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A comparative study of efficacy, safety and compliance of intravenous ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anaemia of pregnancy

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ABSTRACT

Background and Objectives: Iron deficiency is the most common cause of anaemia worldwide and is associated with significant maternal and fetal morbidity. Current options for treatment include oral iron supplementation which can be ineffective and poorly tolerated, intravenous iron which can be used in patients who are intolerant to or unresponsive to oral iron and red blood cell transfusions which carry an inherent risk because of which it should be avoided. Intravenous iron therapy may reduce the requirement for allogenic blood transfusion. Ferric carboxymaltose is a new intravenous iron formulation promising to be more effective and as safe as iron sucrose. It may even have a better compliance as it offers the administration of a much higher iron dosage at a time.

The study was designed to compare the efficacy and safety of IV ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anaemia of pregnant women with moderate anaemia in the second and third trimester.

Materials and Methods: A hospital based randomized prospective study was done from July 2013 to June 2015 in the department of Obstetrics and Gynaecology, A.J. Institute of Medical Sciences, Mangalore. Baseline haemoglobin, peripheral smear and serum ferritin levels were measured to diagnose iron deficiency anaemia. 60 pregnant women who met the inclusion criteria and who formed the study subjects were randomly allocated into two groups comprising of 30 in Group C (Received ferric carboxymaltose) and 30 in Group S (Received iron sucrose). Outcome was assessed by measuring haemoglobin 3 weeks after treatment and a comparison of the safety and efficacy between the two groups was made.

Results: In the present study the commonest age group was 21 to 30 years: 80% in group C and 73.3% in group S and mean age of the study population in group C and S was comparable (25.2±3.54 vs 24.8±4.58 years). The socio demographic characteristics, obstetric history, vitals and pretreatment haemoglobin were comparable in both the groups (p>0.050). The post treatment haemoglobin levels in 63.3% of the women in group C compared to 46.7% in group S were found to be 11 or more and mean post treatment haemoglobin levels were comparable in group C and group S (11.016±0.789 vs 10.73±0.821 gm%; p=0.174). In the present study, post treatment mean increase in haemoglobin levels was noted between 2.0 to 2.5 gm% in 43.3% of the women in group C compared to 50.0% in group S.

Conclusion: Ferric carboxymaltose administration in pregnant women in the second and third trimesters is well tolerated and is not associated with any clinical safety concerns. Both ferric carboxymaltose and iron sucrose have a comparable safety profile even when ferric carboxymaltose was administered in a much higher dosage compared to iron sucrose. Ferric carboxymaltose should be considered as the drug of choice, if i.v. iron treatment becomes necessary in the second or third trimester of pregnancy.

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1. Introduction

Iron is an essential element for the functioning of all types of cells in the body. It plays a vital role in cell cycle regulation, electron transport in the respiratory chain, DNA synthesis and other metabolic reaction. The functioning of the oxygen binding molecules such as haemoglobin largely depends on the availability of iron. Anaemia is a condition in which the number of red blood cells or their oxygen carrying capacity is insufficient to meet physiologic needs.¹⁻³ It is one of the commonest medical disorder among pregnant women in India. Iron deficiency anaemia is accompanied by depleted iron stores and signs of a compromised supply of iron to the tissues.¹ There is physiological variation in haemoglobin levels during pregnancy; at the beginning of a pregnancy, there is a normal reduction in haemoglobin level followed by a slight rise towards the end of pregnancy due to increased haemoconcentration.² The initial reduction has been explained to result from increased red cell mass and demands of the fetus which exceeds iron intake with consequent reduction in iron stores of the woman's body.²

Anaemia is the most common nutritional deficiency disorder in the world. World Health Organization (WHO) has estimated that prevalence of anaemia in developed and developing countries in pregnant women is 14% and 51%. Its alarming to know that the prevalence in India is as high as 65 to 75%.⁴

Prevalence of anaemia in South Asian countries is highest compared to the countries. WHO estimates that even among the South Asian countries, India has the highest prevalence of anaemia. What is even more important is the fact that almost 50% of the global maternal deaths due to anaemia occur in South Asian countries.⁵

It is apparent that India's contribution to the prevalence of anaemia in pregnancy and maternal deaths due to anaemia is higher than warranted by the size of its population.³ On hand estimates also suggest that the magnitude of reduction in the prevalence of anaemia during nineties in India is lower than that in neighboring South East Asian countries. In view of the high prevalence of anaemia in the country, five major surveys National Family Health

Survey (NFHS) 2 and 3,^{6,7} District Level Household Survey 2 (DLHS),⁸ Indian Council of Medical Research (ICMR) Micronutrient Survey⁹ and Micronutrient Survey conducted by National Nutrition Monitoring Bureau (NNMB)¹⁰ were undertaken to find the prevalence of anaemia in the country. The results of these surveys showed that over 70% of pregnant women and adolescent girls in the country were anaemic.

Anaemia gets aggravated by increased requirements during adolescence and during pregnancy.⁸ Assuming that the absorption of iron is 8% in pregnant women, their normal dietary intake will meet only 30-45% of the

requirement.⁴

There are two known factors which play a role in the development of iron deficiency anaemia (IDA) in pregnancy; the first is the woman's iron stores at the beginning of conception and the second is the amount of iron absorbed during gestation. Women in developing countries are not commonly affected by anaemia in pregnancy is an indication that preexisting iron stores are often insufficient and physiological adaptations to pregnancy is lacking to meet the increased requirements.¹¹

Anaemia in pregnancy is associated with unfavorable consequences both for the mother and the foetus. Studies have shown that the adverse consequences of maternal anaemia may affect not only the neonate and infant but also increase the risk of non communicable diseases when the child grows into an adult and the risk of low birth weight in the next generation. The detection of anaemia and its effective management is available, affordable and it is possible to effectively implement these even in the rural setting. Not to mention the fact that these are very cost effective interventions.⁴

There are various promising forms of treatment for iron deficiency anaemia. Oral iron is the most preferred route of administration for mild anaemia. Treatment with iron preparations is used routinely in pregnancy. However, oral iron supplementation often leads to adverse side effects, such as constipation, abdominal pain and other gastrointestinal symptoms. Because of these unwarranted gastrointestinal effects the compliance to iron treatment is highly variable.

Intravenous iron preparations show good potential, especially in cases of severe anaemia. They provide a greater and more rapid iron supply than oral iron therapy without the gastrointestinal side effects of oral preparations and make it possible to avoid blood transfusion which is associated with risks.¹² To date, many studies have focused on the use of i.v. iron and its side effects and safety in pregnant women. Iron sucrose has been used for years for i.v. treatment of iron deficiency in pregnant women after the first trimester.

However, its use is limited by the low maximum dosage due to local and systemic side effects in higher doses. In order to avoid these adverse effects the drug has to be administered in multiple infusions of lower doses less than 200 mg per day. Hence it increases the number of days of admission in the hospital and it becomes an extra burden on the hospital resources.

The search for an ideal parenteral iron preparation has led to the introduction of ferric carboxymaltose. It comprises a macromolecular iron-hydroxide complex of polynuclear iron hydroxide tightly bound in a carbohydrate shell. This new complex has a molecular weight of 150,000 Daltons. This design allows for a controlled delivery of iron within the cells of reticulo-endothelial system and hence subsequent

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delivery to the iron binding proteins, with a minimal risk of release of large amounts of ionic iron in the serum. This iron preparation can be used intravenously in high doses with up to 1000 mg infused in 15 min with low risk of side effects. Its use is approved in the second and third trimesters of pregnancy.¹³ However, there is limited evidence of randomised trials concerning the clinical use of ferric carboxymaltose in pregnant women. The aim of our study is, therefore, to compare i.v. ferric carboxymaltose with i.v. iron sucrose during pregnancy regarding the efficacy and safety profile.

2. Materials and Methods

We performed a randomized prospective study to compare the safety, efficacy and compliance of i.v. ferric carboxymaltose with i.v. iron sucrose in pregnancy at A.J. Institute of Medical Sciences and Research Center between July 2013 to June 2015. The study was approved by the institutional ethics committee. Eligible participants were pregnant women between 12-36 weeks of gestation with iron deficiency anemia who had haemoglobin levels between 7.0-9.9 gm%.

Exclusion criteria were anemia not caused by iron deficiency, previous blood transfusion, known hypersensitivity to i.v. iron preparations, evidence of any significant abnormalities on anomaly ultrasound.

60 patients were recruited from the antenatal clinic of the hospital randomly by computer generated randomization. The participant was assigned to iron sucrose, or iron carboxymaltose group as per the random sequence list in masked fashion. 30 patients were in i.v. ferric carboxymaltose group and 30 patients in i.v. iron sucrose group.

Haemoglobin, peripheral smear and serum ferritin was estimated to diagnose iron deficiency anaemia and the iron deficit was calculated according to the formula:

Deficit = (12-Hemoglobin of the patient) x 2.4 x Weight + 500 (storage)

One group will be given IV ferric carboxymaltose (Group C) and the other will be given IV iron sucrose (Group S).

2.1. Group S – Iron sucrose

Iron sucrose was given in a dose of 200 mg intravenously in 200 ml normal saline over a period of 15-20 min on alternate days until the required total dose was administered; not exceeding the maximum dose of 1000 mg/week.

2.2. Group C – Ferric carboxymaltose

Ferric Carboxymaltose was given as per the total required dose diluted in normal saline over a period of 15-20 min in a single dose; not exceeding the maximum dose of 1000 mg /day/ week.

All the doses were given in the ward where equipment for cardiopulmonary resuscitation was available. Patients were observed during and after transfusion for any adverse reaction immediate or late. They were followed up after 3 weeks, for haemoglobin estimation to note the rise in haemoglobin values.

The primary outcome measure in this study was to assess the rise in haemoglobin levels 3 weeks after treatment and the secondary outcome measures included the adverse effects of the drugs and the compliance to treatment.

Statistical analysis was performed using SPSS software. 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 chi-square 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 0.050 was considered as statistically significant.

3. Results

A total of 60 patients were included in the study; 60 patients received i.v. ferric carboxymaltose and 60 received i.v. iron sucrose. Demographic characteristics and baseline data did not show any statistical significance (Table 1).

In the study most of the women were aged between 21 to 30 years i.e., 80% in group C and 73.3% in group S and this difference was statistically not significant ($p = 0.581$). The mean age of the study population in group C and S was comparable (25.2 ± 3.54 vs 24.8 ± 4.58 years; $p = 0.707$). Most of the women in group C and S were unemployed (73.3% vs 76.7%). The educational status of the study population in group C and group S was comparable ($p = 0.346$). Most of the women were from upper middle class; 36.7% in group C and 46.7% in group S and this was statistically not significant ($p = 0.628$). These findings suggest that the socio-demographic characteristics of the study population were comparable.

With regard to obstetric history in this study, most of the women were primigravidae in group C (56.7%) and group S (46.7%). However, the parity status of study population was comparable in both the groups ($p = 0.314$). Majority of the women in group C (80.0%) and group S (83.3%) presented at 29-36 weeks of gestation ($p = 0.739$). The mean period of gestation was comparable in both the groups ($p = 0.335$); 31.63 ± 2.71 in group C and 31.0 ± 2.319 in group S. These findings rule out the possible bias of obstetric history in group C and S.

In the present study based on clinical examination, the mean weight was comparable in both the groups ($p = 0.982$); 56.2 ± 6.305 in group C and 56.23 ± 5.296 in group S. On general physical examination the mean pulse rate ($p = 1.000$), systolic blood pressure ($p = 1.000$) and diastolic blood pressure ($p = 1.000$) were comparable in both the groups showing that the clinical. In this study pre-treatment

mean haemoglobin levels were comparable in both the groups (8.5 ± 0.676 vs 8.38 ± 0.789 gm%; $p=0.53$). The mean packed cell volume levels (27.07 ± 1.617 vs 27.33 ± 1.749 ; $p=0.542$), mean corpuscular volume levels (75.43 ± 3.766 vs 75.93 ± 3.805 fl; $p=0.611$), mean corpuscular haemoglobin levels (29.13 ± 2.27 vs 29.17 ± 2.692 pg; $p=0.959$), mean corpuscular haemoglobin concentration levels (29.73 ± 2.449 vs 30.73 ± 2.377 g/dL; $p=0.114$) were comparable in both the groups. The serum ferritin levels were also comparable in both the groups (11.63 ± 1.217 vs 11.43 ± 1.223 ng/L; $p=0.528$). The mean iron requirement in group C was 843.47 ± 101.848 compared to 894.2 ± 126.397 and this difference was statistically not significant ($p=0.092$).

The post treatment haemoglobin levels were found to be 11gm% or more in 63.3% of the women in group C and 46.7% in group S. However, this difference was statistically not significant ($p = 0.292$). The mean post treatment haemoglobin levels were comparable in both the groups ($p = 0.174$); 11.016 ± 0.789 in group C vs 10.73 ± 0.821 in group S. The mean increase in haemoglobin levels post treatment was noted between 2.0 to 2.5 gm% in 43.3% of the women in group C compared to 50.0% in group S and this difference was statistically not significant ($p = 0.437$). The mean increase in haemoglobin levels post treatment were comparable in both the groups ($p = 0.162$); 2.51 ± 0.421 in group C vs 2.35 ± 0.486 in group S. 53.3% of the women in group C were found to have increase in haemoglobin percentage between 15 to 30 percent compared to 66.7% in group S. However, the difference was not statistically significant ($p = 0.292$). The mean percentage change in haemoglobin levels post treatment was comparable in both the groups ($p = 0.415$); 29.797 ± 5.60 in group C vs 28.424 ± 7.247 in group S.

There were no side effects noted in either groups.

4. Discussion

These findings suggest that, both the i.v iron preparations, iron sucrose and ferric carboxymaltose are equally effective in the treatment of iron deficiency anaemia among pregnant women. IV iron sucrose (IS) has been used for many years to treat iron deficiency in pregnant women after the first trimester. However its use is limited by a low maximum dose due to side effects at higher doses. IV ferric carboxymaltose (FCM) can be administered at a higher doses and has a good side-effect profile. Ferric carboxymaltose is approved for use in pregnancy in the second and third trimesters.¹⁴

The rapid delivery option of a large single dose of ferric carboxymaltose offers a promising treatment modality for pregnant women who need correction of iron deficiency and anaemia over other IV iron formulations that have low dosage limits, such as iron sucrose (200 mg).

Christoph et al.¹⁴ undertook a retrospective analysis of 206 pregnant women who were treated either with FCM ($n=103$) or IS ($n=103$) to assess maternal tolerability and safety and to exclude safety concerns for the foetus. The incidence of drug-related adverse events was low and mostly mild in both groups, patients treated with FCM had fewer side effects (FCM, 7.8%; IS, 10.7%, NS). The mean rise of haemoglobin was 15.4 g/L for FCM and 11.7 g/L for IS. This study nevertheless showed that the tolerance of FCM in pregnancy is good and that side effects are rare, even when administered in a much higher dose than IS and it also offers the advantage of requiring less administrations thereby increasing patient comfort. The authors concluded that FCM would seem to be the drug of choice if IV iron treatment is necessary in the second or third trimester of pregnancy. The findings of the present study were in agreement with the results of Christoph et al,¹⁵ except the mean haemoglobin levels which were 11.016 ± 0.789 in the present study compared to 15.4 g/L in FCM group and 10.73 ± 0.821 compared to 11.7g/L in group S and no side effects were noted in either groups in the present study.

In a prospective observational study done by Bernd Froessler et al.¹⁶ in Australia¹⁷ anaemic pregnant women received ferric carboxymaltose up to 15 mg/kg between 24 and 40 weeks of pregnancy. Intravenous ferric carboxymaltose infusion significantly increased Hb values ($p<0.01$) above baseline levels in all women. Increased Hb values were observed at 3 and 6 weeks post infusion and up to 8 weeks post-infusion. Fetal heart rate monitoring did not indicate a drug related negative impact on the foetus. No serious adverse effects were found and minor side effects occurred in 13 (20%) patients. Even though the rise in haemoglobin in our study was comparable to this study, there were no side effects noted in our study.

Myers B et al.¹⁸ conducted a retrospective analysis of pregnant women treated with ferric carboxymaltose and iron dextran. Of the 92 women, 44 received i.v FCM and 48 received i.v Iron Dextran. At two weeks, the mean Hb rise in the FCM group was 1.73 g/dL and 1.34 g/dL in the Iron Dextran group. At four weeks, the total rise in Hb was 2.57 g/dL FCM, 2.34 g/dL Iron Dextran. At six weeks the rise was 3.01 g/dL and 3.2 g/dL respectively. The rise in Hb at the end of four weeks was comparable to our study.

Although ferric carboxymaltose has a higher cost per treatment than iron sucrose, the greater number of infusions with iron sucrose resulted in a higher overall treatment cost.

In the present study, no side effects were noted in either groups.

The tolerance and efficacy of ferric carboxymaltose has been demonstrated previously in several studies for different groups of patients with iron-deficiency anaemia¹⁹⁻²³ with similar results. Bailie GR²⁰ showed in a review paper, including nine randomized studies with more than 3000 patients, that ferric carboxymaltose had a good tolerability

Table 1: Demographic characteristics and base data

	Ferric carboxymaltose(n=30)	Iron sucrose(n=30)	p - value
	Mean±SD	Mean±SD	
Age (years)	25.2±3.547	24.8±4.582	0.707
Gestational age (weeks)	31.63±2.71	31.0±2.319	0.335
Weight (kilograms)	56.2±6.305	5.23±5.296	0.982
Pre-treatment haemoglobin (g%)	8.5±0.6761	8.38±0.7893	0.530
Packed cell volume	27.07±1.617	27.33±1.749	0.542
Mean corpuscular volume (fl)	75.43±3.766	75.93±3.805	0.611
Mean corpuscular haemoglobin (pg)	29.13±2.27	29.17±2.692	0.959
Mean corpuscular haemoglobin concentration (g/dL)	29.73±2.449	30.73±2.377	0.114
Serum ferritin (ng/L)	11.63±1.217	11.43±1.223	0.528
Mean iron requirement (gms)	843±101.848	894.2±126.397	0.092

Table 2: Haemoglobin values after treatment

	Ferric carboxymaltose (n=30) Mean±SD	Iron sucrose (n=30) Mean±SD	p - value
Mean post-treatment haemoglobin (g%)	11.016±0.7896	10.73±0.8217	0.174
Increase in haemoglobin (g%)	2.516±0.4218	2.350±0.4868	0.162

and efficiency profile. The use of ferric carboxymaltose for treatment of postpartum anaemia has been extensively investigated.^{19,20,24,25} No safety concerns have been identified in breastfed infants of mothers receiving ferric carboxymaltose.¹⁹

In the three cohort studies²⁶⁻²⁸ 345 patients were treated with IV ferric carboxymaltose. Of these 75 (21%) withdrew for any reason, and 14 (4%) because of adverse events. At least one adverse event was experienced by 197 (56%), serious adverse events by 35 (10%), and hypotension by 10 (3%).

Overall, the data from this study is consistent with existing data that intravenous iron carboxymaltose administration in pregnancy is likely to be safe and effective. However, the limitation of the study was that, the follow up of patients was done only at the end of three weeks. Serial follow ups at the end of two, three, six and eight weeks would have been better in observing the trend in rise of haemoglobin values.

The cost of the ferric carboxymaltose drug is relatively high when compared to other available parenteral iron preparations. This high cost of the drug is very well compensated when the number of visits and number of days of hospital admission is taken in to account. However studies for observing the cost effectiveness of the treatment needs to taken up. Further studies including large number of women in a randomized controlled trial along with the long term follow up of the neonates would extend the effectiveness, safety and efficacy of intravenous ferric carboxymaltose in the treatment of iron deficiency anaemia in pregnancy.

5. Conclusion

Based on the results of this study, it may be concluded that, both the i.v iron preparations are equally effective in treating iron deficiency anemia in pregnancy. This study shows that the tolerance of ferric carboxymaltose in pregnancy is excellent with no side effects, even when administered in a much higher iron dose compared to iron sucrose. However, compared to iron sucrose, ferric carboxymaltose offers the advantage of administration of a much higher iron dosage at a time reducing the need for repeated applications and increasing patients' comfort.

Although FCM and IS are almost comparable in terms of cost, the dosage schedule makes it more cumbersome and inconvenient for the patient and reduces the compliance as IS has to be administered in multiple doses.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare no conflict of interest.

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