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Original Research Article

A comparative study between ferrous carboxy maltose and iron sucrose in the management of post-partum anaemia in tertiary care hospital

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ABSTRACT

Background: Anaemia is a global public health problem contributing tremendously to maternal morbidity and mortality. It is the most common indirect cause of maternal mortality. Variety of injectable iron preparations are now available which can be effective tools for combating post-partum anaemia. This study aims to compare FCM (Ferrous carboxy maltose) and iron sucrose in the treatment of iron deficiency anaemia in post-partum women at KIMS, Hubli, Karnataka, India.

Methods: This study was conducted at KIMS, Hubli in the year 2018-19 wherein 100 post-partum women with hb levels ranging from 5-10g% were selected for the study and randomly allocated into 2 groups- FCM group and iron sucrose group. They were administered 1g of FCM and 1g of iron sucrose respectively after clinical evaluation and baseline measurement of hb. They were followed up after 2 weeks for repeat hb% and review of signs and symptoms. FCM and iron sucrose were compared in terms of their efficacy.

Results: The mean increase in hb% was found to be 3.2 g% in the FCM group and 2 g% in the iron sucrose group. FCM was also found to be more efficacious in providing relief of common signs and symptoms like easy fatigability and pallor compared to iron sucrose.

Conclusions: Ferrous carboxy maltose was found to be more efficacious compared to iron sucrose.

Keywords: Anaemia, Ferrous carboxy maltose, Iron sucrose, Postpartum

INTRODUCTION

Pregnancy and puerperium are conditions that create an increased demand for nutrients in a woman's body. It is often difficult to be fulfilled by rich diet alone and makes supplementation a necessity. Anaemia is the commonest haematological disorder that may occur during pregnancy and puerperium. WHO defines anaemia as Hb < 11 g% in 1st trimester, Hb < 10.5 g% in 2nd and 3rd trimesters and Hb < 10 g% in the postnatal period.¹ It is a global public health problem and is responsible for 40% of maternal deaths in developing countries out of which it is responsible for 25% of direct maternal deaths. The prevalence of Iron deficiency anaemia (IDA) in

pregnancy in India ranges from 23.6%-61.4%.² India alone contributes 50% of global maternal deaths due to anaemia.³ It is estimated that in India 50% of population suffering from anaemia. About 20-40% of maternal deaths in India are due to anaemia and one in every 2 Indian women (56%) suffers from some form of anaemia.⁴ It contributes heavily to maternal morbidity and mortality. Anaemia is the most common indirect cause of maternal mortality.

The major causes of anaemia in the postnatal period are lack of iron supplementation during pregnancy and post-partum haemorrhage.⁵ Women with iron deficiency anaemia especially during the 3rd trimester of pregnancy

are more likely to suffer from postpartum anaemia. On the other hand, anaemia increases the risk of PPH in these women. The other risk factors identified to be associated with postpartum anaemia are multiparity, multiple pregnancy and closely spaced pregnancies. All these conditions Intern increase the risk of PPH making it a vicious cycle.

Some of the common complications of post-partum anaemia are puerperal sepsis, surgical site infection, delayed wound healing post cesarean section, sub-involution, poor lactation; others being puerperal venous thrombosis, pulmonary embolism. The traditional treatment for post-partum anaemia is oral iron supplementation while blood transfusion is reserved for more severe cases of anaemia. High doses of oral iron usually cause side effects including constipation, nausea, gastric irritation which affect compliance. Also, oral iron is often not capable of replenishing severe iron deficits. In inflammatory states, upregulation of hepcidin causes poor intestinal absorption of iron.⁶

Parenteral iron therapy is effective alternative to oral iron. The intramuscular iron formulation is available but complications like pain, skin discolouration, abscess formation, allergic reaction, fever, lymphadenopathy and rarerly anaphylaxis limits its use. Iron sucrose is widely being used all over the world with a good safety profile in pregnancy.⁷ Main disadvantage of intravenous (IV) iron sucrose is that it cannot be administered in a higher dose because of the risk of toxicity associated, thus requiring frequent visits to the hospital which puts a heavy burden on the hospital resources.

Intravenous ferric carboxy maltose is a novel iron complex which consists of a ferric hydroxide core stabilized by a carbohydrate shell. Its properties like near neutral pH, physiological osmolarity and increased bioavailability permit the administration of large doses (15 mg/kg; maximum of 1000 mg/infusion) in a single and rapid session (15-minute infusion) without the requirement of a test dose.⁸ It has a very low immunogenic potential and therefore not predisposed to anaphylactic reactions. This study is devised to measure and compare the average increase in Hb% and clinical improvement following FCM and Iron sucrose infusion in postpartum women with Iron deficiency anaemia.

Objective of the study were;

- To assess the average increase in hb% from the baseline following 1 g FCM infusion in postpartum women with IDA
- To assess the average increase in hb% from the baseline following 1g Iron sucrose infusion in postpartum women with IDA
- To compare the efficacy of FCM with iron sucrose in terms of increase in hb% and clinical improvement.

METHODS

A prospective clinical study (experimental) conducted at KIMS, Hubli, Karnataka, India. A total 100 women with post-partum anaemia included in this study. The duration of this study was 1 year (May 2018 to April 2019).

Inclusion criteria

Women admitted in the postnatal ward at KIMS, Hubli < 6 weeks after delivery with postpartum anaemia i.e, local laboratory hb > 5 g% and < 10 g% with microcytic hypochromic blood picture.

Exclusion criteria

- Women who do not give consent for the study
- Anaemia other than due to iron deficiency or increased blood loss at the time of delivery
- Women on myelosuppressive treatment
- Women with history of bleeding disorders and haemoglobinopathies
- H/o vaginal bleed > 1000 ml in the last 24 hours prior to enrolment
- Women who have received blood transfusion or erythropoietin in the last 3 months before screening
- Women with chronic diseases
- Women with history of reactions to injectable iron preparations.

If any subject required additional intervention like oral iron, other IV or IM preparations, blood transfusion, erythropoietin, they were considered as study drop out.

Methods of data collection

History

Demographic data of the patient like age, qualification, occupation; complaints/symptomatology, obstetric history, past menstrual history H/o chronic diseases, bleeding disorders, haemoglobinopathies, myelosuppressive treatment, recent blood transfusion (to apply the exclusion criteria).

Clinical examination

General appearance, pallor, nail and skin changes (general physical examination) followed by systemic examination.

Investigations

Baseline hb% and peripheral smear

Infusion of FCM/
Iron sucrose (1g) ↓ 2 weeks

Repeat hb% (follow up)

(Note: serum ferritin was not considered as it gets altered due to inflammation especially in post LSCS patients)

Intervention

The study population was divided randomly into 2 groups:

1. FCM group
2. Iron sucrose group
 - The 1st group received inj FCM 1g irrespective of the grade of anaemia (1000 mg in 200 ml of NS over 20 min)
 - The 2nd group received inj Iron sucrose 1 g irrespective of the grade of anaemia (200 mg in 200 ml of NS over 15 min - 5 doses on alternate days).

The two study groups were compared in terms of:

- Average increase in hb% over 2 weeks
- Clinical improvement over 2 weeks.

Statistical analysis

The categorical data was expressed in terms of frequencies and percentages while continuous data was expressed as mean±standard deviation (SD). The two groups were compared using chisquare test for categorical data and independent sample ‘t’ test was used to compare the means of different parameters. A ‘p’ value of less than or equal to 0.05 was considered as statistically significant.

RESULTS

The study comprised of women in the reproductive age group with maximum frequency in the age group 23-27 years (56%) followed by 18-22 years.

About half of them were home makers and half of them unskilled labourers.

The study population comprised of mostly women with parity 2 (42%).

Table 1: Socio-demographic profile.

Demographic	Frequency	Percentage (%)
Age group (years)		
18-22	38	38
23-27	56	56
28-32	4	4
>32	2	2
Occupation		
House wife	49	49
Unskilled labour	44	44
Skilled labour	7	7

Table 2: Obstetric profile.

Parity	Frequency	Percentage (%)
Para 1	30	30
Para 2	42	42
Para >/=3	28	28

Table 3: Grading of anaemia by laboratory values.

Grade	Frequency	Percentage (%)
Mild	16	16
Moderate	46	46
Severe	38	38

Considering laboratory Hb values, about half (46%) of the study subjects fell under the category of moderate anaemia and 38% were severely anaemic.

Table 4: Clinical features.

Symptoms	Frequency	Percentage (%)
Asymptomatic	34	34
Easy fatigability	44	44
Headache	18	18
Giddiness	12	12
Loss of appetite	14	14
Breathlessness/ palpitations	5	5

About half of the study population complained of easy fatigability and generalised weakness (44%). About 34% of them were asymptomatic (mostly those with mild-moderate anaemia).

Table 5: Sign.

Signs	Frequency	Percentage (%)
Conjunctival pallor	78	78
Pale tongue	84	84
Facial pallor	31	31
Pale palmar creases	28	28
Nail changes	42	42
Skin changes	7	7
Tachycardia	28	28
Cardiac murmur	2	2

Conjunctival pallor and pale tongue were evident in about 80% of the cases. Nail changes (mostly loss of convexity with longitudinal ridges) were seen in about half of the cases (42%).

The pre-infusion mean hb were 7.2 g% and 7.4 g% in the FCM and iron sucrose groups respectively, the two groups being comparable (p > 0.05). The average increase in laboratory haemoglobin was found to be 3.2 g% in the FCM group and 2 g% in the iron sucrose group. On applying tests of significance, this was found to be statistically very significant (p < 0.001).

Table 6: Average increase in HB%.

Average HB (g%)	FCM group	Iron sucrose group
Pre-infusion	7.2	7.4
Post-infusion	10.4	9.4
Increase	3.2	2

A better improvement in hb% from the base line was observed in patients with severe anaemia compared to moderate anaemia and those with mild anaemia showed the least increase. This pattern was common to both FCM and iron sucrose groups and was found to be statistically significant.

FCM showed a better symptomatic improvement compared to iron sucrose in common symptoms of anaemia like easy fatigability (78% relief in FCM group and 62% in iron sucrose group) and headache (73% showed improvement in FCM group and 57% in iron

sucrose group). However, those who received iron sucrose showed better improvement in symptoms like loss of appetite.

Table 7: Comparison of average increase in HB based on the grade of anaemia.

Grade of anaemia	Average increase in HB in FCM group	Average increase in HB in is group
Mild	1.9	1.2
Moderate	3	2
Severe	3.6	2.8

Disappearance of conjunctival pallor after 2 weeks was observed in 70% of the FCM group and 53% of iron sucrose group. Similar results were observed with lingual pallor. FCM was observed to be better in resolving other signs like nail and skin changes, tachycardia.

Table 8: Symptomatic improvement.

Symptoms	No. of cases with the symptom in FCM group	Frequency of improvement in FCM group (%)	No. of cases with the symptom in iron sucrose group	Frequency of improvement in iron sucrose group (%)
Easy fatigability	23	78	21	62
Headache	11	73	7	57
Giddiness	6	83	6	67
Loss of appetite	5	60	9	67
Breathlessness/palpitations	2	50	3	67

Table 9: Improvement with respect to signs.

Signs	No. of cases with the sign in FCM group	Frequency of disappearance of sign (%)	No. of cases with the sign in iron sucrose group	Frequency of disappearance of sign (%)
Conjunctival pallor	40	70	38	53
Pale tongue	40	75	44	55
Facial pallor	15	67	16	63
Pale palmar creases	14	64	14	50
Nail changes	22	54	20	40
Skin changes	3	33	4	25
Tachycardia	13	77	15	60
Cardiac murmur	1		1	

DISCUSSION

Postpartum anaemia being a major cause of morbidity and mortality in countries like India needs to be addressed with an effective solution. Infusion of injectable iron post-delivery gives us a better opportunity for anaemia correction with easy motivation and better compliance.

This study was devised to compare the efficacy of FCM and iron sucrose in terms of elevation of hb levels and symptomatic betterment and comprised of population of reproductive age group, mostly between 23 and 27 years of age. Half of them were home makers and the other half unskilled labourers. On classifying them based on laboratory values, about a half of them were moderately anaemic. They most commonly presented with

complaints of easy fatigability (44%) and signs of lingual and conjunctival pallor (80%).

The average increase in laboratory haemoglobin (measured 2 weeks post infusion of 1000 mg of injectable iron) was found to be 3.2 g% in the FCM group and 2 g% in the iron sucrose group in our study in contrast to the study conducted by Garag R et al wherein the increase in hb were 2.48 g% and 2.1 g% in the FCM group and iron sucrose group respectively.⁹ A study conducted by Shah S et al, showed an average increase of 2.52 g% in hb following FCM infusion.¹⁰

FCM showed a better relief of common symptoms like headache and easy fatigability in comparison to iron sucrose. Similar results were obtained by many other studies wherein most of the women who were treated with FCM had an improved sense of wellbeing. FCM was also found to be superior in causing disappearance of signs of anaemia like pallor.

It was also seen that FCM had better acceptance by the subjects due to its easy administration (up to 1000 mg in 15-20 min) and decreased duration of stay in the hospital in contrast to iron sucrose which was given in 5 divided doses of 200 mg each on alternate days requiring motivation for prolonged stay at the hospital or multiple visits to the OPD.

The cost of the FCM drug is relatively high when compared to other available parenteral iron preparations like iron sucrose. This high cost of the drug would be compensated when the number of visits and number of days of hospital admission are considered. However, post-partum infusion of FCM in women with anaemia as part of the national programme for anaemia control would be of great value to Indian women. This would give us an opportunity to correct anaemia and also iron stores of several Indian women who had been chronically anaemic and would continue to be so even during the next pregnancy if left untreated.

Also, reduced frequency of venous access in case of FCM reduces the risk of infection and pain to the patient.

CONCLUSION

In a country like India where about a half of the women suffer from anaemia and its complications post-partum, correction of anaemia through injectable iron seems an effective strategy due to better and predictable absorption, effective motivation and implementation during the woman's stay at the hospital and better compliance.

FCM was found to be better than iron sucrose in terms of increasing the laboratory hb values as well as providing symptomatic relief in women with post-partum anaemia. It was also found to have better compliance and acceptability and hence should be considered a first line drug in managing post-partum anaemia and decreasing the huge burden of anaemia and its related morbidity and mortality.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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