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Comparing the efficacy between ferrous carboxymaltose and iron sucrose therapy in iron deficiency anemia during pregnancy in Obstetrics and Gynecology ward at tertiary care hospital, Jaipur

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Abstract: *Aim:* Comparing the efficacy between ferrous carboxymaltose and iron sucrose therapy in iron deficiency anemia during pregnancy in obstetrics and gynecology ward at tertiary care hospital, Jaipur. *Methods:* The study was conducted on 60 pregnant women who were diagnosed with iron deficiency anemia in the department of obstetrics and gynecology at NIMS hospital, Jaipur. The subjects were divided into two groups, first group was treated with iron sucrose (200mg/ dose) and second group was treated with ferrous carboxymaltose (500mg/ dose). *Results:* The mean rise of hemoglobin was 2.92 g/l for Ferrous Carboxymaltose and 1.08 g/l for iron sucrose. The rise in the hemoglobin concentration shows that ferrous carboxymaltose is more efficaous than iron sucrose. *Conclusion:* In this study it was found that ferrous carboxymaltose is efficaous in comparison to the Iron sucrose among the pregnant women with Iron deficiency anemia.
Keywords: Ferrous Carboxymaltose, Iron Sucrose, Iron Deficiency Anemia, Hemoglobin, Serum Ferritin.

Abbreviations: WHO- World Health Organization; ICMR- Indian Council of Medical Research; IS- Iron Sucrose; FCM-Ferrrous Carboxymaltose; Hb-Hemoglobin; SPSS-Ststistical Package for Social Science.

Introduction

Anemia is the major health problem associated during pregnancy. Iron deficiency anemia is the most common cause of anemia during pregnancy [1]. According to WHO (2015) the rate of prevalence of anemia during pregnancy is 33-89% and rate of incidence is 42%. As per ICMR (2010) 87% of pregnant women are found to be anemic out of which 10% have severe anemia. As per WHO, anemia during pregnancy is defined as hemoglobin concentration of <11gm% (7.45mmol/l) and haemotocrit <33%. The Center of Diseases Control & Prevention (1990) defined anemia as <10.5 gm/dl in first and third trimester and <11 gm/dl in second trimester [2].

Iron deficiency is the major nutritional deficiency worldwide, 1.6 billion people suffering from iron deficiency anemiaapprox quarter of the world population [3]. Iron deficiency anemia during pregnancy defined as low ferritin levels [4].

Iron Sucrose (IS): Iron sucrose was first approved in November, 2000 by FDA. Iron sucrose contain iron hydroxide sucrose complex in H_2O. Iron sucrose is infused in 100ml of normal saline over a time period of 15-20 minutes. The average dose of 200mg can be infused at a time, not more than thrice a week. Common side effects include metallic taste, local irritation, dizziness, nausea and vomiting [5].

Ferrous Carboxy Maltose (FCM): Ferrous carboxymaltose was approved in 2004. It consists of macromolecular iron hydroxide tightly bound in a carbohydrate shell. The average dose is 500/ 1000mg in 250ml normal saline over a time periods 15 minutes, not exceeding the maximum dose of 1000mg/ day/ week [6].

Material and Methods

Study was carried out in the department of obstetrics and gynecology, Jaipur, Rajasthan, India, during a time period of 6 months.

Sample Size: In this prospective observational study, the participants were classified into two groups consisting of 30 cases each;

- Group A: Iron sucrose.
- Group B: ferrous carboxymaltose.

Inclusion Criteria

- Pregnant women
- Iron deficiency anemia
- Iv iron treatment
- Gestational age (12-36 weeks)
- Hemoglobin level (6.9-10.9 gm/dl)
- Serum ferritin

Exclusion Criteria

- Incomplete information regarding patients
- Patients who are not willing to participate in the study
- Anemia not linked to iron deficiency
- Any associated Comorbidity
- Oral iron treatment
- Patients allergic to iron (intravenously)
- Blood transfusion.
- Multiple pregnancies.
- Known history of hypersensitivity to any iron preparation.

Methods of data collection: The patients were participated from obstetrics and gynecology department after completing the selection criteria and fulfilling the patient consent form. The demographic data like age, sex, education, occupation, socioeconomic status was ruled out. The initial iron status in pregnancy was assessed by the clinical and laboratory investigation. The calculating dose requirement for iron was calculated by the formula on the basis of hemoglobin deficit and body weight using Ganzoni formula.

Total iron deficit (mg) = Body weight (kg)*(target Hb-actual Hb) *0.23+ depot iron (mg)

Depot iron= 15 mg/kg in case of body weight < 35 kg and 500 mg in case of body weight > 35 kg.

Target Hb has been taken as 11g/dl as per WHO [7].

Institutional ethical approval: The current research was approved by the IEC, National Institute of Medical Science and Research, Jaipur (Ref no.: NIMSUNI/IEC/2018/35).

Statistical Analysis: Data will be analyzed through SPSS v22, chi square test and Confidence level will be 95% and level of significance will not be more than 5%. For this study, the sample size will be calculated by using the following formula: $n=Z^2*p*q/ d^2$ Where N = Sample Size at 95% confidence level**,** Z=1.96, p=0.56, q=1-p=0.44**,** d = allowable error of 5%= 0.05.

Results

The table 1 showed that hemoglobin concentration was 8.06±0.71 in iron sucrose which increased to 9.14±1.16 and Sr. Ferritin was 25.86±5.52 to 57.86±20.95 after dose administration. Where as in Ferrous carboxymaltose hemoglobin concentration were 8.05±0.84 to 10.97±0.55 and Sr. Ferritin increased from 29.93±7.04 to 34.9±13.18 after dose administration. Ferrous carboxymaltose were found to be more efficacious than Iron Sucrose.

Table-1: Laboratory parameter observed in study population

	Iron Sucrose			Ferrous Carboxymaltose		
Variables	**Pre value**	**Post value**	**P value**	**Pre value**	**Post valve**	**P value**
Hb	8.06 ± 0.71	9.14 ± 1.16	0.115	8.05 ± 0.84	10.97 ± 0.55	0.009
Sr, Ferritin	25.86 ± 5.52	57.5 ± 20.95	0.099	29.93 ± 7.04	94.9 ± 13.18	0.138
All values represent Mean±SD (standard deviation)						

The table number 2 showed the frequency of iron sucrose and ferrous carboxymaltose doses were such as: First dose of iron sucrose was administered to 17 pregnant women, Second dose of iron sucrose were administered to 8 pregnant women and Third dose of iron sucrose were administered to 5 pregnant women. Similarly, the first dose of ferrous carboxymaltose was administered to 23 pregnant women, Second dose of ferrous carboxymaltose were administered to 6 pregnant women and Third dose of ferrous carboxymaltose were administered to 1 pregnant women. The First dose of both the drug was found to be the highest frequency than others.

Table-2: Frequency of Dose Administered to study population

No of Doses (vials)	Iron Sucrose (200mg)	Ferrous Carboxymaltose (500 mg)
1	17 (56.6%)	23 (76.6%)
2	8 (26.6%)	6 (20%)
3	5 (16.6%)	1 (3.33%)

Discussion

This prospective observational study compares the efficacy between ferrous carboxymaltose and iron sucrose. In this study most of cases belonged to lower socioeconomic status, consuming low calories and protein diet and were illiterate. In developing countries like India, marriage at early age and childbearing is highly prevalent in rural area and also female are deprived from education as compared to urban area [8]. The major causes of Iron deficiency anemia in pregnancy is due to low socioeconomic status, illiteracy, customs, beliefs and low priorioty of female child as compared to male child in the society, multiple pregnancy and less birth spacing [9].

In this study total of 60 pregnant women was administerd iron therapy. The participants were divided into two groups of 30 pregnant women each, First group was administered ferrous carboxymaltose while second group was administered iron sucrose. There was a statistically significant increase in hemoglobin in ferrous carboxymaltose group (2.92 gm/dl) as compared to that of iron sucrose (1.08 gm/dl) and serum ferritin was also higher in FCM group as compared to iron sucrose with lower side effects. The rise in the hemoglobinconcentration shows that ferrous carboxymaltose is more efficacious than iron sucrose in treating the iron deficiency anemia and increasing the iron stores in the body [10].

This statistics corresponds to the other studies being conducted across till date. Therefore, FCM has better efficacy than IS and highly recommendable for treating anemia during pregnancy.

Conclusion

Based on the result of this observational study, it can be concluded that ferrous carboxymaltose is more effective in comparison to iron sucrose therapy .It can be used as most preferable drug for the management of the iron deficiency anemia.

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