ORIGINAL RESEARCH PAPER

Obstetrics & Gynaecology

A COMPARATIVE STUDY OF INTRAVENOUS IRON SUCROSE AND FCM IN IRON DEFICIENCY ANEMIA OF PREGNANCY

KEY WORDS: Ferric carboxymaltose,Iron deficiency anaemia, Iron sucrose

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ABSTRACT

Iron deficiency is the most common nutritional deficiency worldwide. Anemia, defined by World Health Organization as hemoglobin < 11 g/dl, is frequently seen in the antenatal period and affects 5-50%of women who give birth with hemoglobin levels <11 g/dl In mild to moderate anemic ANC .This study is to evaluate the efficacy and safety of intravenous Ferric Carboxymaltose. (FCM) in comparison with intravenous Iron sucrose complex (ISC) for treatment of iron deficiency anemia in pregnancy. Between 16-38week of gestation.

INTRODUCTION

The most typical cause of anemia in poor nations is iron deficiency anemia. According to the WHO, iron deficiency anemia causes 115,000 maternal deaths and 591,000 perinatal deaths per year. Of these, India is responsible for 80% of fatalities in Southeast Asian nations. The high incidence of anemia in India is caused by dietary deficiencies, low iron bioavailability, a diet high in phytates, recurrent menstrual blood loss, hookworm infestation, and a high rate of diseases like malaria. Pregnancy-related physiological hemodilution and increasing demands make this condition even worse. Anemia is associated with several adverse pregnancy outcomes including preterm birth (Kidanto 2009), intrauterine growth restriction, lactation failure, and lower mental development scores in neonates. Intravenous iron administration with iron sucrose has been available for several years and is routinely used to treat moderate anemia. Contrary to prior intravenous formulations like ferrous dextran, which have been linked to a considerable risk of anaphylactic reactions, iron sucrose has a stellar safety record. Small dosages (200 mg) of iron sucrose are infused over the course of 30 minutes, necessitating numerous dosing sittings. Ferric carboxymaltose can be given in higher single doses of up to 1000 mg with a minimum administration period of less than 30 minutes, providing quick replacement of iron stores. Ferric carboxymaltose though reported safe in the literature, the data are sparse in second trimester. In this study, we compare and evaluate the safety and efficacy of parenteral ferric carboxymaltose and iron sucrose in the treatment of iron deficiency anemia during pregnancy from gestation age of 16 weeks to 38 weeks.

MATERIAL AND METHODS

A comparative, interventional, prospective study was carried out in 100 antenatal patients with Anemia (hemoglobin level between 7 to 10.9 gm/dl) in the department of obstetrics and gynaecology index medical college Indore India from December 2024 to November 2025 The subjects were randomized in two groups. First group receiving 1000 mg of intravenous iron sucros divided in five doses on alternate days (200 mg each) and Second group receiving 1000 mg of intravenous Ferric Carboxymaltose.

Inclusion criteria-100 pregnant women between 16 to 38 weeks of gestation with mild to moderate iron deficiency anemia

Exclusion criteria - Known hypersensitivity to FCM or IRON SUCROSE ,Sickle cell disease, Not consenting On enrollment, a detailed clinical history (menstrual, obstetric), previous treatment history including iron therapy, compliance with oral iron and chronic medical illness was taken. Detailed examination including anthropometry, general physical examination and obstetric examination was done. Routine antenatal investigations were done according to the standard departmental protocol. Investigations specific to anemia included hemogram, reticulocyte count and peripheral blood smear, red cell indices including mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), corpuscular hemoglobin concentration (MCHC), red cell distribution width (RDW), hemoglobin electrophoresis, serum ferritin levels, serum iron, total iron binding capacity (TIBC) and transferrin saturation were done. After calculating total iron deficit, patients in the FCM group were administered i.v. FCM Maximal dose per sitting was 1000 mg which was diluted in 200 ml 0.9% normal saline and administered as an IV infusion over 30 min (Due to the limited availability of safety data for its use in pregnancy, a longer infusion protocol (30 min) Patients in ISC group were administered IV ISC as 200 mg in 200 ml NS over 15-20 min twice weekly till dosage was completed, not to exceed 600 mg per week. The general condition of the patient, blood pressure and pulse rate were noted before infusion and every five minutes during infusion and fetal heart rate monitoring was done before and after infusion. All ANC women were given 5 mg Folic acid once daily. Any minor or major adverse effects were monitored All patients were followed up after 4weeks and 80-90 days of initiation of treatment. Hemoglobin, RBC indices and serum iron studies were done after80-90 days. Patients reported minor or major adverse events at follow-up visits. Primary outcome was change in hemoglobin level from baseline after 80-90 days. Secondary outcomes were change in ferritin levels, improvement in serum iron studies and RBC indices, safety and side effects of treatment and perinatal outcome. From an earlier study by Christophe et al. (2012) where the final Hb after administering iron sucrose hemoglobin increased from 95.6 g/L to 110.4 g/L with a standard deviation of 11.9, taking non-inferiority limit difference in mean of hemoglobin between the two groups as 10 g/L, and the expected mean difference as zero, and standard deviation as 11.9, alpha error 5% and power of the study as 90%, the estimated sample size was 24 per group. Considering 10% loss to follow up, a minimum of 27 iron-deficient pregnant anemic women needed to be included in each group in the study; hence 50 patients were included in each group.

Data were presented as number (%) or mean SD/median (min-max) as appropriate. Baseline categorical variables were compared between the groups using Chi-square/Fisher's exact test and continuous variables were compared using Student's t-test.

The p value less than 0.05 was considered statistically

TABLE 1- DISTRIBUTION OF SIDE EFFECTS IN EACH GROUP

SIDE EFFECTS	GROUP A (%)	GROUP B (%)
NAUSEA	8%	8%
VOMITING	2%	2%
ITCHING	0%	5%
PAIN IN ABDOMEN	10%	0%

TABLE 2- DISTRIBUTION OF DEGREE OF ANEMIA

HAEMOGLOBIN	DEGREE OF ANEMIA	GROUP A	GROUP B	P VALUE
7 TO 9.9	MODERATE	30 (60%)	19 (34%)	
10 TO 10.9	MILD	19 (38%)	30 (68%)	
TOTAL		49	46	0.723

TABLE 3 – COMPARISON OF MEAN HEMOGLOBIN VALUES BEFORE AND AFTER TREATMENT

PARAMETERS	FCM MEAN HB (GROUP A)	IRON SUCROSE MEAN HB (GROUP B)	P VALUE
BEFORE TREATMENT	7.80	7.62	0.843
4 WEEKS AFTER TREATMENT	9.23	9.48	
80-90 DAYS AFTER TREATMENT	9.83	10.68	_0.001

RESULT

the current study's analysis of the demographic profile, the majority of the women (49%)in group A were between the ages of 25 and 29while the majority of the women (46%)in group B were between the ages of 30and 35. However, this difference was not statistically significant (p = 0.342); instead, it represented a trend. Majority of the women were unbooked in both group A (48%) and group B (44%). With regard to obstetrical parameters, most of the women had parity of ≥2 that is 55%in group A and 57%in group B, without being statistically significant. In group A, 15 patients were in second trimester and in group B 19 patients were in second trimester. Pretreatment mean hemoglobin levels in both groups in this study (8.18 0.73 vs 8.10 0.56 gm%; p = 0.265) were comparable. The mean rise in hemoglobin after 2 weeks of initiating treatment in group A (ISC) was 9.07 ± 0.71 and group B (FCM) 8.78 ± 0.52. The average rise in hemoglobin after 4 weeks in group A was 9.58± 0.74 and group B 9.32 ± 0.52The rise in hemoglobin after treatment was statistically significant in group B getting Ferric carboxymaltose injections. The mean percentage improvement after 2 weeks and 4 weeks of treatment in group A was 11.14 ± 5.72 and 17.55± 7.14 respectively. The mean improvement after 2 weeks and 4 weeks of treatment in group B was 9.30± 2.02 and 16.89 ± 3.41, respectively The mean improvement in serum ferritin levels in group A was 61.90 ± 44.40and group B 53.70± 23.42 This improvement in serum ferritin levels in each group is not significant. When side effect profile was studied, 8% of patients had nausea in group A and 8%in group B. Approximately 10%of patients complained of pain in abdomen in group A, whereas no patient complained of pain in group B .Two patients complained of vomiting in each group. Itching was not noted in any patient in group A, whereas 5 patients reported itching in group B.

DISCUSSION

The present study suggests that the majority of participants were unbooked, multiparous women, which increased their risk of developing iron deficiency anemia. Hemoglobin levels before treatment were comparable between the two groups. The study conducted over one year demonstrated that iron sucrose can be effectively used for the treatment of iron deficiency anemia during pregnancy. A significant improvement in hemoglobin levels was observed following treatment, with mean hemoglobin values increasing from 8.15 ± 0.52 g/dL to 11.15 ± 0.50 g/dL after therapy. Similarly, ferric carboxymaltose showed early and sustained correction of hemoglobin levels, with measurements recorded at 2, 4, and 12 weeks. The findings were consistent with recent studies conducted over the last two years, which reported a mean increase in hemoglobin of approximately 3.08 g/dL. In the present study, around 10% of patients belonged to Group A and 8% to Group B. Advanced gestational age was noted in both groups. Ferric carboxymaltose was found to be well tolerated and more effective than iron sucrose. Overall, intravenous ferric carboxymaltose administration in pregnant women was safe, successful, and produced a faster rise in hemoglobin and serum ferritin levels within 6–8 weeks. Although the cost of treatment was not evaluated in this study, ferric carboxymaltose demonstrated excellent tolerability and effectiveness, making it a preferred choice for the management of iron deficiency anemia during the second and third trimesters of pregnancy.

CONCLUSION

This study evaluated the effectiveness of intravenous iron sucrose and ferric carboxymaltose in the treatment of iron deficiency anemia. The findings showed that both therapies were effective in improving hemoglobin levels; however, ferric carboxymaltose demonstrated a greater increase in hemoglobin and serum ferritin levels compared to iron sucrose. Adverse reactions were observed less frequently with ferric carboxymaltose, indicating better tolerability and safety. Therefore, ferric carboxymaltose appears to be a more effective and convenient treatment option for patients with iron deficiency anemia than iron sucrose.

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