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Original Research Article

Comparative Study of IV Ferric Carboxymaltose Vs Inj Iron Sucrose in Antenatal Women with Iron Deficiency Anemia

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Abstract:

Background: Iron deficiency anemia is most communal medical condition during pregnancy in developing countries. It is a universal public health problem and is accountable for 40% of nurturing demises in developing countries out of which it is responsible for 25% of direct maternal deaths. The prevalence of Iron deficiency anemia (IDA) in pregnancy in India ranges from 23.6%-61.4%. The study aims in comparing the safety and efficacy of intravenous ferric carboxymaltose (FCM) vs iron sucrose in iron deficiency anemia in pregnancy and to develop a protocol for managing iron deficiency anaemia patients attending antenatal OPD so as to ensure proper feto-maternal outcome. An experiment nonrandomized cohort study was conducted among 56 ANC women came to OPD or admitted in ward at Department of Gynecology, SBKS Hospital, Pipariya, Vadodara. In our study, our results showed enhancement in hemoglobin, serum ferritin, and blood indices in both groups, but it was faster, greater, and with less feto-maternal complications with FCM, when compared with iron sucrose.

Keywords: Antenatal Women, Iron Sucrose, Ferric Carboxymaltose, Iron Deficiency Anaemia.

Introduction

Anemia is defined as decreased oxygen carrying capacity of blood. Most common type is the nutritional anemia: Iron Deficiency Anaemia (IDA). Menstruation and pregnancy are the leading reasons Iron deficiency anemia is most communal medical condition Generally it is more in developing counties. [1] The prevalence of IDA in pregnancy in India ranges From 23.6% to 61.4%. [2]

World Health Organization (WHO) defines Anemia as hemoglobin less than 11g/dl during pregnancy Development from iron deficiency to IDA in pregnancy is communal due to the enlarged mandate for iron during pregnancy (about 1000mg), required to support maternal hemoglobin bulk extension as well as the growing fetus and placenta. [3]

Anemia is also physiological due to hemodilution Iron deficiency (IDA) in pregnancy can serve as basis of different kinds of gestational complications, as we as enlarged maternal and infant morbidity and mortality. [4,5] The long term Maternal complications embrace cardiovascular disease, abridged physical, mental and immune function and peripartum iron stashes [6,7] due to less bioavailability of iron only iron cannot supply more amount.[8]

The iron supplementation is inevitability in all pregnant women, either in oral or parenteral from substance. The suggestions for parenteral iron treatment are fanaticism to oral iron, non- compliance to oral iron and patients who need speedy reinstatement of iron stores. Recently intravenous iron formulations include ferric gluconate, iron sucrose, iron polymaltose and newly ferric carboxymaltose. All have parallel configuration, but vary by the size of the core and the surrounding carbohydrate The dextran free intravenous alternatives are Iron sucrose and ferric carboxymaltose available. [9]

Iron sucrose has been extensively used due to its advanced bioavailability for erythropoiesis than iron dextran and offers a good safety profile. [10] But disadvantage of this substance is that it cannot be given in advanced doses and necessitates frequent doses for administration Ferric carboxymaltose is an innovative iron complex which consist of an iron- hydroxide core chelated in a carbohydrate shell and this complex is taken up as a whole by macrophages, leading to very low levels of nontransferrin bound iron, avoiding iron toxicity and oxidative stress. [11] It has an adjacent neutral pH (5_7), physiological

osmolarity and enlarged bioavailability, so it can be easily given higher amount of dosage at a time. Due to free of dextran and its derivatives, FCM does not cross react with dextran antibodies and does not need the administration of a test dose.[12]

Anaphylactic reaction did not occur in this substitute. There was a paucity of literature regarding Comparison of Ferric carboxymaltose versus Iron sucrose among ANC women suffering from Iron deficiency anemia, so present research was accompanied.

Aims & Objectives:

Aim: To compare the safety and efficacy of intravenous ferric carboxymaltose (FCM) vs iron sucrose in iron deficiency anemia in pregnancy.

OBJECTIVES:

- To correct Iron deficiency anemia in patients attending antenatal OPD in tertiary care center.
- To find out the efficacy of intravenous Ferric carboxymaltose and inj Iron Sucrose in correcting hematocrit values.
- To find out and compare the patient tolerance of each drug including anaphylactic reaction, compliance and other adverse outcomes.
- To develop a protocol for managing iron deficiency anaemia patients attending antenatal OPD so as to ensure proper feto-maternal outcome.

Materials & Methods:

Study Design: Experimental Non-Randomized Cohort study.
Study Duration: One and Half year.
Study Place: Department of Obstetrics & Gynaecology of Dhiraj Hospital, Pipariya.
Study Population: All Antenatal Patients Came to OPD of Department of Obstetrics & Gynaecology of Dhiraj Hospital, Pipariya.
Sample Size: Approximately 56 cases are likely to be enrolled in this study 28 patient s each in Group A And Group B respectively Group A patients will be treated with injection Iron sucrose and Group B will be treated with injection FCM.

Sampling Method: Purposive Sampling

Inclusion Criteria:

- Pregnant women with iron deficiency anemia in second and third trimester of pregnancy.
- Hemoglobin level 4-8gm%.
- S Ferritin level less than 40ng/dl.
- Non-compliant or refractory to Oral Iron treatment.

Exclusion Criteria:

- Patients who were not willing to participate in the study.
- Anemia other than Iron deficiency anemia.
- Any associated Comorbidity.
- History of blood transfusion and bleeding tendencies.
- Hypersensitivity reaction to any iron preparation.

Methods: When a pregnant patient comes in our OPD, a detailed history and thorough clinical examination of each patient was carried out. After this, routine blood investigations and urine was sent for biochemical evaluation.

First Visit: All patients with Hb 4 to 8gm% were taken in our study after applying the inclusion and exclusion criteria and taking informed consent of the patient. Then iron profile, which was confirmatory test for detecting the type of anaemia, was sent.

Then, divide the cases into two subgroups: Group A received Inj Iron sucrose and Group B received inj Ferric Carboxymaltose. Patients were divided randomly by allotting alternate group as they were admitted.

Iron Dosage needed in mg = Normal Hb – Patient's Hb * Weight in kg * 2.21+1000. GROUP A: The total dosage of iron sucrose was administered in divided doses of 200mg/day as alternate day infusions over a period of 20-30 min A test dose was not required.

GROUP B: Ferric Carboxymaltose was given as IV infusion Dosage of 500mg in 100 mL 0 9% Normal Saline was given in a single dose over a period of 30min. It can be repeated after a week if two or more doses were needed according to patient's existing requirement.

Follow-Up:

- The haemoglobin values were repeated 21 days after administering complete doses to check for improvement Same was done at 1.5 months and 3 months to monitor long- term effects of these drugs. The ultrasonographic findings was also be taken into account before and after the treatment so as to monitor fetal growth especially by EFW (effective fetal weight).

The patients were also be counselled about the disease pattern and symptoms The patients were be advised to:

1) Get enough sleep.
2) Eat plenty of ascorbic acid-rich fruits, fruit juice and green leafy vegetables, whole grains, and protein.

Results:

Table 1: Age group wise distribution among study participants

Age group (in years)	Frequency (%)
≤ 20	10 (17.24)
21-25	24(41.3)
26-30	22(37. 9)
31-35	1(1.7)
> 35	1(1.7)

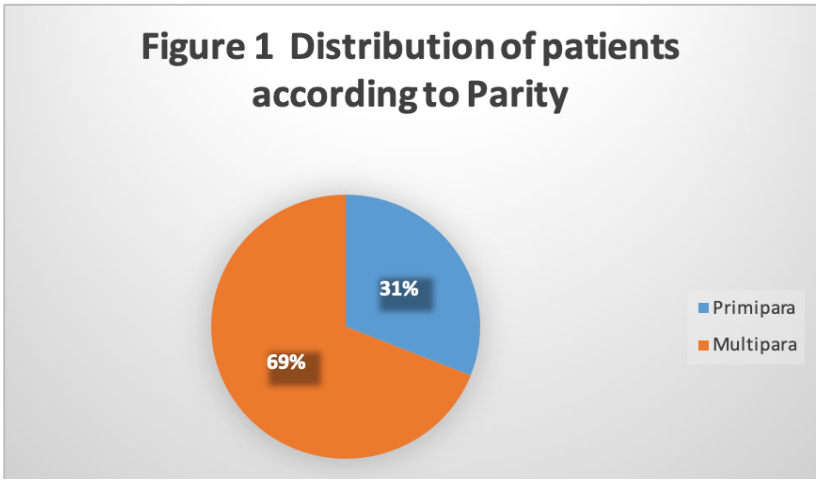


Figure 1: Distribution of patients according to parity

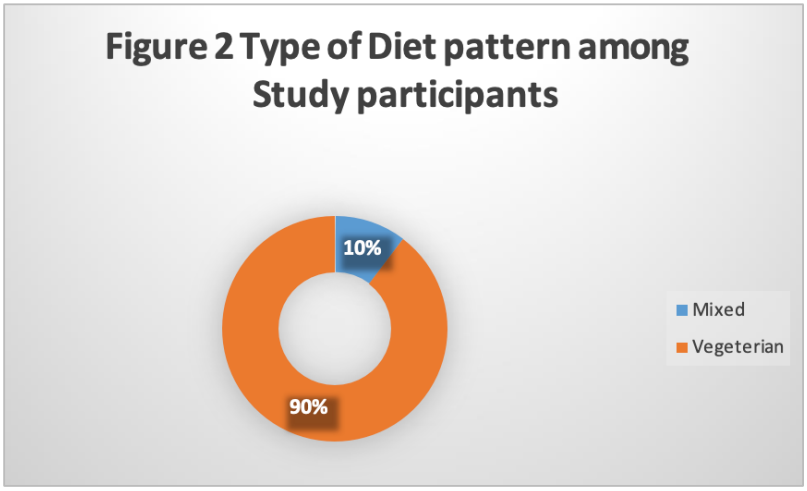


Figure 2: Type of diet pattern among study participants

Table 2: Comparison between Mean age among both groups

Mean Age	Group A	Group B	p-value
	25.4 ± 3.1	23.38 ± 3.98	0.478

Table 3: Distribution of Various Blood parameters at time of Diagnosis among both group cases

Blood Parameters	Group A	Group B
Hemoglobin	7.22 ± 0.42	7.39 ± 0.33
PCV	21.91 ± 1.6	21.91 ± 1.6
S ferritin	26.08 ±1.4	26.4 ± 3.8

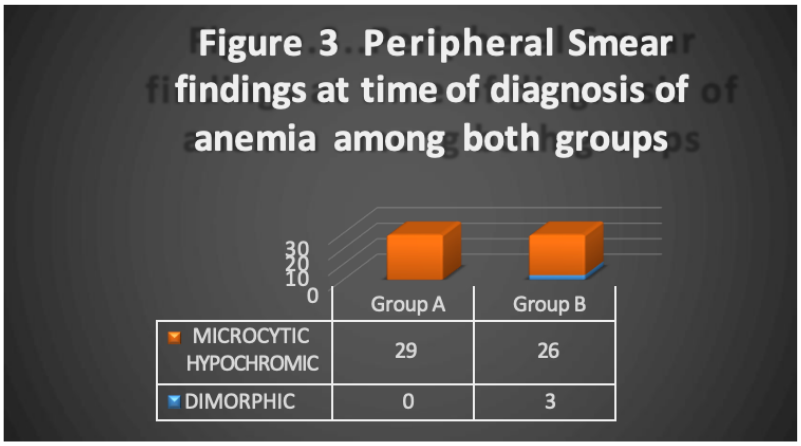


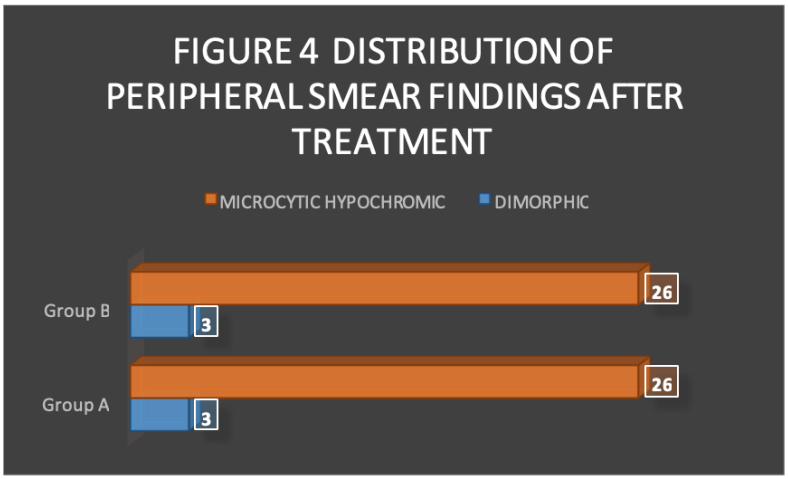
Figure 3: Peripheral smear finding at time of diagnosis of anaemia among both groups

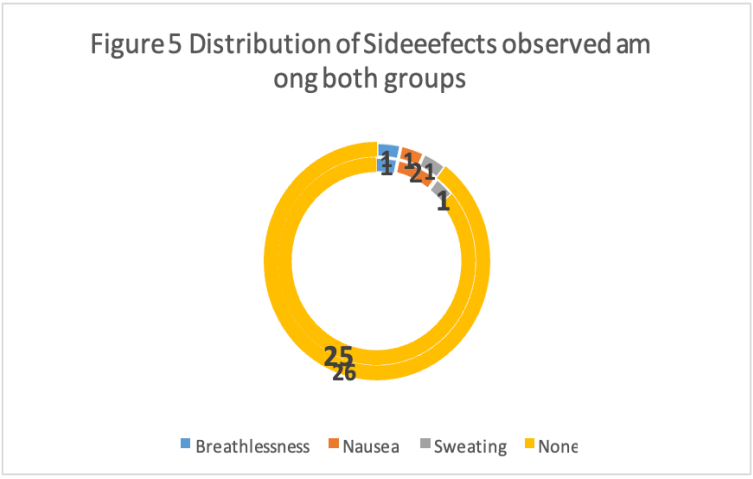
Table 4: Distribution of Effective Fetal weight before treatment among both group cases

Effective Fetal weight	Group A	Group B
< 500 grams	10	12
500-1000 grams	11	11
> 1000 grams	8	6

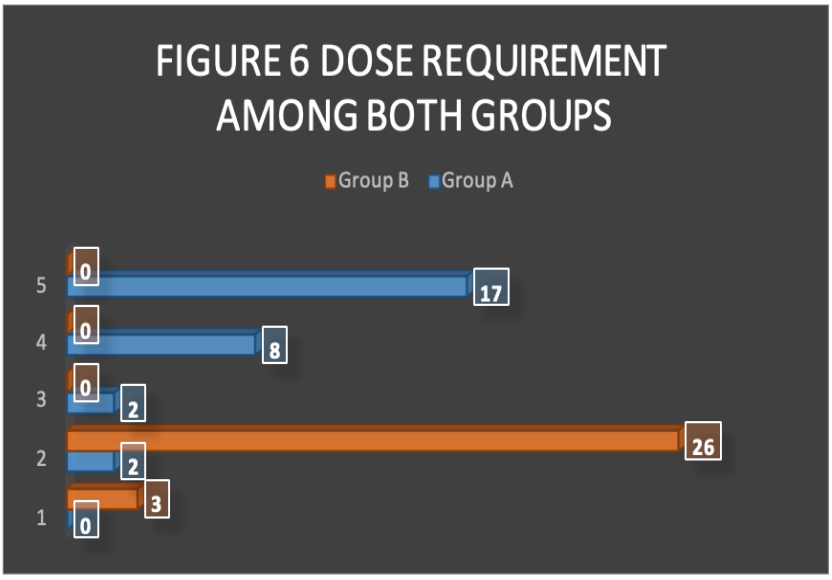
Table 5: Distribution of various Blood parameters after treatment among both groups

Blood Parameters	Group A	Group B
Rise in Hemoglobin after 21days	8.36 ± 0.42	8.42 ± 0.41
Rise in Hemoglobin after 1 5 months	8.99± 0.49	9.9± 0.91
Rise in Hemoglobin after 3 months	9.41 ± 0.5	10.26± 0.83





Inner ring represents Group A and outer ring represents Group B. Out of total, 1 patients in each group had complained of breathlessness and Sweating. Only 2 Patients in Group A had complained of Nausea [Figure 5].



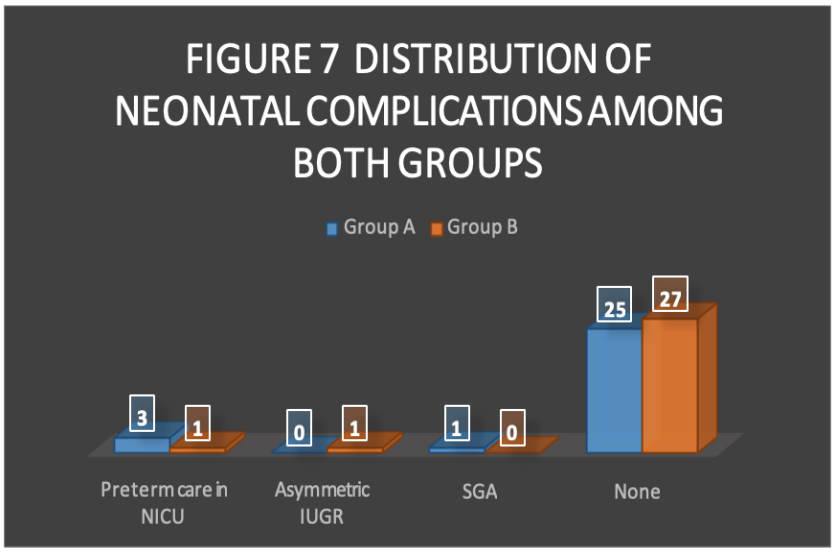


Table 6: Comparison of neonatal complications among both groups

Neonatal Complications	Group A	Group B	p-value
Preterm Care in NICU	3	1	0.782
Asymmetric IUGR	0	1	
SGA	1	0	
None	25	27	

Table 7: Distribution according Mode of Delivery among both groups

Mode of Delivery	Group A	Group B
LSCS	12	13
Normal Vaginal Delivery	14	14
Assisted Vaginal Delivery	3	2

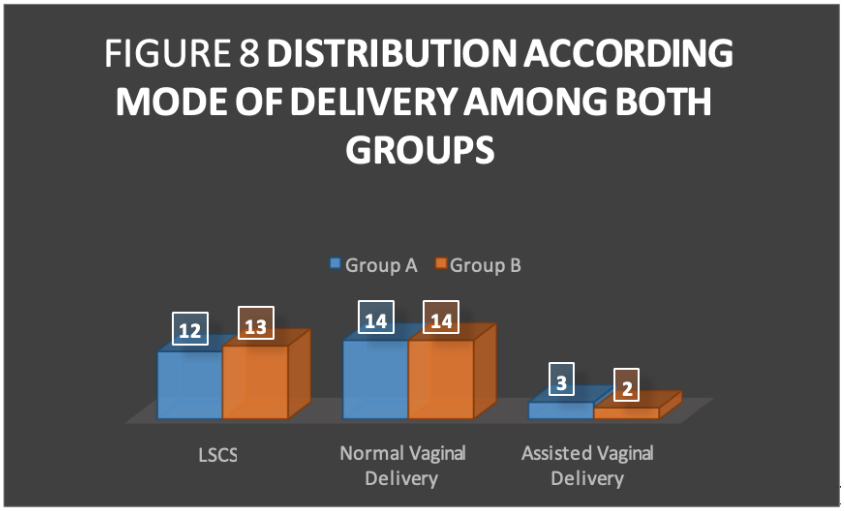
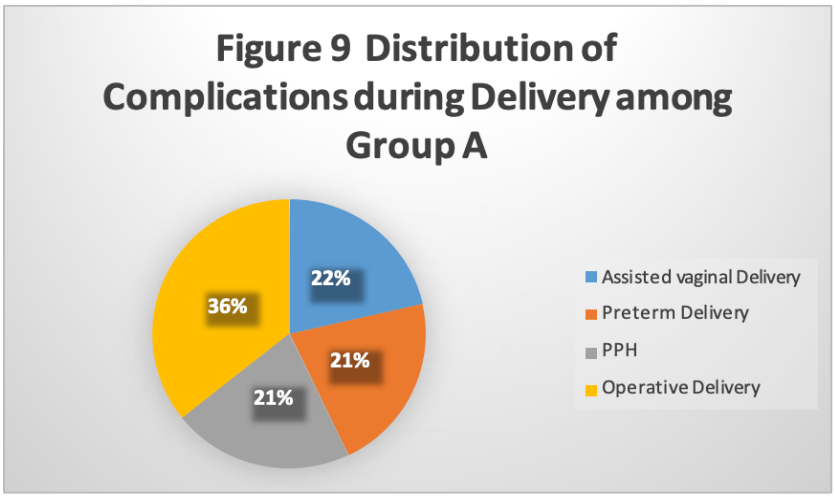
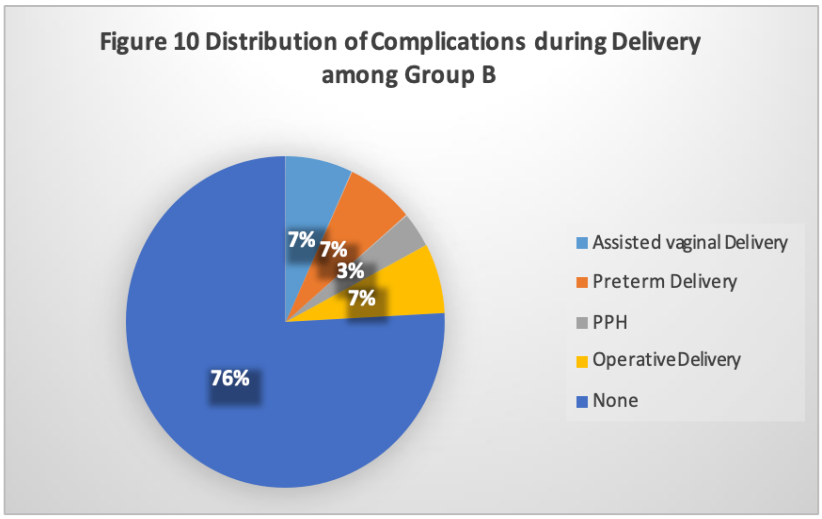


Table 8: Distribution according Complications during Delivery among both groups

Complications During Delivery	Group A	Group B
Assisted vaginal Delivery	3	2
Preterm Delivery	3	2
PPH	3	1
Operative Delivery	5	2
None	15	22





- The mean age was 24.38 ± 4.1 years Out of total, majority 41.3% (24) patients were belonged to 21-25 years age group followed by 37.9% from 26-30 years of age group. Only one case was more than 35 years of age.
- In the study, 18(31%) and 40(69%) patients were Primipara and Multipara, respectively.
- Of total, only 6(10%) cases had mixed type of diet, while remaining 52(90%) had Vegetarian Diet.
- There was no significant difference found between age group and type of Injection given.
- The mean hemoglobin level was 7.22gm/dl and 7.39 gm/dl, in Group A & Group B respectively Almost similar PCV and S Ferritin level in both groups at time of diagnosis.

In group A among all patients on observing, peripheral smear Microcytic Hypochromic anaemia changes was found, while in Group B patients 26 had Microcytic Hypochromic Anaemia and remaining 3 had Dimorphic changes.

- Out of total, 1 patient in each group had complained of breathlessness and Sweating Only 2 Patients in Group A had complained of Nausea.
- There was no more than 2 dose required in Group B patients While in Group A majority of patients required more than 5 dose in the study.
- In the study, 3 and 1 patients respectively in Group A & Group B neonates required Preterm care in NICU One patient in Group B had Asymmetric IUGR complication and in group A one patients had SGA.
- There was no significant association between Neonatal complications and type of iron therapy given.
- Out of total, in Group A, 12, 14 and 3, respectively patients had LSCS, Normal Vaginal Delivery and Assisted Vaginal type of mode of Delivery.
- Among the study participants, 3 and 2 Patients had Complications of Assisted vaginal Delivery, respectively in Group A And Group B.
- In group A, 3 patients had Preterm Delivery and other 3 patients suffered from PPH In group B, 2 patients had Preterm Delivery and other 1 patients suffered from PPH.

Discussion:

Anemia is one of the major health issues worldwide Iron deficiency anemia is the most common type of nutritional deficiency affecting all countries at global level. Around 50% maternal deaths due to anemia occur in South Asian countries and India is contributes 80% of that figure [13]. Anemia affects all age groups starting from puberty and adolescence to perimenopausal age. The reasons for high incidence of anemia in India include low dietary intake of iron, poor bio-availability of iron, phytate-rich Indian diet, faulty food habits, chronic blood loss during menses and high prevalence of infections like malaria and hookworm infestations.[14] The condition gets aggravated in pregnancy due to increased demand of the growing fetus The main issue with oral iron therapy is compliance due to associated gastrointestinal side effects like bloating, diarrhea, sickness, constipation, and dark colored feces.[15] Also, only oral therapy is not adequate for the management of moderate to severe anemia, especially in the late second and third trimester of pregnancy. [16] The most commonly used iron preparation for anemia in pregnancy is iron sucrose complex (ISC) It has negligible safety issues and no test dose is required. The only disadvantage with iron sucrose is limited dose per sitting. The maximum permissible dose is 300 mg per sitting or 600 mg per week. This adds to the total cost of therapy as it requires multiple visits The latest addition in i.v. iron preparations is Ferric Carboxymaltose (FCM), which is a dextran free type I iron complex. The present study compared two intravenous iron preparations for the correction of iron deficiency anemia in pregnancy Ferric carboxymaltose was found superior to Iron sucrose in correction of anemia and it led to significantly higher and rapid Hb rise as compared to ISC group and with significantly less number of visits. Iron sucrose has been the standard of care for parenteral iron therapy for treatment of anemia in pregnancy. However, the main disadvantage with iron sucrose is limited maximum permissible dose per week thus need of multiple visits to deliver the required iron dose, while FCM can be administered in a larger amount at a time.

Conclusion

In present study associated the efficacy of ferric carboxymaltose over iron sucrose in the managing of antenatal iron deficiency anemia. Though our results showed improvement in Blood parameters in both iron sucrose and FCM group but it was faster and greater with FCM when compared with iron sucrose. Other advantages are more doses can be administered at a single visit and the hospitalization duration of the patients are reduced greater. The quality of life is also better with FCM group FCM deficiencies dextran content so anaphylactic reactions are also less. So out of two intravenous iron FCM seems to be clinically better than iron sucrose in treatment of antenatal iron deficiency anemia. Significantly shorter duration of treatment when considered in a community setting with the patient friendly dosing, may translate to better patient compliance to treatment.

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