e-ISSN: 0975-1556, p-ISSN:2820-2643
Available online on www.ijpcr.com
International Journal of Pharmaceutical and Clinical Research 2024; 16(2); 554-557

Original Research Article

# Comparison between Ferric Carboxymaltose and Iron Sucrose in Pregnant Women with Iron Deficiency Anaemia

**Puja Verma[1], Akriti Prasad[2], Dipti Roy[3]**

[1]Senior Resident, Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital, Patna
[2]Senior Resident, Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital, Patna
[3]Associate Professor, Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital, Patna

**Received: 21-12-2023 / Revised: 14-01-2024 / Accepted: 11-02-2024**
**Corresponding Author: Dr. Akriti Prasad**
**Conflict of interest: Nil**

**Abstract:**
Iron deficiency anaemia is the commonest haematological disorder of pregnancy in India. In pregnant women intolerant to oral iron intravenous iron in various forms is available. This study compares intravenous ferric carboxymaltose and iron sucrose in 100 pregnant women. . After therapy the mean Hb at 2 weeks was 10.59 ± 0.73 and 11.61 ± 0.54 in IS and FCM group respectively. The mean Hb level at 4 weeks was 11.19 ± 0.8 g/dl and 12.01 ± 0.64 g/dl in IS and FCM group respectively. The mean MCV increased to 82.71 ±3.6 fl in 2 weeks and 84.61 ± 3.4 in 4 weeks in women treated with iron sucrose. The rise in mean MCV was also seen in women in FCM group which was 86.76±3.1 fl after 2 weeks and 87.84±3.4 fl after 4 weeks. FCM was found to be better as it increased Hb levels in lesser number of doses and less number of hospital visits as compared to IS.
**Keywords**: anaemia in pregnancy, ferric carboxymaltose, iron sucrose.


## Introduction

Anaemia is a major cause of morbidity and mortality in pregnant women in India. Iron deficiency is the most common type of anaemia in pregnant women. Prevalence of anaemia in South Asian countries is the highest in the world. About half of the global maternal deaths due to anaemia occur in South Asian countries and India contributes to about 80% of it [1].

Anaemia in pregnancy is defined by the World Health Organization (WHO) as a hemoglobin (Hb) value below 11 gm% and a haematocrit below 33% in pregnant women(2). Centre for drug control (CDC) takes a cut-off point of 11 gm% in first and second trimesters and 10.5 gm% in third trimester to define anaemia in pregnancy(3). According to ICMR, severity of anaemia is graded as: Mild degree if Hb is 10-10.9 gm%; moderate degree if Hb is 7-10 gm%; severe anaemia if Hb is less than 7 gm% and very severe anaemia if Hb is less than 4 gm% [4].

Anaemic pregnant women will have poor weight gain, decreased immune response, easy fatiguability, decreased work capacity, preterm labour, congestive heart failure. During labour they can have dysfunctional labour, heart failure, inability to stand even slightest blood loss, increased risk of anaesthesia etc. In puerperium they can have subinvolution, puerperal sepsis, pulmonary embolism, lactation failure. Babies to anaemic mothers can have intrauterine growth restriction, poor apgar score, low iron stores and decreased immunity.

There is increased demand of iron during pregnancy which is not met by the daily Indian diet and thus routine prophylactic iron supplement is required. The National Anaemia Control Program recommends 100 mg of elemental iron along with 500 mcg of folic acid in tablet form for at least 100 days to prevent anaemia in pregnancy [5]. The therapeutic dose of elemental iron is 180-200 mg daily in divided doses in between meals. The various oral iron preparations available are ferrous sulphate, ferrous fumarate, ferrous ascorbate, ferrous gluconate, carbonyl iron etc. The parenteral forms of iron available are iron dextran, iron sorbitol citrate complex, iron sucrose, ferrous gluconate, ferric carboxymaltose. The rise in haemoglobin after parenteral therapy is same as with oral therapy (0.7-1.0 mg% per week). The indications of parenteral iron therapy are: intolerance to oral iron, gastointestinal disorders which gets aggravated by oral iron, non-compliance, chronic blood loss. After 32 weeks of pregnancy, parenteral iron is preferred

as the compliance is 100%. Iron sucrose which is given as intravenous infusion has minimum side effects, is not associated with anaphylactic reactions and no test dose is recommended. It can be given as 600 mg (maximum dose/ week) in 2 or 3 divided doses per week. The latest addition in intravenous iron preparations is Ferric Carboxymaltose (FCM), which is a dextran free type I iron complex. It can be given upto 1000 mg per week.

**Objective**

To study the effectiveness of ferric carboxymaltose and iron sucrose in treatment of iron deficiency anaemia in pregnant women in a tertiary care centre.

**Materials and Method**

The study was a prospective study conducted in the department of obstetrics and gynaecology, Nalanda medical college and hospital from December 2018 to July 2019. One hundred pregnant women attending outpatient department of obstetrics and gynaecology, NMCH between gestational age 28 weeks to 34 weeks and haemoglobin levels between 7 gm/dl to 9 gm /dl were recruited for the study. Ethical clearance for the study was obtained from the Institutional Ethics Committee.

After proper written consent, 100 pregnant women were enrolled during the study period. All recruited subjects underwent a detailed history and examination as per standard pre-structured protocol. Detailed history was taken and patient's age and last menstrual period was noted. The period of gestation was calculated by last menstrual period. The demographic and clinical details were noted. Patient's menstrual history, obstetric history, past medical and surgical history and family history of anaemia were also elicited in detail. A general physical examination was done.

Patients with multifetal gestation, known metabolic disorders like diabetes, hypertension, chronic liver and renal diseases and known case of haemoglobinopathies or family history of haemoglobinopathies were excluded from the study.

Before starting therapy blood samples were taken for estimation of complete haemogram . One hundred pregnant women were blindly divided into 2 groups. Fifty subjects received intravenous ferric carboxymaltose (FCM) on day 0 and 7. Another fifty subjects received intravenous iron sucrose (IS) on day 0, 2, 4 and 6 and 8 according to their calculated iron requirement.

The total iron required was calculated according to the Ganzoni's Formula [6] *Total iron dose = {(Body weight) [kg] × (Target Hb -Actual Hb) [g/L]} × 0.24 + Iron stores [mg]* where, 0.24 is a correction factor that takes into account the patient's blood volume, estimated at 7% of body weight and Hb iron content which is 0.34%.

Intravenous (IV) iron infusion was given according to the iron deficit calculated by and rounded up to the nearest multiple of 100 for each individual. Before starting the infusion, a test dose was given to check for any adverse reaction for both, FCM and IS. In case of IS, the maximum dose of 200 mg was diluted in 200 ml of sterile normal saline 0.9% and was given as slow infusion over 30 min. The rest of the doses, as and when required, were given on alternate days following the same procedure. For FCM, the maximum single dose of 500 mg diluted in 250 ml of sterile normal saline 0.9% was given as slow infusion over 45 min. If needed, rest of the doses were given on the 7$^{th}$ day. In case of any adverse drug reaction (ADR), the infusion was stopped, documented, and the patient was treated for the respective ADR. After the treatment, the patient's progress towards accomplishment of the goal of therapy was evaluated and the outcomes were analyzed.

Primary outcome was change in Hb level from baseline after 2 weeks and 4 weeks. Secondary outcomes were change in fatigue levels, safety and side effects of treatment.

**Results**

A total of 100 pregnant women were recruited for this study. Fifty women were given iron sucrose infusion. Four women were lost to follow up thus only 46 women were followed for result. The second group of 50 pregnant women received ferric carboxymaltose. Only 43 women were followed as 7 women lost to follow up. There were 15 primi gravida and 31 multi gravida in IS group. The FCM group included 17 primigravida and 26 multigravida women. The mean age in IS group was 28.4 ±4.16 and 29.10 ± 7.15 in FCM group. The mean body mass index (BMI) in IS group was 23.71 ± 3.1 and in FCM group, it was 24.11 ± 2.6. The mean systolic blood pressure in IS group was 110.76 ± 7.8 as compared to 110.56 ± 6.8 in FCM group. The mean diastolic blood pressure was 79.5 ± 4.1 and 81.43 ± 5.66 in IS and FCM group respectively.

The mean baseline haemoglobin (Hb) level in IS group and FCM group was 7.84 ± 0.81g/dl and 7.61 ± 0.74 g/dl respectively. The mean MCV value( mean corpuscular volume) was 67.41 ± 5.14 fl in IS group and 67.84 ± 5.56 fl in FCM group before starting treatment. After therapy the mean Hb at 2 weeks was 10.59 ± 0.73 and 11.61 ± 0.54 in IS and FCM group respectively. The mean Hb level at 4 weeks was 11.19 ± 0.8 g/dl and 12.01 ± 0.64 g/dl in IS and FCM group respectively. The mean MCV increased to 82.71 ±3.6 fl in 2 weeks and 84.61 ± 3.4 in 4 weeks in women treated with iron sucrose. The rise in mean MCV was also seen in women in FCM group which was 86.76±3.1 fl after 2 weeks and 87.84±3.4 fl after 4 weeks.

**Table1: Comparison of Hb and MCV in IS and FCM group**

| | Iron sucrose group | Ferric carboxymaltose group |
|---|---|---|
| Mean haemoglobin (baseline) g/dl | 7.84 ± 0.8 | 7.61 ± 0.74 |
| Mean haemoglobin at 2 weeks (g/dl) | 10.59 ± 0.73 | 11.61 ±0.51 |
| Mean haemoglobin at 4 weeks (g/dl) | 11.19 ± 0.8 | 12.01 ±0.64 |
| Mean MCV in fl(baseline) | 67.41 ± 5.14 | 67.84 ± 5.56 |
| Mean MCV at 2 weeks(fl) | 82.71 ± 3.2 | 86.76 ± 3.1 |
| Mean MCV at 4 weeks(fl) | 84.61 ± 3.4 | 87.84 ± 3.44 |

## Discussion

The present study was done to compare the effectiveness of iron sucrose and ferric carboxymaltose in pregnant women in a tertiary care centre. The study showed that rise in haemoglobin was greater in ferric carboxymaltose group than iron sucrose group. Total number of doses given in IS group was more as compared to FCM group thus requiring multiple visits to hospital in IS group.

The study conducted on 210 anaemic postpartum women concluded that iron carboxymaltose is as safe as IS in the management of postpartum iron deficiency anemia despite five times of higher dosage. Both drugs are effective and offer a comparable improvement in anaemia. The single application of iron carboxymaltose shows advantages of lower incidence of side effects at the injection site, a shorter treatment period, and better patient compliance which was also seen in the present study [7].

In a study done by Seid et al on 291anaemic women concluded that Ferric carboxymaltose treated subjects were significantly more likely to achieve haemoglobin greater than 12 g/dL in a shorter time period [8].

A randomized control trial was done on 100 pregnant anaemic women in a tertiary care centre in India. In this study the mean rise in Hb at 12 weeks was significantly higher in FCM group than ISC group (29 g/L vs 22 g/L; p value $< 0.001$. It also concluded that FCM is a safe intravenous agent in pregnancy and is non-inferior to the current standard therapy (iron sucrose complex) for the treatment of iron deficiency anaemia in pregnancy [9].

Another retrospective analysis which compared the efficacy of IV FCM versus IV iron sucrose in 206 pregnant women with IDA and intolerant to oral iron showed that FCM was the treatment of choice, owing to its safety and efficacy [10].

a randomized study compared IV FCM and iron sucrose (IS) for 12 weeks in 200 pregnant women with IDA showed that IV FCM improved laboratory biomarkers (Hb, mean corpuscular volume, serum iron, serum ferritin, total iron-binding capacity, and transferrin saturation) in a shorter duration of time as compared with IS [11].

An observational prospective study in done in pregnant women of 12–34 weeks gestation having Hb between 7 to 9.9 g/dL to compare FCM infusion ($n = 30$) with iron sucrose infusion (IS) ($n = 30$) concluded that mean increase in Hb levels post treatment in group IS was $2.35 \pm 0.41$ vs. $2.52 \pm 0.073$ in group FCM ($p < 0.0000001$). Intravenous FCM administration in pregnancy is likely to be safe and effective [12].

## Conclusion

This study was done to compare the efficacy of ferric carboxymaltose and iron sucrose in the treatment of pregnant women with iron deficient anaemia. The improvement in laboratory biomarkers i.e., Hb, MCV levels was seen better with FCM than IS and that too in short duration of time and less number of doses as compared to IS. The patient compliance was better with FCM as compared to IS as FCM reduces the number of hospital visits.

## Abbreviations:

Hb- haemoglobin

MCV – mean corpuscular volume

FCM – ferric caroxymaltose

IS – iron sucrose

IDA – iron deficiency anaemia

ADR – adverse drug reaction

BMI – body mass index

## References

1. Ezzati M, Lopez AD, Rodgers A, Vander Hoorn S, Murray CJL. Comparative risk assessment collaborating group. Selected major risk factors and global and regional burden of disease. Lancet Lond Engl. 2002; 360(9343):1 347–1360.
2. . WHO. Nutritional anemias. Report of a WHO scientific group. Geneva, World Health Organization, 1968. (WHO Technical Report Series, No. 405) . http://apps.who.int/iris/bitstream/10665/40707/1/WHO_TRS_405.pdf. Accessed 5 Nov 2017.
3. CDC (1989) CDC criteria for anemia in children and childbearing-aged women. MMWR

Morbidity and mortality weekly report. 138(22): 400–404.
4. Indian Council of Medical Research. Evaluation of the National Nutritional Anemia Prophylaxis Programme. An ICMR Task Force Study. New Delhi ICMR; 1989.
5. Kumar A. National nutritional anaemia control programme in India. Indian J Public Health. 1999; 43:3–5.
6. Ganzoni AM. Intravenous iron-dextran: therapeutic and experimental possibilities. Schweiz Med Wochenschr. 1970;100(7):301–303.
7. Pfenninger A, Schuller C, Christoph P, Surbek DSafety and efficacy of hig dose intravenous iron carboxymaltose vs. iron sucrose for treatment of postpartum anemia.j. peinat Med.2012 apr 2;40(4):397-402
8. Seid MH, Derman RJ, Baker JB, Banach W, Goldberg C, Rogers R. Ferric carboxymaltose injection in the treatment of postpartum iron deficiency anemia: a randomized controlled clinical trial. Am J Obstet Gynecol. 2008;19 9(4):435.
9. Jose A., Mahey R., Sharma J. B., et al. Comparison of ferric Carboxymaltose and iron sucrose complex for treatment of iron deficiency anemia in pregnancy-randomised controlled trial. BMC Pregnancy and Childbirth. 2019; 19(1): 54.
10. Christoph P., Schuller C., Studer H., Irion O., De Tejada B. M., Surbek D. Intravenous iron treatment in pregnancy: comparison of high-dose ferric carboxymaltose vs iron sucrose. Journal of Perinatal Medicine. 2012;40 (5):469–474.
11. Naqash A., Ara R., Bader G. N. Effectiveness and safety of ferric carboxymaltose compared to iron sucrose in women with iron deficiency anaemia: phase IV clinical trials. BMC Women's Health. 2018;18(1): 6.
12. Shah S., Swapna K. A comparative study of efficacy and safety of intravenous Ferric Carboxymaltose versus intravenous Iron Sucrose in the treatment of Iron Deficiency Anaemia of pregnancy. IOSR Journal of Dental and Medical Sciences. 2018;17(9):13–17.