Original Article

Comparing the Safety 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

Background: Pregnancy is the most vulnerable condition prone for anemia (most commonly iron deficiency anemia). Hence requires drug therapy for iron store replenishment. Comparing the safety between ferrous carboxymaltose and iron sucrose therapy in iron deficiency anemia during pregnancy in obstetrics and gynecology ward at a tertiary care hospital. **Methods:** A prospective observational single centered study was conducted on 60 pregnant women who were diagnosed with iron deficiency anemia in the department of obstetrics and gynecology at tertiary care teaching hospital. The subjects were divided into two groups, first group was administered iron sucrose 200mg and second group was administered ferrous carboxymaltose 500mg. The relative incidence of drug administrative adverse event was low in Ferrous Carboxymaltose than compare to Iron Sucrose. **Result:** The adverse event occurred in 3.33% for Ferrous Carboxymaltose and 13.33% for Iron Sucrose. The mean rise of hemoglobin was 2.92 g/l for Ferrous Carboxymaltose and 1.08 g/l for iron sucrose. **Conclusion:** In this study it was found that Ferrous carboxymaltose is safer in comparison to the Iron sucrose among the pregnant women with Iron deficiency anemia.

Key words: Ferrous Carboxymaltose, Iron Sucrose, Iron Deficiency Anemia, Pregnant woman, Haemoglobin.

INTRODUCTION

Anemia is one of the main causes of the maternal mortality and morbidity worldwide, according to the WHO, about 20% deaths were estimated in the developing country like India, Anemia is more prevalent in women of childbearing age group particularly pregnant women with an estimation of approximately two-thirds of all pregnant women. Iron deficiency constitutes to be the main cause of anemia; it is approximately 95%.[1]

Anemia is the commonest hematological abnormality diagnosed during pregnancy. As per WHO, anemia during pregnancy is defined as the hemoglobin concentration of less than 11 gm% (7.45 mol/L) and hematocrit less than 33%. The center of disease control and Prevention (CDC) defined anemia as less than 11gm/dl in the first and third trimester and less than 10.5 gm/dl in the second trimester.[2,3]

Iron deficiency anemia (IDA)

It occurs due to decrement of the dietary iron absorption (e.g., inflammatory bowel disease (IBD) and gastrointestinal surgery) or increment of the iron need in an organism or increased iron loss (e.g., during pregnancy, excessive uterine bleeding, lactation or hemodialysis). According to the literature, the mean prevalence of IDA is 36.4% in women.[3-5]

Iron sucrose (IS)

Iron sucrose (IS) was FDA approved in

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November 2000. The molecular weight is 34,000-60,000 Dalton's. It is administered by IV injection for 5-10 min or as short infusion in 100 ml of normal saline for 15-20 min. The maximum daily bolus dose of 200 mg can be given at a time, that's not more than thrice a week. The side effect includes metallic taste, anaphylaxis, nausea, dizziness and local irritation.[4,5]

Ferrous carboxymaltose (FCM)

FCM was FDA approved in 2004. The single dose of Iv FCM, not exceeding 1500 mg of iron (30 ml) per day was given. The administered infusion diluted in sterile 0.9% sodium chloride (NaCl) solution and 500 mg dose can be diluted with 100 ml NaCl and administered for 6 min. Doses between 1000 mg and 1500 mg can be diluted with 250 ml NaCl and an administration time for 15 min.[6-10]

MATERIALS AND METHODS

In this prospective observational study, data were collected from 60 antenatal patients were administered ferrous carboxymaltose (FCM) and iron sucrose (IS) treatment (n=30 for each) were carried out in the department of obstetrics and gynecology ward at tertiary care teaching hospital. The study was approved by the ethical committee of the respective institution.

The participants were classified into two groups, each having 30 pregnant women with gestational age between 12-36 weeks with hemoglobin level between 6.9-10.9 gm/dl. The first group patients were treated with iron sucrose (IS) and second group patients were treated with ferrous carboxymaltose (FCM).

Inclusion Criteria

- Pregnant women
- Anemic patient (iron deficiency anemia)
- Iv iron treatment Gestational age (12-36 weeks)
- Hemoglobin level (6.9-10.9 gm/dl).

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.

Methods of data collection

The participants were enrolled after fulfilling the selection criteria and also giving valid consent. The history was taken through clinical examination and laboratory investigations and other causes of anemia were ruled out. The initial iron status of pregnant women was assessed by the clinical and laboratory examinations (complete blood count (CBC) and serum ferritin levels). The amount of iron needed by an individual patient was calculated by the following formula:

The total required dose will be calculated 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 if body weight < 35 kg and 500 mg if body weight > 35 kg.

They were divided into two groups, first was administered iron sucrose (200mg/dose) and second was administered ferrous carboxymaltose (500mg/dose). 60 pregnant women were followed up after two weeks of the treatment and laboratory examinations (complete blood count (CBC) and serum ferritin levels) was done.

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

Sixty pregnant women diagnosed with Iron deficiency anemia in the Department of Obstetrics and Gynecology, were enrolled on the basis of selection criteria during the considered study period.

The prevalence of IDA among the various age group is depicted in Table 1 were its depicted that reproductive age group (21-25 years) constituting of 30 pregnant women.

Above Table 2 shows, multiparity (49 pregnant women) to be more predisposed to develop iron deficiency anemia in compare to primigravida.

As mention above in Table 3, Three patients were showing local reaction and one patient was showing systemic reaction when they were on iron sucrose therapy.

Table 1: Distribution of age on study population.

AGE (YEARS)	NUMBER OF WOMEN
<20	8
21-25	30
26-30	15
31-35	4
36-40	2
>40	1

Table 2: Prevalence of Anemia according to parity.

Parity	No of women	Percentage
Primigravida	11	18.33%
Multigravida	49	81.66%

Table 3: Adverse Effects observed on FCM and IS

	IS	FCM
Local reaction	3(10%)	1(3.33%)
Systemic reaction	1(3.33%)	0 (0%)
Total Adverse event	4(13.33%)	1(3.33%)

Similarly, one patient was showing local reaction and none of them were showing systemic reaction when they were on ferrous carboxymatose therapy.

DISCUSSION

In this study, more pregnant women were found to be at age group 21-25years. Multiparity (49 pregnant women) to be more predisposed to develop iron deficiency anemia in compare to primigravida. The first dose of both the drug was found to be the highest frequency than others. Common side effects of both the drugs were found to be headache, nausea, vomiting, Hypertension and Hypotension. The result shows that the Ferrous Carboxymaltose increased more hemoglobin concentration as compare to iron sucrose so that the Ferrous Carboxymaltose had advantage of increased more iron to be injected in few dose infusion and rapid correction of serum ferritin levels in iron deficiency anemia. Ferrous carboxymaltose (500-1000mg) had higher dose as compare to Iron Sucrose (200mg) so the higher dose at the time of administered can reduce the need of repetition that's increased patients comfort. Ferrous carboxymaltose had lower adverse event as compare to iron sucrose. Three patients were showing local reaction and one patient was showing systemic reaction when they were on iron sucrose therapy. Similarly, one patient was showing local reaction and none of them were showing systemic reaction when they were on ferrous carboxymaltose therapy. Total adverse event was found to be 4 (13.33%) of total study population during treatment of iron sucrose therapy. Similarly, total event was found to be 1 (3.33%) of total study population during treatment of Ferrous Carboxymaltose therapy. The adverse event of ferrous carboxymaltose comparatively less so the drug had more safety as compare to Iron Sucrose.

CONCLUSION

The study conducted at Department of obstetrics and gynecology, National Institute of Medical Science and Research among the 60 pregnant women with iron deficiency anemia. The total adverse event (local and systemic) was found to be more in pregnant women when they were on iron sucrose therapy as compared to ferrous carboxymaltose. So, it was found that ferrous carboxymaltose is safer as comparison to iron sucrose therapy.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

WHO: World Health Organization; **CDC:** Center of disease control and Prevention; **IDA:** Iron Deficiency Anemia; **IBD:** Inflammatory Bowel Disease; **IS:** Iron Sucrose; **FDA:** Food and Drug Adminsistration; **FCM:** Ferrous carboxymaltose; **NaCl:** Sodium Chloride; **CBC:** Complete Blood Count; **Hb:** Hemoglobin; **SPSS:** Statistical Package for Social Science.

SUMMARY

This study was conducted to assess the safety of the drugs i.e, ferric carboxymaltose and ferrous sucrose for treatment of iron deficiency anemia during pregnancy. It was observed that ferric carboxymaltose is comparatively safer with better outcome than ferrous sucrose.

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