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Original Research Article.

Iron Sucrose or Ferric Carboxy Maltose: Comparative Study for Treatment of Post-Partum Iron Deficiency Anemia

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ABSTRACT

Background: Iron deficiency anemia (IDA) is commonly observed due to blood loss at the time of delivery or lack of adequate supply during pregnancy, thus increasing the risk of morbidity and mortality. Iron supplementation is currently used to treat postpartum anemia, however oral iron supplementation is associated with unwanted side effects especially gastrointestinal. Parenteral iron therapy is effective than oral iron supplementation in replenishment of haemoglobin and iron stores (ferritin) with much better compliance. Thus, we aimed to evaluate efficacy of two commonly used parental preparations of iron viz sucrose and ferric carboxymaltose.

Materials and Methods: This study was conducted at Katihar Medical College, katihar in the department of Obstetrics and Gynaecology from november 2012 to october 2013. We included 120 female with post-partum anemia. The patients were divided into two groups name Group 1 and Group 2. Patinets in Group 1 received multiple doses of iron sucrose each in small quantity while patients in Group 2 were administered single high dose of ferric carboxymaltose. The changes in haemoglobin and ferritin levels post therapy were noted.

Results: The level of haemoglobin post therapy increased to 10.48±0.56gm% and 11.83±0.79gm% from 8.27±0.53gm% and 8.305±0.609gm% in group 1 and group 2 respectively. Similarly the level of serum ferrtin increased from 77.91±27.14 ng/dl and 78.05±34.69ng/dl to 182.86±33.36ng/dl and 195.39±44.6ng/dl respectively. The mean increase of hemoglobin in group 1 was by 2.2 gm% while it was 3.53gm% in group 2.

Conclusion: We found that FCM is more effective than iron sucrose for treatment of iron deficiency anemia.

Key words: Ferric Carboxymaltose, Iron Sucrose, Post-Partum Anaemia, Efficacy.

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INTRODUCTION

It is not an unknown fact that iron deficiency anemia is high prevalent among the women of reproductive age and the rate is even high in under privileged groups.[1] A comparative study. As far as regional prevalence is concerned, the disorder is very common in South Asian Countries with the estimate of almost half of the maternal deaths globally occurring in those countries.[2] According to the reports of national pregnancy nutrition surveillance system, post-partum anemia is found among 29.8 % of the females after delivery[3,4] and, it acts as the major and indirect factor for maternal mortality.[4]

Post-partum anemia once develops, results in prolonged hospital stay, anxiety, depression, failure of lactation and persistence of ill maternal health that also influence the growth and development of infants.[5] As per the criteria given by WHO concentration of hemoglobin in peripheral blood, it is less than 11 gm/dl, it is indicative of anemia in pregnancy. Based on level of hemoglobin, anemia can be graded as:

- Mild Anemia: Hb Level 9-11 gm/dl
- Moderate Anemia: Hb Level 7-9 gm/dl
- Severe Anemia: Hb Level <7 gm/dl

Iron demand increases in pregnancy. In case of singleton pregnancy, the average demand is 1000mg, of which 300 mg is utilized by fetus and placental, 500 mg is consumed for maternal hemoglobin synthesis, while 200 mg is lost normally. Via, skin, urine and gut.[6] The causative factors for anemia in pregnancy may be insufficient dietary intake, infections (parasitic0 or loss of blood at the time of delivery.[7] Since iron deficiency anemia during pregnancy increases the risk of maternal and fetal morbidity and mortality, it is important to the anemia effectively, so as to reduce the associated risk factors during pregnancy, to fetus and after

delivery. Appropriate treatment facilitates improvement in living quality of females in reproductive age.[8]

Currently, measurement of both hemoglobin and ferritin level is considered gold standard for identifying iron deficiency anemia. Decreased ferritin levels are suggestive of depleted iron storage.[9,10] Various treatment modalities have been developed over the past year such iron supplementation via oral, intramuscular or intravascular routes and blood transfusions. However, oral iron supplementation posed several side effects like nausea, vomiting, diarrhea, intolerance, epigastric pain, constipation and poor compliance.[11] Other therapeutic techniques such as iron Textron which is given both intravenously or intramuscularly is also associated with pain, bleeding, tissue necrosis, skin staining, sterile abscess, myalgia, arthralgia and atrophy.[12]

Therefore in order to avoid these unwanted side effects, there is a requirement of new iron therapeutic methods which have higher efficacy and compliance with lesser side effects. According to various observations studies iron sucrose and ferric carboxymaltose have been proven better in treatment of post-partum anemia.[12] Thus in this study we aimed to compare the efficacy of these two therapeutic modalities in treatment of postpartum anemia.

MATERIALS AND METHODS

The study was undertaken in the department of Obstetrics and Gynaecology at Katihar Medical College, katihar from november 2012- to october 2013. 120 post natal females were enrolled and they were categorized randomly in two groups. Group 1 and Group 2 respectively, each group comprising 60 females. Group 1 received iron sucrose (IS) as treatment modality while groups 2 were provided ferric carboxy maltose (FCM).

Inclusion Criteria

- Post-partum females with hemoglobin level between 6-11 gm/dl
- Patients only having iron deficiency anemia

Exclusion Criteria

- Patients with other hematological disorders than IDA
- Patients with history of allergy to iron hepatic products
- Patients suffering from cardiac, hepatic, renal or immunological disorders
- Patients with history of recent blood transfusion
- Patients with history of thromboembolism, asthma and symptoms of infection

Before proceeding, patients were thoroughly counseled about the effects of therapy and written consents were taken from each of them. Detailed patients history including age, menstrual history, family history and medical history were taken. Physical examination followed by measurements of hematological parameters like, MCV, MCHC, PCV, MCH, hemoglobin, reticulocyte count and serum ferritin were carried out and the values were recorded.

Dose was calculated as=24 X bodyweight (Kg) x (Target Hb-Actual Hb) +500 mg

Factor 2.4 was calculated from blood volume (75 of body weight) and iron content of hemoglobin (0.34%) i.e. 0.07 X0.0034X100=2.4 mg

For Group 1

- 5 doses of iron sucrose were prepared, comprising 200 mg in 100 ml of normal saline.
- The prepared dose were infused intravenously over 20 min period and as per requirement on alternate days

For Group 2

- Single dose of ferric carboxymaltose was prepared which consisted of 1000mg in 150 ml of normal saline
- The prepared dose was infuse intravenously over the period of 15 min for not more than once a week

Statistical Analysis

It was done by using SPSS 16.0. The data was analyzed using Student's t test and Fischer's exact test. P value of less than 0.05 was considered statistically significant.

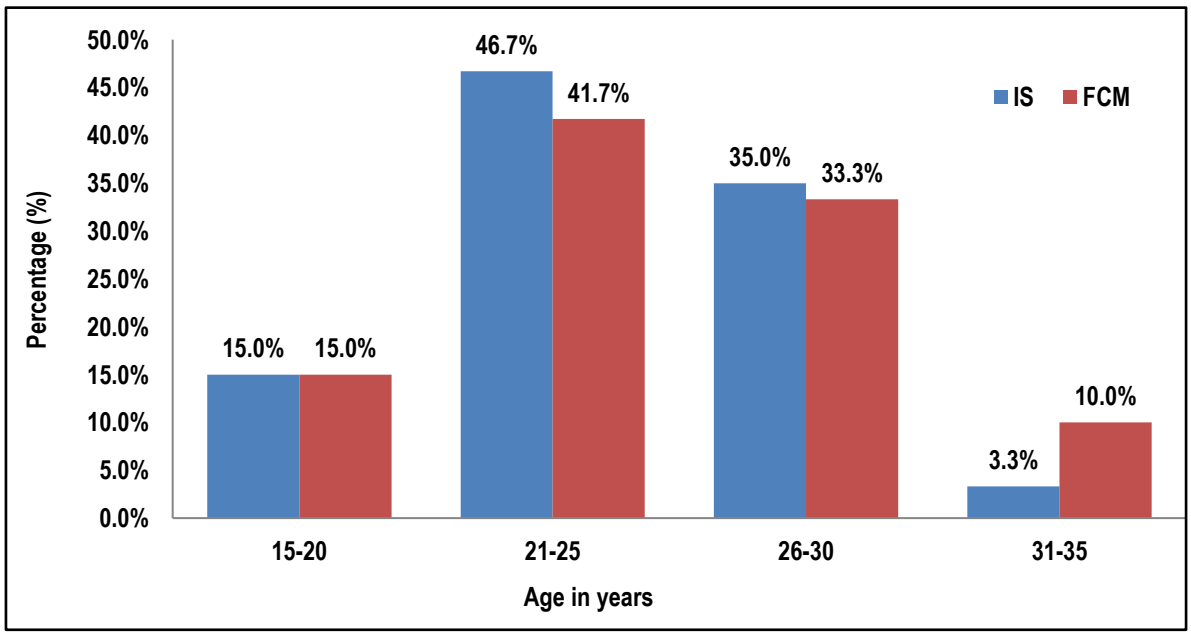

Figure 1: Age of patients in iron sucrose (IS) group and ferric carboxymaltose group (FCM)

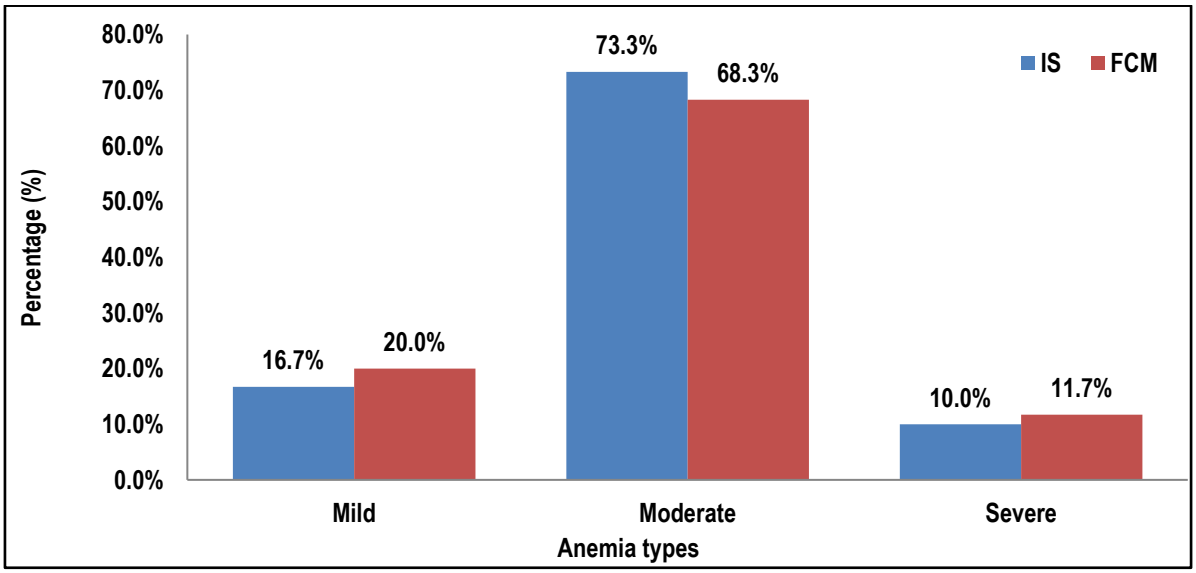

Figure 2: Types of anemia among patients in iron sucrose (IS) group and ferric carboxymaltose group (FCM)

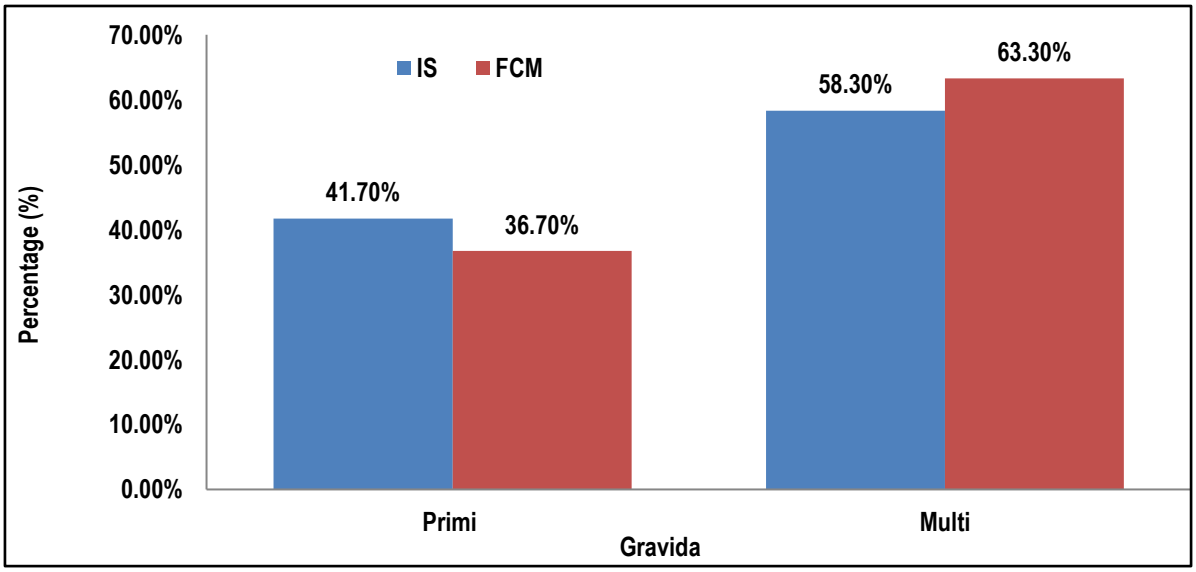

Figure 3: Gravidum of patients in iron sucrose (IS) group and ferric carboxymaltose group (FCM)

Table 1: Comparison of hematological parameters before therapy in both groups

Parameters	1 (Group 1 or Iron Sucrose)	Group 2 (Ferric carboxymaltose group)
Hb	8.27±0.53	8.305±0.609
Ferritin	77.91±27.14	78.05±34.69
RBC Count	3.58±0.26	3.59±0.21
MCV	71.55±5.2	71.62±6.39
PCV	22.66±1.83	22.66±1.95
MCHC	28.03±2.63	28.47±2.57
MCH	25.28±2.38	26.90±2.83

Table 2: Comparison of hematological parameters after therapy in both groups

Parameters	1 (Group 1 or Iron Sucrose)	Group 2 (Ferric carboxymaltose group)
Hb	10.48±0.56	11.83±0.79
Ferritin	182.86±33.36	195.39±44.6
RBC Count	3.67±0.25	3.75±0.19
MCV	74.05±4.84	77.57±6.57
PCV	27.41±2.37	28.4±2.52
MCHC	31.2±2.65	32.26±2.45
MCH	34.14±2.95	36.86±3.34

Table 3: Mean Difference of Hb before and after therapy in both groups

	Pre Therapy	Post Therapy	Difference	p
Group 1 (IS)	8.27	10.48	2.21	<0.05
Group 2 (FCM)	8.30	11.83	3.53	

Table 4: Mean Difference of ferritin before and after therapy in both groups

Ferritin	Pre Therapy	Post Therapy	Difference	p
Group 1 (IS)	77.91	182.86	104.95	<0.05
Group 2 (FCM)	78.05	195.39	117.34	

Table 5: Percentage of patients receiving target hemoglobin

	Group 1 (IS)	Group (FCM)	P
Hemoglobin rise to ≥12gm%	9.33%	30%	<0.01
Hemoglobin rise of>2gm% after 4 weeks	31%	79%	<0.01

Table 6: Weekly assessment of hemoglobin and ferritin in both groups

Duration	Group 1 (IS)		Group (FCM)	
	Hemoglobin (Gm %)	Ferritin (ng/dl)	Hemoglobin (Gm %)	Ferritin (ng/dl)
Baseline (before therapy)	8.27	77.91	8.305	78.05
After 2 weeks	9.17	229.37	10.77	281.06
After 4 weeks	10.48	182.86	11.83	195.39

Table 7: Side effects Therapy

Side effects	Group 1 (%)	Group 2 (%)
Nausea	1.4	1.8
Vomiting	0.9	0.6
Pain at injecting site	2.1	2.7
Abdominal pain	3.2	3.4
Rashes and itching	0.8	0.9
Headache	2.5	2.8
Fever	0.8	-
Hypotension	-	-
Diarrhea	0.7	0.5
Flushing	0.3	1
Dizziness	1.1	1.3

RESULTS AND DISCUSSION

The basic characteristics (age, anemia types and gravida) of study population is shown in figures 1, 2 and 3.

Nutritional anemia especially iron deficiency anemia has emerged as a serious public health issue during pregnancy and post-partum state. It has been associated significantly with both maternal and fetal morbidity and mortality. Thus in our study we selected the patients with post-partum anemia and treated them with iron sucrose and ferric carboxymaltose. We also compared the efficacy of these two treatment modalities.

India is developing country where there is still prevalence of early marriage delivery especially in rural areas which is contributed by ill literacy, low socio-economic status, customs and beliefs, poor nutrition and personal hygiene Drop in hemoglobin level due to blood loss is considered normal after child birth if it increase within next 2-5 days and return to normal after a week of delivery. However, if the level of hemoglobin does not increase adequately, post-partum IDA can occur posing a serious health problem in mother.[13] Therefore, it is essential to monitor postpartum in hemoglobin level and appropriate treatment modalities must be taken into account so at to reduce the recovery time in post-partum anemic cases.

We found that hemoglobin was increased in both the groups (Group 1 and Group 2). In Group 1 patients when received iron sucrose hemoglobin was increase from 8.27 gm% to 10.48 gm% post therapy while in case of group 2 who were given ferric carboxymaltose hemoglobin increased from 8.3 gm% to 11.83 gm%. Similarly levels of serum ferritin also increased from 77.91 ng/dl to 182.86 ng/dl in group 1 and from 78.05 ng/dl to 195.39 ng/dl in group 2 patients. Our results were similar to that of Bayoumeu et al who showed the rise of hemoglobin from 9.6±0.7 gm to 11.11±1.3gm/dl 4 weeks after the treatment with iron sucrose.[14]

Study of Singh S et al showed significant increase of ferritin in patients receiving FCM (Group 2). In their study serum ferritin increased from 14.29 to 81.91 mg/ml in group 1 while the increase was from 14.31 to 81.91 ng/ml.[15] Lunagariya M et al also reported significant increase in serum ferritin in FCM group compared to IS

group. In their study, level of ferritin increase from 13.34±3.37 to 83.95±14.37 in FCM group while in IS group, the value increased from 14.166±3.55 to 76.06±16.56 mg/dl.[16]

We also compared other hematological parameters like RBC count, PCV, MCV, MCH and MCHL in both the groups before and after the therapy. We observed improvement in theses parameters, in both groups after the therapy. Further the improvement was significant in those patients receiving ferric carboxymaltose. Our results were similar to that of Ruchika et al.[17] Van wyck et al reported significant increase of MCV in groups receiving FCM.[18] Likewise Dede A et al[19] and Khursid SR et al[20] also demonstrated increase mean value of MCV from baseline levels. Their results were further supported by that of Sumathy C et al who showed rise of MCV from 80.12 to 85.44 in iron sucrose group and from 78.94 to 88.18 in FCM group.[21]

In our study the mean rise in hemoglobin was 0.9 gm% and 2.21 gm% 2 weeks and 4 weeks after iron sucrose therapy while among those receiving FCM, mean increase were respectively 2.04 gm% and 3.53 gm%. David B et al reported increase of hemoglobin by 2g/dl in 1st week and 4 gm/dl by 2-4 weeks of therapy in those receiving FCM.[22] Rothod S et al demonstrated rise of hemoglobin by 2.4gm/dl and 3.4 gm/dl 2 and 6 weeks after the iron therapy.[23] In study of Sumathy C et al among iron sucrose group, increase in level of hemoglobin was observed by 1.65gm/dl and 2.35 gm/dl after 2 and 4 weeks of treatment. Similarly in case of FCM groups they observed the increase by 2.04 and 2.83gm/dl at 2 and 4 weeks of treatment.[21]

According to Christian Breymann et al serum increased form base line value 39.9 ng/ml to 368.2 ng/ml at 1st week and 161.2ng/dl at 12th week. In FCM group compared to those receiving ferrous sulphate in which the rise of ferritin from baseline value was 32.4 ng/ml, 34.8 ng/ml and 43.3 ng/ml at 2nd, 9th and 12th week respectively.[24] Further, Kharde PS et al elucidated the mean increase of ferritin level from 11.47 ng/ml to 47.69 ng/ml and 53.47 ng/ml at 2nd and 6th week of treatment.[9]

We analyzed the mean rise of hemoglobin in both the groups in this study. It was 2.21 gm% for those receiving iron sucrose and 3.53 gm% for those receiving FCM. Similarly, according to Giannoulis et al, the mean rise of hemoglobin by 4-6g/dl in patients who received iron sucrose.[25] Our finding was in accordance with Ruchika et al who showed mean hemoglobin to be increased by 2.48gm/dl FCM group and 2.1gm/dl in iron sucrose groups after 4 weeks of treatment.[17] This result was further supported by that of Lunagariya M et al.[16] As per them mean rise of Hb in FCM group was 2.086 gm/dl as compared to 1.766 gm/dl in iron sucrose group.

Van wynk et al reported increase of mean Hb by 2gm% and 3 gm%. At 1st week and 3-4 weeks post treatment respectively.[18] Patel J et al estimated Hb level in pregnant women pre and post iron therapy. They observed that in females receiving iron sucrose hemoglobin levels increased by 4.1 gm/dl while in those receiving FCM, the mean rise was 5.2g/dl similar pattern of increment was also observed in the level of serum ferritin.[26]

We also assessed the mean rise of serum ferritin. It was 104.95 ng/dl for those receiving IS and 117.34 ng/dl for those receiving FCM which was similar to that of Lal M et al (113.37 ng/dl in IS and 124.61 ng/dl in FCM groups).[27] The estimated target hemoglobin was 12 gm/dl in our study. About 9.33% of patients in IS group showed the targeted outcome while those in FCM it was 30%. Seid et al showed higher percentage of patients attaining Hb>12gm/dl in the group receiving paranteral therapy compared to the oral therapy.[28] Similarly Bhandel et al[29] and Breyman et al[30] also reported higher percentage of women achieving targeted Hb of >12gm/dl among those who received IV iron therapy (IS and FM). On evaluation of the side effects post therapy among the patients in both groups we found common side effects to be nausea, pain at injection site, dizziness and abdominal pain. Patel J et al reported that 40% of patients receiving IS and 16.67% of patients receiving FCM showed the side effects. Likewise in case of study of Lunagariya M et al[16], it was 32% and 24% respectively. As per Ruchika et al the percentage of patients showing side effects were 16% for FCM group and 20% of IS group.[17]

We also compared efficacy of IS and FCM in treatment of IDA in post-partum state and we observed FCM to be more effective. However as per Lal M et al both IS and FCM were equally effective for the treatment of post-partum anaemia.[27] Malek A et al[31] and Khalafallah AA et[32] reported FCM to be more effective with less side effects and better compliance compared IS group. Seid et al in their controlled randomized clinical trial assessed the efficacy and safety of FCM and oral ferrous sulphate among 29 women with post-partum IDA. They reported that treatment with FCM were more effective in.[28]

Achieving Hb level of ≥ 12gm/dl in short duration attaining higher levels of serum ferritin and transferring. Thus the author concluded FCM to be superior in the treatment of post-partum IDA compared to oral ferrous sulphate. Similarly as per Ruchika et al, FCM is more effective safe and easy to administer as it is required in single dose compared to small and multiple doses of IS. The author also added that FCM can be also given on out patient's basis and it is well tolerated with fewer side effects. Further application in single doses minimizes hospital visit frequency.[17]

CONCLUSION

Our study showed that the mean rise of both Hb and ferritin were high in group receiving FCM compared to these receiving IS. Thus we conclude that treatment of post-partum. IDA using FCM in single large dose is more effective, safe and promising compared to other preparations of iron which are required in small and multiple doses. Further FCM group patient showed better satisfaction rate and lesser hospital stay.

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