron sucrose (IS) and ferric carboxymaltose (FCM) are dextran free iron preparation for parenteral therapy. This study provides valuable insights into the efficacy and safety of Ferric Carboxymaltose (FCM) and Orofer. Understanding the comparative benefits of these therapies can help healthcare providers make informed decisions about the best treatment options for their patients. **Aim & Objectives:** To study the efficacy and safety of injectable iron therapy in treating iron deficiency anemia (IDA) during pregnancy, comparing Ferric Carboxymaltose (FCM) and Orofer and to compare their efficacy and safety.

Material and Methods: A hospital based study was conducted among 200 antenatal anemicfemales who came between 12-24 weeks of gestation in Muzaffarnagar Medical College & Hospital, Muzaffarnagar, Uttar Pradesh. Study was conducted for 18 months.Data was analysed statistically.

Results: Ferric Carboxymaltose (FCM) showed greater improvement in hemoglobin levels, mean corpuscular volume (MCV), and serum ferritin compared to Orofer in pregnant women with iron deficiency anemia. FCM patients saw hemoglobin increase from 8.62 ± 3.20 to 11.14 ± 12.51, while Orofer patients increased from 8.50 ± 4.75 to 9.29 ± 10.34. Serum ferritin levels significantly rose in the FCM group (32.27 ± 8.33 to 97.11 ± 12.37) but not in the Orofer group (29.25 ± 43.8 to 34.45 ± 76.56). Additionally, FCM had fewer side effects, making it a more effective and safer option for treating iron deficiency anemia in pregnancy. Most participants were aged 25-30 and were primarily in their first pregnancy. Severity of anemia varied, with 52% mild, 34% moderate, and 14% severe.

Conclusion: Ferric Carboxymaltose (FCM) demonstrated greater efficacy and a more favorable safety profile compared to Orofer in treating iron deficiency anemia during pregnancy. These findings suggest that FCM may be a more effective and safer option for managing iron deficiency anemia in pregnant women.

Keywords: Anemia, IDA, Inj. FCM, Inj. Orofer.

Introduction

Iron deficiency anemia is the most common and major hematological, nutritional deficiency but manageable health problem encountered among the pregnant women globally but more common in developing countries, especially in tropics like India, especially in under privileged population. Iron deficiency anemia is the most common anemia with significant effect over health status.[1]

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According to the World Health Organization (WHO), prevalence of anemia in developed and developing countries in pregnant women is 14% and 51%, respectively. About half of the global maternal mortality due to anemia occurs in South Asian countries and India contributes to 80% of it.[2] The WHO defined anemia in pregnancy as Hb level <11g/dL and hematocrit <33%. Anemia affects all age groups starting from puberty and adolescence to peri-menopausal age. High incidence of anemia in India is because of low dietary intake of iron, poor bio-availability of iron, faulty food habits, phytate-rich Indian diet, chronic blood loss during menses, and high prevalence of infections such as malaria and hookworm infestations. [3]

IDA can cause various complications during pregnancy like increase susceptibility towards infection, reduce physical and mental functions, increase need of blood transfusion during delivery, cardiovascular complications, intra uterine growth retardation, preterm delivery, and perinatal mortality and morbidity. [1,2] Almost 53.7% of Indian pregnant women are anemic as reported in NHFS 5 survey.[4]Ministry of Health and Family Welfare, Government of India released operational guidelines of an intensified national iron plus initiative (I NIPI), AnemiaMukt Bharat. This guideline provides protocols for management of anemia during pregnancy. [5] As per the guidelines, parental iron (IV Iron sucrose or Ferric Carboxy maltose) may be considered as the first line of management in pregnant women with mild (10-10.9 g/dL) or moderate anemia (7-9.9 g/dL) detected late in pregnancy or in whom compliance to oral iron is likely to be low. Also, IS or FCM is considered as a second-line treatment in case no improvement is observed with the oral iron supplement. In severe anemia (5.0-6.9 g/dl), IS or FCM is recommended as first-line treatment.[5]

Iron sucrose (IS) and ferric carboxymaltose (FCM) are dextran free iron preparation for parenteral therapy. The most commonly used intra venous iron preparation is iron sucrose. It does not require test dose and it is safe. The only disadvantage is limited dose can be given at one time. The maximum permissible dose is 200mg per day or 600 mg per week and requires multiple hospital visits and puts a heavy burden on hospital resources. IV FCM has a near neutral pH (5-7), physiological osmolarity and increased bioavailability, which makes it possible to administer high single doses over shorter time periods (up to 1000mg in a single dose infused in 15 minutes) than other parenteral preparations. It is dextran free; therefore, the risk of anaphylaxis or serious hypersensitivity reactions is very low, and a test dose is also not required. [6]

This study provides valuable insights into the efficacy and safety of Ferric Carboxymaltose (FCM) and Orofer. Understanding the comparative benefits of these therapies can help healthcare providers make informed decisions about the best treatment options for their patients.The findings from this study can contribute to the development of updated clinical guidelines for the management of IDA in pregnancy, ensuring that pregnant women receive the most effective and safe treatment options.

Aim & Objectives

1. Tostudy the efficacy and safety of injectable iron therapy in treating iron deficiency anemia (IDA) during pregnancy, comparing Ferric Carboxymaltose (FCM) and Orofer.
2. To compare the efficacy and safety of FCM and Orofer in treating IDA during pregnancy.

Material and methods

A hospital based observational study was carried out on 200antenatal anemic women between 12-24 weeks of gestation who came tothe Department of Obstetrics &Gynaecology, Muzaffarnagar Medical College & Hospital, Muzaffarnagar. This study was done for 18 months. 200women were selected on the basis of average number of antenatal anemic patients between 12-24 weeks of gestation bySimple Random Sampling. Antenatal anemic women between 12-24 weeks of gestation with singleton pregnancy and who gave informed written consent were included in the study. All pregnant women with >12 weeks and <24 weeks of gestationand who did not give consent were excluded from the study. Blood sample for Hb level, Serum ferritin, MCV and TIBCwere collected at the time of registration. Patients were divided randomly in 2 groups- 100 were given Inj. FCM and 100 were given Inj. Orofer. Patients were followed after 6 weeks. Blood samples were again collected and laboratory parameters were compared with the pre-treatment values. Ethical approval was taken from the Institutional Ethics Committee of Muzaffarnagar Medical College, Muzaffarnagar. The P-value 0.05 was considered statistically significant. Discrete data was entered in MS-Excel sheet and data was analysed using the software SPSS 21.0.

Results

Most participants were in the 25-30 age range. The distribution across age groups did not show a significant difference (P value = 0.14). The majority of participants were primigravida (first pregnancy), with 69 in the FCM group and 74 in the Orofer group. This difference was not significant (P value = 0.53).The presence of diabetes mellitus (DM), hypothyroidism, and hypertension (HTN) were similar across both groups, with no significant differences (P value = 0.76). A slight difference was observed in the intake of iron supplements between the two groups, but it was not statistically significant (P value = 0.45).**(Table 1)**

Both groups had similar Hb levels (8.62 ± 3.20 for FCM and 8.50 ± 4.75 for Orofer).The FCM group showed a significant increase to 11.14 ± 12.51, while the Orofer group increased to 9.29 ± 10.34. Both

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changes were statistically significant (P value <0.0001).Both groups had similar MCV values (72.29 ± 8.4 for FCM and 72.13 ± 6.3 for Orofer).The FCM group showed a slight increase to 74.53 ± 11.63, while the Orofer group increased to 74.0 ± 7.9. Both changes were statistically significant (P value 0.05 for FCM and 0.02 for Orofer).Both groups had similar serum ferritin levels (32.27 ± 8.33 for FCM and 29.25 ± 43.8 for Orofer). The FCM group showed a significant increase to 97.11 ± 12.37, while the Orofer group increased to 34.45 ± 76.56. The change was statistically significant for the FCM group (P value <0.0001) but not for the Orofer group (P value 0.49).Both groups had similar TIBC values (483.7 ± 32.3 for FCM and 489.8 ± 56.5 for Orofer).The FCM group showed a significant decrease to 320 ± 21.9, while the Orofer group decreased to 368 ± 47.2. Both changes were statistically significant (P value <0.0001.**(Table 2)**

Figure1displays the distribution participants on the basis of severity of anemia. 52% had mild anemia, 34% had moderate anemia and 14% had severe anemia.

Figure 2displays the distribution of patients on the basis of side effects of Inj. FCM and Inj. Orofer.The data indicates that participants receiving Orofer experienced higher incidences of side effects compared to those receiving FCM. Swelling on the injection site and gastritis were particularly more common in the Orofer group.

Table 1: Socio- demographic details of participants: (N=200)

Variable	Inj. FCM (n=100)	Inj. OROFER (n=100)	P value
Age group			
20-25	28	24	0.14
25-30	52	42	
30-35	13	25	
35-40	07	09	
Gravida			
Primigravida	69	74	0.53
Multigravida	31	26	
Co-Morbidities			
DM	04	06	0.76
Hypothyroidism	23	27	
HTN	07	05	
No	66	62	
Intake of iron supplement			
Yes	31	37	0.45
No	69	63	

Table 2: Comparison of laboratory parameters before and 6 weeks after treatment with Inj. FCM and Inj. Orofer: (N=200)

Laboratory Parameters	Inj. FCM (n=100)	Inj. OROFER (n=100)
Hb level		
Before treatment	8·62 ± 3·20	8·50 ± 4·75
After 6 weeks	11·14 ± 12·51	9.29±10.34
p value	**<0.0001**	**<0.0001**
MCV		
Before treatment	72.29 ± 8.4	72.13 ± 6.3
After 6 weeks	74.53 ± 11.63	74.0 ± 7.9
p value	**0.05**	**0.02**
Serum ferritin		
Before treatment	32.27± 8.33	29.25± 43.8
After 6 weeks	97.11± 12.37	34.45± 76.56
p value	**<0.0001**	0.49
TIBC		
Before treatment	483.7 ±32.3	489.8±56.5
After 6 weeks	320 ± 21.9	368 ± 47.2
p value	**<0.0001**	**<0.0001**

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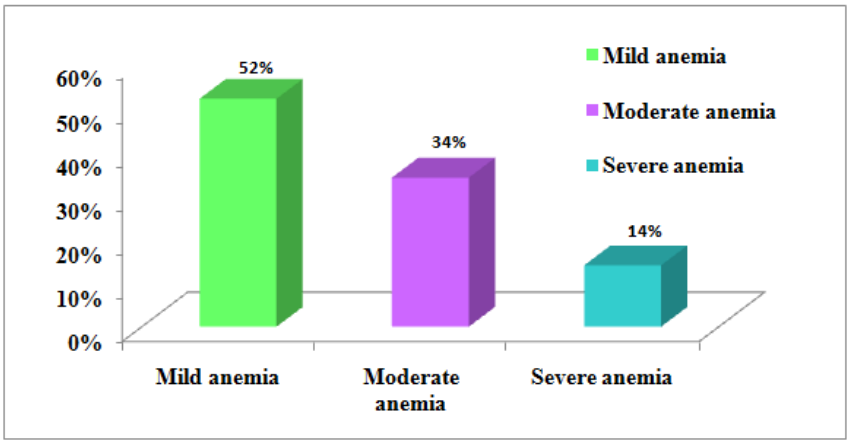

Figure 1: Bar diagram showing distribution of participants according to type of anemia

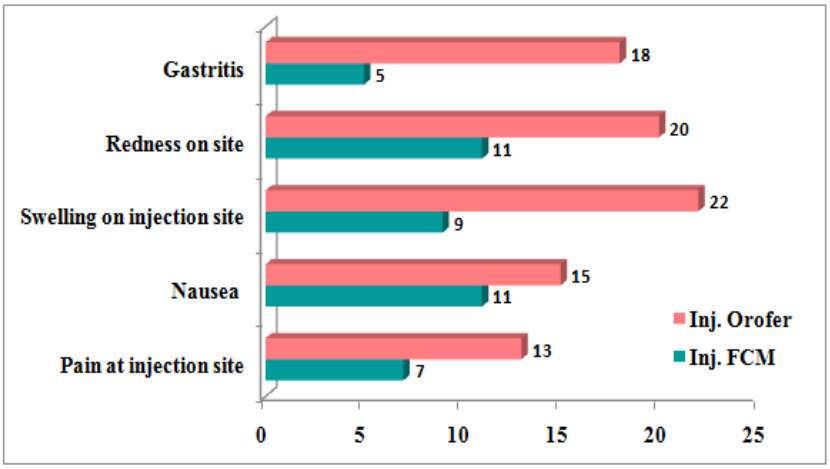

Figure 2: Bar diagram showing distribution of participants according to side effects of both IV iron formulations (Inj. FCM & Inj. Orofer)

Discussion

Most participants were in the 25-30 age range. The distribution across age groups did not show a significant difference (P value = 0.14). The majority of participants were primigravida (first pregnancy), with 69 in the FCM group and 74 in the Orofer group (p value = 0.53).In a study done by **Sanavelli RJ et al in 2024**,age distribution showed that 77% in group A and 93% in group B were between 20 to 30 years of age, whereas 20% in group A and nil patients in group B were less than 20 years of age and 3% in group A and 7% in group B were above 35 years of age in this study, 85% of the women in both groups were between 20 to 30 years of age.[11] This finding was almost same as the finding of our study. Regarding parity, 57% in group A and 48% in group B were primigravidae where is 43% in group A and 52% in group B were multigravidae. [7] This finding was different from our study.

In present study, FCM group showed a highly statistically significant increase to 11.14 ± 12.51, while the Orofer group increased to 9.29 ± 10.34 (p value <0.0001).The FCM group showed a slight increase to 74.53 ± 11.63, while the Orofer group increased to 74.0 ± 7.9. Both changes were statistically significant (P value 0.05 for FCM and 0.02 for Orofer).The FCM group showed a significant increase to 97.11 ± 12.37, while the Orofer group increased to 34.45 ± 76.56. The change was statistically significant for the FCM group (p value <0.0001) but not for the Orofer group (P value 0.49).The FCM group showed a significant decrease to 320 ± 21.9, while the Orofer group decreased to 368 ± 47.2. Both changes were statistically significant (p value <0.0001).In a study done by**Naqash QA et al in 2018,** the rise in mean corpuscular volume was from 66.82±5.24 to 86.76±3.765 and 68.05±5.56 to 93.80±3.80 and rise in serum ferritin levels were from 8.32 ± 1.787 to 38.94 ± 6.095 µg/L and 8.16 ± 1.540 to 27 ± 8.175 µg/L in patients treated with FCM and IS respectively after four weeks of therapy.[8] In a study done by **Jose et al in 2019,** mean rise in Hb at 12weeks was significantly higher in FCM group (29g/L vs 22g/L; p value <0.01).[9] In a study done by **Parikh A et al in 2022,** mean rise of hemoglobin was 1.9 g/dl for FCM group and 1.66gm/dl for iron sucrose group, which was also significant. Serum ferritin level in ferric carboxymaltose group was rises more as compared to iron sucrose group.[10]In a study done by**Papaniya TD et al in 2023,** mean rise in Hb

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at 4 weeks was significantly higher in FCM group (1.67±0.47 vs 1.07±0.25; p<0.0001) as compared to IS group. There was also rise in other biochemical parameters like MCV and MCHC in both groups. [11]

In our study, 52% had mild anemia, 34% had moderate anemia and 14% had severe anemia.In a study done by **Sanavelli RJ et al in 2024**, 17% in group A and 20% in group B were having mild anemia; 80% in group A and 70% in group B were having moderate anemia and 3% in group A and 7% in group B were having severe anemia. Majority of the women were in the category of moderate anemia that is hemoglobin between 7 to 9 g/dl. [7]

In present study, participants receiving Orofer experienced higher incidences of side effects compared to those receiving FCM. Swelling on the injection site and gastritis were particularly more common in the Orofer group.In studies done by **Naqash et al in 2018, Jose A et al in 2019, Papaniya TD et al,** no serious adverse effects were reported. [8,9,11] In a study done by **Sanavelli RJ et al in 2024,** there were no adverse reactions with Iron sucrose group whereas with FCM group, minor adverse reactions were noted in 10% which were managed symptomatically. [7] These findings were different form our study.

Conclusion

Our findings conclude that Ferric Carboxymaltose (FCM) demonstrated greater efficacy and a more favourable safety profile compared to Orofer in treating iron deficiency anemia during pregnancy. These findings suggest that FCM may be a more effective and safer option for managing iron deficiency anemia in pregnant women.

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