

A COMPARATIVE STUDY OF IV FERRIC CARBOXYMALTOSE VERSUS IRON SUCROSE IN THE TREATMENT OF IRON DEFICIENCY ANAEMIA IN PREGNANCY

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Abstract

Background: To compare IV ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anaemia of pregnancy. **Materials and Methods:** 140 pregnant ladies were divided equally into 2 groups of 70 each. Group I subject received ferric carboxymaltose. Ferric Carboxymaltose was administered as needed, diluted in normal saline over the course of 15-20 minutes, in a single dosage, keeping the dose under the weekly maximum of 1000 mg and group II subjects received iron sucrose. Iron sucrose was given in a dose of 200 mg intravenously in 200 ml normal saline over a period of 15-20 minutes on alternate days. **Result:** Age group 18-28 years comprised of 52 patients in group I and 50 in group II and age group 28-38 years had 18 in group I and 20 in group II. The mean serum ferritin level before treatment in group I was 12.0 ng/L and 11.6 ng/L in group II. The mean iron requirement was 848.3 grams in group I and 893.2 grams in II. The mean packed cell volume was 27.4 in group I and 27.9 in group II, mean corpuscular volume was 75.7 fl in group I and 75.6 fl in group II, mean corpuscular haemoglobin was 29.9 pg in group I and 29.8 pg in group II, mean corpuscular haemoglobin concentration was 30.4 g/dL in group I and 30.5 g/dL in group II. A non-significant difference was observed ($P < 0.05$). The mean serum ferritin level after treatment in group I was 14.0 ng/L and 13.4 ng/L in group II. The mean iron requirement was 910.3 grams in group I and 905.2 grams in II. The mean packed cell volume was 29.8 in group I and 30.2 in group II, mean corpuscular volume was 78.4 fl in group I and 79.2 fl in group II, mean corpuscular haemoglobin was 30.5 pg in group I and 30.8 pg in group II, mean corpuscular haemoglobin concentration was 32.4 g/dL in group I and 31.6 g/dL in group II. A non-significant difference was observed ($P < 0.05$). **Conclusion:** Results revealed that in women with iron deficient anaemia, ferric carboxymaltose and iron sucrose were found to be equally beneficial.

INTRODUCTION

Anemia is defined as the reduction in absolute number of circulating red blood cells (RBC)s, indirectly measured by a reduction in hemoglobin (Hb) concentration, hematocrit (Hct) or RBC count.⁴ WHO has defined it as Hb of <11 g/dl but, during pregnancy, definition of anemia is different depending on trimester (<11 g/dl in the first trimester, <10.5 g/dl in the second trimester, <11 g/dl in the third trimester).^[1]

Poor nutrition, iron deficiency, micronutrient deficiencies (including folic acid, vitamin A, and

vitamin B12), illnesses including malaria, hookworm infestation, and schistosomiasis, HIV infection, and genetically inherited hemoglobinopathies like thalassemia are the most frequent causes of anaemia.^[2] Additionally, there may be a connection between anaemia and Helicobacter species infection. The most common dietary deficiency in the world, iron deficiency causes 75% of all types of anaemia in pregnancy. It is because pregnant women's diets don't include enough iron to meet their needs. Although it is very common in developing nations, it is equally

important in developed nations where other nutritional illnesses have all but disappeared.^[3] In cases of severe anaemia, intravenous iron formulations have good potential. They enable patients to avoid risky blood transfusions and give a higher and faster iron supply than oral iron therapy without the gastrointestinal side effects of oral preparations.^[4] The use of intravenous iron, its safety, and its negative effects in pregnant women have been the subject of numerous research to date. Since many years ago, iron sucrose has been administered intravenously to treat iron insufficiency in pregnant women after the first trimester.^[5] In this study, we compare IV ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anaemia of pregnant women.

MATERIALS AND METHODS

A sum total of 140 pregnant ladies were selected for the study. All agreed to participate with their written consent. Ethical approval for the study was taken before commencing the study.

Baseline characteristic data was recorded in case history proforma. After careful screening of all subjects, they were divided equally into 2 groups of 70 each. Group I subject received ferric carboxymaltose. Ferric Carboxymaltose was administered as needed, diluted in normal saline over the course of 15-20 minutes, in a single dosage, keeping the dose under the weekly maximum of 1000 mg and group II subjects received iron sucrose. Iron sucrose was given in a dose of 200 mg intravenously in 200 ml normal saline over a period of 15-20 minutes on alternate days. Iron deficiency anaemia was diagnosed using haemoglobin,

peripheral smear, and serum ferritin estimates, and the iron deficit was computed according to the formula: Deficit = (12-Hemoglobin of the patient) x 2.4 x Weight + 500 (storage). Thus, the outcomes were assessed. P value under 0.05 was regarded as significant.

RESULTS

Age group 18-28 years comprised of 52 patients in group I and 50 in group II and age group 28-38 years had 18 in group I and 20 in group II. [Table 1] The mean serum ferritin level before treatment in group I was 12.0 ng/L and 11.6 ng/L in group II. The mean iron requirement was 848.3 grams in group I and 893.2 grams in II. The mean packed cell volume was 27.4 in group I and 27.9 in group II, mean corpuscular volume was 75.7 fl in group I and 75.6 fl in group II, mean corpuscular haemoglobin was 29.9 pg in group I and 29.8 pg in group II, mean corpuscular haemoglobin concentration was 30.4 g/dL in group I and 30.5 g/dL in group II. A non-significant difference was observed (P< 0.05) [Table 2]

The mean serum ferritin level after treatment in group I was 14.0 ng/L and 13.4 ng/L in group II. The mean iron requirement was 910.3 grams in group I and 905.2 grams in II. The mean packed cell volume was 29.8 in group I and 30.2 in group II, mean corpuscular volume was 78.4 fl in group I and 79.2 fl in group II, mean corpuscular haemoglobin was 30.5 pg in group I and 30.8 pg in group II, mean corpuscular haemoglobin concentration was 32.4 g/dL in group I and 31.6 g/dL in group II. A non-significant difference was observed (P< 0.05) [Table 3].

Table 1: Distribution of patients in both groups

Age groups	Group I (Ferric carboxymaltose)	Group II (Iron sucrose)
18-28	52	50
28-38	18	20

Table 2: Assessment of parameters before treatment

Parameters	Group I	Group II	P value
Serum ferritin (ng/L)	12.0	11.6	0.17
Mean iron requirement (gms)	848.3	893.2	0.05
Packed cell volume (PCV)	27.4	27.9	0.91
Mean corpuscular volume (MCV) (fl)	75.7	75.6	0.94
Mean corpuscular haemoglobin (MCH) (pg)	29.9	29.8	0.82
Mean corpuscular haemoglobin concentration (MCHC) (g/dL)	30.4	30.5	0.94

Table 3: Assessment of parameters after treatment

Parameters	Group I	Group II	P value
Serum ferritin (ng/L)	14.0	13.4	0.64
Mean iron requirement (gms)	910.3	905.2	0.86
Packed cell volume (PCV)	29.8	30.2	0.92
Mean corpuscular volume (MCV) (fl)	78.4	79.2	0.91
Mean corpuscular haemoglobin (MCH) (pg)	30.5	30.8	0.85
Mean corpuscular haemoglobin concentration (MCHC) (g/dL)	32.4	31.6	0.92

DISCUSSION

For all types of cells in the body to operate properly, iron is a necessary ingredient. It is essential for the control of the cell cycle, respiratory chain electron transport, DNA synthesis, and other metabolic processes.⁶ The availability of iron is a key factor in how well oxygen-binding molecules like haemoglobin operate. Anaemia is a condition where there are not enough red blood cells or that they are not able to carry enough oxygen to meet physiologic requirements.⁷ In India, it is one of the most prevalent medical conditions affecting expectant mothers. Depleted iron reserves and hampered iron delivery to the tissues accompany anaemia. During pregnancy, haemoglobin levels fluctuate physiologically; during the start of a pregnancy.⁸

The primary symptoms of this condition are glossitis and pallor, though patients may also experience weakness, anorexia, palpitations, and dyspnea.⁹ Hb fluctuates during the three trimesters during pregnancy due to a physiological hemodilution that peaks between 30 and 32 weeks of gestation. It is widely known that Hb levels physiologically decrease towards the middle of the third trimester.¹⁰ This physiological decline results from a greater rise in plasma volume during pregnancy than from a small increase in RBC mass. This physiological mechanism results in relative hemodilution blood viscosity, which aids placental blood flow.^{11,12} In this study, we compared IV ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anaemia of pregnant women.

In our study, age group 18-28 years comprised of 52 patients in group I and 50 in group II and age group 28-38 years had 18 in group I and 20 in group II. Parikh et al,¹³ included 100 prenatal patients with anaemia. Two groups of individuals were randomly assigned. First group was given 1000 mg of intravenous ferric carboxymaltose while the second group was given 1000 mg of iron sucrose in five 200 mg doses given on alternate days. The majority of patients were from poor socioeconomic backgrounds, and a considerably higher proportion of women in the FCM group increased their haemoglobin levels above 2 g/dl, which was very significant (p value 0.001). It was also significant that the mean increase in haemoglobin for the FCM group was 1.9 g/dl and for the iron sucrose group was 1.66 g/dl. serum ferritin concentration.

In this study, the mean serum ferritin level before treatment in group I was 12.0 ng/L and 11.6 ng/L in group II. The mean iron requirement was 848.3 grams in group I and 893.2 grams in II. The mean packed cell volume was 27.4 in group I and 27.9 in group II, mean corpuscular volume (fl) was 75.7 fl in group I and 75.6 fl in group II, mean corpuscular haemoglobin was 29.9 pg in group I and 29.8 pg in group II, mean corpuscular haemoglobin concentration was 30.4 g/dL in group I and 30.5

g/dL in group II. Patients with anaemia and women with iron shortage but no anaemia had significantly higher ferritin levels after receiving FCM infusions, according to research by Froessler et al.¹⁴

It was found that the mean serum ferritin level after treatment in group I was 14.0 ng/L and 13.4 ng/L in group II. The mean iron requirement was 910.3 grams in group I and 905.2 grams in II. The mean packed cell volume was 29.8 in group I and 30.2 in group II, mean corpuscular volume (fl) was 78.4 fl in group I and 79.2 fl in group II, mean corpuscular haemoglobin was 30.5 pg in group I and 30.8 pg in group II, mean corpuscular haemoglobin concentration was 32.4 g/dL in group I and 31.6 g/dL in group II. Reddy et al,¹⁵ randomly divided 60 pregnant women into two groups, with 30 in group C receiving ferric carboxymaltose and 30 in group S receiving iron sucrose. Three weeks following therapy, haemoglobin levels were measured to evaluate the outcome and compare the two groups' safety and efficacy. The study's largest age range was 21 to 30 years, which was represented by 80% in group C and 73.3% in group S. The average age of the study population in groups C and S was similar (25.23.54 vs. 24.84.58 years), as were their median ages. Both groups' sociodemographic traits, obstetric history, vital signs, and pre-treatment haemoglobin levels were equivalent (p>0.050). 63.3% of the women in group C had post-treatment haemoglobin levels of 11 or more, compared to 46.7% of the women in group S, and the mean post-treatment haemoglobin levels were similar in group C and group S (11.0160.789 vs. 10.730.821 gm%; p=0.174). In this study, 43.3% of the women in group C had a post-treatment mean increase in haemoglobin levels between 2.0 and 2.5 gm%, compared to 50.0% of the women in group S.

CONCLUSION

Results revealed that in women with iron deficient anaemia, ferric carboxymaltose and iron sucrose were found to be equally beneficial.

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