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IV Ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anaemia of pregnant women

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Abstract
Background: 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. The present study was conducted to compare IV ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anaemia of pregnant women.
Materials and Methods: 140 pregnant women were divided equally into 2 groups of 70 each. Group I received ferric carboxymaltose and Group II received iron sucrose. Haemoglobin, peripheral smear and serum ferritin was estimated to diagnose iron deficiency anaemia. Outcome was assessed by measuring haemoglobin 3 weeks
Results: In group I, ferric carboxymaltose and in group II iron sucrose was given. Each group had 70 patients. The mean gestational age (weeks) was 32.4 and 31.7, packed cell volume was 27.1 and 27.5, mean corpuscular volume (fl) was 75.4 and 75.3, mean corpuscular haemoglobin (pg) was 29.6 and 29.5, mean corpuscular haemoglobin concentration (g/dL) was 29.9 and 30.2, serum ferritin (ng/L) was 11.7 and 11.3 and mean iron requirement (gms) was 845.3 and 890.4 in group I and II respectively.
Conclusion: Both ferric carboxymaltose and iron sucrose found to be equally effective in women with iron deficiency anaemia.

Keywords: Ferric carboxymaltose, iron sucrose, Anaemia

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 [1]. 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 [2]. 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. 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 [3].
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) [5].
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 [6]. 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 [7, 8]. The present study was conducted to compare IV ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anaemia of pregnant women.

Materials and Methods
The present study was conducted in the department of gynaecology and Obstetrics. It comprised of 140 pregnant women. All were informed regarding the study and their written consent was obtained.

Data such as name, age, etc. was recorded. A thorough examination was done. All were divided equally into 2 groups of 7 each. Group I Received ferric carboxymaltose and Group II received iron sucrose. 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.

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. 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). Outcome was assessed by measuring haemoglobin 3 weeks. Results thus obtained were evaluated. P value less than 0.05 was considered significant.

Results

Table 1: Distribution of patients

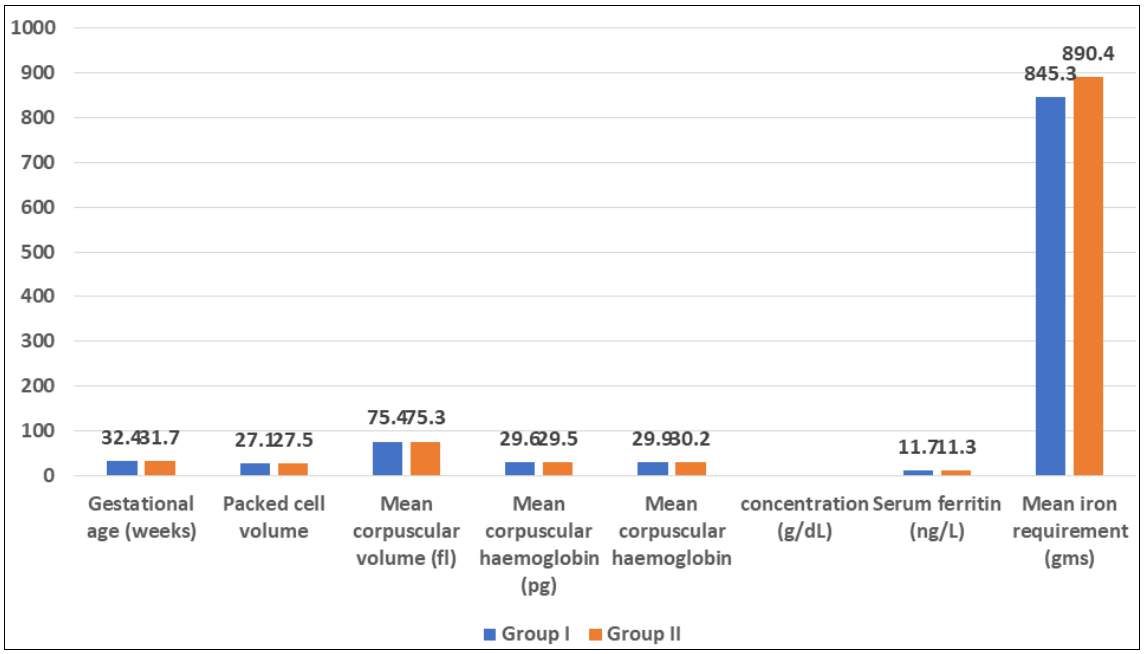
Groups	Group I	Group II
Method	Ferric carboxymaltose	Iron sucrose
Number	70	70

Table I shows that in group I, ferric carboxymaltose and in group II iron sucrose was given. Each group had 70 patients.

Table 2: Assessment of parameters

Parameters	Group I	Group II	P value
Gestational age (weeks)	32.4	31.7	0.90
Packed cell volume	27.1	27.5	0.82
Mean corpuscular volume (fl)	75.4	75.3	0.95
Mean corpuscular haemoglobin (pg)	29.6	29.5	0.85
Mean corpuscular haemoglobin concentration (g/dL)	29.9	30.2	0.92
Serum ferritin (ng/L)	11.7	11.3	
Mean iron requirement (gms)	845.3	890.4	0.05

Table II, graph I shows that mean gestational age (weeks) was 32.4 and 31.7, packed cell volume was 27.1 and 27.5, mean corpuscular volume (fl) was 75.4 and 75.3, mean corpuscular haemoglobin (pg) was 29.6 and 29.5, mean corpuscular haemoglobin concentration (g/dL) was 29.9 and 30.2, serum ferritin (ng/L) was 11.7 and 11.3 and mean iron requirement (gms) was 845.3 and 890.4 in group I and II respectively. The difference was significant (P< 0.05).



Graph 1: Assessment of parameters

Discussion

The most common causes of anemia are poor nutrition, deficiencies of iron, micronutrients deficiencies including folic acid, vitamin A and vitamin B12, diseases such as malaria, hookworm infestation and schistosomiasis, HIV infection and genetically inherited hemoglobinopathies, such as thalassemia [9, 10]. There is also a possible association between Helicobacter species infection and anemia [11]. Iron deficiency is the most widespread nutritional deficiency in the world and it accounts for 75% of all types of anemia in pregnancy. It is due to the fact that diet in pregnancy is insufficient to supply iron requirement. It has high prevalence in developing countries, but it is also relevant in developed countries where other nutritional disorders have been almost eliminated. Main manifestations of this disorder are pallor, glossitis and while patient may complain lassitude, weakness, anorexia, palpitation and dyspnea [12]. During pregnancy, there is a physiological hemodilution, with a peak during 20–24 weeks of gestation, and Hb varies through trimesters. In fact, it is well established that there is a physiological drop in Hb in mid-trimester. This physiological drop is due to the higher increase in plasma volume, compared with RBC mass, which slightly increases during pregnancy. This physiological process produces relative hemodilution blood viscosity, helping the blood circulation in the placenta [13]. The present study was conducted to compare IV ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anaemia of pregnant women.

We observed that in group I, ferric carboxymaltose and in group II iron sucrose was given. Each group had 70 patients. Reddy *et al.* [14] 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. In the 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 pre-treatment 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. 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

We found that the mean gestational age (weeks) was 32.4 and 31.7, packed cell volume was 27.1 and 27.5, mean corpuscular volume (fl) was 75.4 and 75.3, mean corpuscular haemoglobin (pg) was 29.6 and 29.5, mean corpuscular haemoglobin concentration (g/dL) was 29.9 and 30.2, serum ferritin (ng/L) was 11.7 and 11.3 and mean iron requirement (gms) was 845.3 and 890.4 in group I and II respectively. Anemia in pregnant women has been considered as harmful for the fetal growth and fetal outcome. Low birth weight and preterm delivery have been persistently linked to anemia in pregnancy. A significant increased risk of preterm birth in case of second trimester anemia has been demonstrated. This could be explained to the state of chronic hypoxia consequent to anemia, which may induce a stress response, resulting in production of corticotropin releasing hormone (CRH), elevated concentrations of which have been identified as a major risk factor of preterm birth [15].

Conclusion

Authors found that both ferric carboxymaltose and iron sucrose found to be equally effective in women with iron deficiency anaemia.

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