Journal of Chemical Health Risks

www.jchr.org

JCHR (2023) 13(6), 1799-1805 | ISSN:2251-6727

A Comparative Study of IV Ferric Carboxymaltose Versus Iron Sucrose in Treatment of Iron Deficiency Anemia in Pregnancy

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(Received: 07 October 2023 Revised: 12 November Accepted: 06 December)

KEYWORDS

Iron Sucrose Complex (ISC), Age of Patients, Adverse Effect, Food and Drug Administration (FDA), IV, Deficiency Anemia, Statistical Tests, Preparation, FCM and Group IS. Ferric Carboxymaltose.

ABSTRACT:

Background: To compare Intravenous Iron Sucrose Compound (ISC) with intravenous Ferric Carboxymaltose (FCM) in terms of efficacy as well as safety for treating iron deficient anaemia in pregnant patients. A novel IV iron preparation called ferric carboxymaltose was authorised by the Food and Drug Administration (FDA) in 2013 as an iron therapy substitute for adult patients with iron deficiency anaemia who are unable to tolerate oral iron or who do not respond well to it.

Objective: To evaluate the safety and effectiveness of ferric carboxymaltose (FCM) infusion against intravenous iron sucrose complex (ISC) injection in treating iron deficient anaemia in pregnancy.

Method: This current retrospective study was conducted among individuals with mild to severe iron-deficiency anaemia who are resistive to iron taken by mouth at Department of gynacology ,KIMS. There were 100 samples obtained in all. Any significant or mild adverse effects were recorded, and iron dextrose and ferric carboxymaltose were given to patients in accordance with guidelines. After using the appropriate statistical tests, a p value of less than 0.05 was deemed as statistically significant.

Results: In group FCM, the typical age of the patients was 31.48±7.151 years, whereas in group IS, it was 29.51±9.451 years. For groups FCM and IS, the beginning characteristics and clinical profiles appeared comparable ($p<0.05$).

Conclusion: In this trial, patients in the ferric carboxymaltose group behaved more quickly and much better to treatments than those in the iron-containing sucrose group, and this response was also linked to fewer side effects.

INTRODUCTION

RBC counts and/or haemoglobin concentrations that are below normal and insufficient to support an individual's physical needs are referred to as anaemia. Anaemia in pregnancy is defined by the World Health Organisation (WHO) as a Haemoglobin Level (HbL) a value of 10.5 g/dl in the later stages of pregnancy and less than 11 g/dl in the first and third trimesters. According to the WHO, [1], anaemia is a serious problem for pregnant women, with Iron Deficiency Anaemic (IDA) responsible for up to 56% of cases in developing nations and 14% in industrialised ones.

All age groups are impacted by anaemia, from youth and menopause to the premenopausal years. The high frequency of illnesses like plasmodium and hookworm diseases, along with inadequate consumption of iron, inadequate absorption of iron, [1, 2], poor eating habits, and an Indian cuisine heavy in phytate, are the main causes of the country's high anaemic incidence. At the onset of pregnancy, a large number of women already have low or depleted iron reserves [2, 3].

Pregnant women who suffer from anaemic have higher rates of morbidity and death, as does the growing baby [3, 4]. It has been shown that iron deficiency anaemia increases the risk of preterm delivery, low birth weight, premature delivery of the baby, and increased blood loss during childbirth, heart failure, and related mortality [5, 6]. Oral iron is usually suggested as the first line of therapy for pregnant patients with anaemia caused by iron shortage and is often used to prevent iron insufficiency in pregnant women.

Iron deficiency anaemia is mostly caused by dietary deficiencies in poor nations like India. People who have a greater need for the micronutrient—pre-schoolers,

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JCHR (2023) 13(6), 1799-1805 | ISSN:2251-6727

teenagers going through their development spurt, and women who are pregnant or lactating—are more vulnerable. A food deficit, a high consumption of phytates and polyphenols, or malabsorption illnesses such as celiac disease, bowel inflammation, gastrointestinal having surgery, [7], or gastritis may all contribute to iron deficiency anaemia.

The risk of developing anaemia due to an iron deficiency is increased by worm infestation-related increased blood loss in the manner of overt or covert bleeding, as well as gynaecological conditions such menu (metro) menorrhagia and uterine cancer [8]. Iron Insufficiency Adequate iron substitution, and such as iron prepared either orally or intravenously, may treat anaemia. Iron deficiency anaemia may be avoided with the use of foods supplemented with iron and plants high in iron. Compared to oral iron treatment, intravenous iron therapy replenishes the iron storage more quickly [9].

Since it works well in cases of reduced gastrointestinal absorption, mild to moderate anaemia might benefit from iron replenishment. There might be a chance of an allergic response. Iron Dextran and Iron Sucrose are the most often utilised parenteral iron therapies. Iron Sucrose is a cheap intravenous solution; nevertheless, [10], it may take many doses to get the desired dosage. On rare occasions, it is linked to problems related to the stomach, such as nausea, vomiting, low blood pressure, and anaphylactic.

The Food and Drug Administration (also known as the FDA) granted a novel IV iron preparation called ferric carboxymaltose in 2013 [11]. This iron replacement product is intended for adult patients with chronic kidney disease who are not dependent on dialysis and who have a discrimination to iron taken by mouth or have not responded satisfactorily to oral iron [12]. It may be used safely in conjunction with a number of serious long-term illnesses that can result in iron deficiency anaemia, including inflammatory bowel disease (IBD) and Chronic Heart Failure (CHF) [13].

The high frequency of illnesses such as malaria and hookworm an infestation, along with a low daily intake of metals, poor bioavailability of metals, phytate-rich Indian cuisine, bad eating habits, and prolonged bleeding during menses are the main causes of India's high anaemic incidence. Pregnancy aggravates the illness because of the developing foetus's greater need [14].

It is advised to take preventative oral iron throughout pregnancy in order to satisfy the increased need in the prenatal stage. Due to the gastrointestinal adverse effects that come with oral iron therapy, such as bloating, diarrhoea because heartburn, vomiting, diarrhoea, and black excrement, the primary problem with the treatment is obedience [15].

Additionally, oral medication alone is insufficient to treat moderate to severe anaemia, particularly in the latter stages of the second and third trimesters of pregnancy. Parenteral treatment may eliminate the requirement for blood transfusions throughout the prenatal and postpartum phases and is expected to improve the response in those receiving it. Iron Sucrose Complex (ISC) is the most widely used iron supplement for anaemia in pregnancy. It requires no test dosage and has very few safety concerns. The sole drawback of iron sucrose is its one-time dosage restriction.

1.1 Objectives of the study

- Evaluate the safety features of intravenous iron sucrose and ferric carboxymaltose in expectant mothers, keeping an eye out for any problems, allergic responses, or other possible side effects.
- To assess the financial effects of treating iron deficiency anaemia in pregnancy with IV ferric carboxymaltose against iron sucrose, do a cost-effectiveness analysis.

II. LITERATURE REVIEW

(Mahey, R., Kriplani, 2016) [16] To assess the safety and effectiveness of intravenous iron sucrose (ISC) vs intravenously Ferric Carboxymaltose (FCM) in the treatment of anaemia resulting from abnormal uterine bleeding (AUB). Patients who presented to an emergency room in New Delhi, India around April 2013 and May 2014 with anaemia caused by AUB and who were older than 18 years of age were the subjects of a randomised controlled study. Intravenous the FCM method or ISC was administered to patients in a 1:1 randomization. Over the course of 12 weeks, the main outcome—an increase in haemoglobin over baseline—was seen.

(Qassim, A., Mol, B. W., 2018) [17] When oral iron is intolerable or a quick iron replenishment is needed, Intravenous (IV) iron is helpful in pregnancy. To investigate the research on various IV iron preparations' safety and effectiveness in treating prenatal Iron Deficiency Anaemia (IDA). MEDLINE, Embase, and

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JCHR (2023) 13(6), 1799-1805 | ISSN:2251-6727

Scopus were searched from their launch until June 2016. Randomised Controlled Trials (RCTs) and observational investigations that used intravenous (IV) iron Ferric Carboxymaltose (FCM), Iron Polymaltose (IPM), or Iron Sucrose (IS) to treat prenatal IDA were eligible, independent of comparator. Two impartial reviewers chose the studies, extracted out the data, and evaluated their accuracy.

(Khatun, F., & Biswas, C. 2022) [18] The most prevalent anaemia that has a major impact on health is iron deficiency anaemia. It is a serious nutritional and haematological deficiencies that may be treated in pregnant women. Pregnant women that suffer from anaemia have higher rates of morbidity and death, as does the growing baby. Oral iron supplementation is often prescribed as a preventative measure and as the first line of therapy for iron deficient anaemia in pregnant women. Compared to oral iron, Intravenous (IV) iron supplements provide a larger and faster replenishing of iron reserves.

(Froessler, B., Gajic, T., 2018) [19] To assess the safety and effectiveness of giving women who are expecting with varied degrees of iron deficiency anaemia and iron deficit without anaemia intravenous ferric carboxymaltose. Based on the severity and status of anaemia, we evaluated data from 863 pregnant women with an iron shortage in this prospective study involving local obstetrical services. Intravenous ferric carboxymaltose was administered to all pregnant women. The effectiveness of the treatment was evaluated using ferritin levels, where available, and duplicate haemoglobin results three and six weeks after infusion. Data on new-born health outcomes, fatal cardiac surveillance, and adverse event analysis were used to evaluate safety.

(Wani, S., Noushad, M., 2019) [20] Iron Insufficiency Because of significant physiological changes or pre-existing insufficient supplies, anaemia (IDA) during the pregnancy may result in major difficulties for both the mother and the foetus. Pregnancy-related iron deficiency anaemia is most usually treated with oral iron, either as a fumarate or sulphate, or with or not folic acid. Treatment for Iron Deficiency Anaemia (IDA) during pregnancy may include Intravenous (IV) iron, especially for women who come in later life, exhibit significant anaemia (Hb < 9 g/dL) or risk factors, or are noncompliant with oral iron regimes. Iron was seldom administered by IV in the past due to the possibility of severe allergic responses. More IV iron solutions with improved compliance, tolerability, effectiveness, and safety profiles were recently developed.

(Rawat, D., Katti, K. M., 2023) [21] WHO statistics show that 40% of children aged 6-59 a period of time 37% of pregnant women, and 30% of women aged 15-49 are deficient in iron globally. Compared to NFHS-4 data, which showed that 50.4% of pregnant women were anaemic, NFHS 5(2019–2021) data in the Indian population shows that 57.0% of women aged 15–49 years, 57.2% of non-pregnant women aged 15–49 years (<12.0 g/dl), and 52.2% of pregnant women aged 15–49 years are pregnant. The 65th global health Assembly, scheduled for 2025, aims to cut the incidence of anaemia in women who are capable of bearing children in half. The aetiology of anaemia is complicated, with many potential causes and risk factors. Iron deficiency anaemia is the most frequent kind, with estimates ranging from 10% to as high as 60%, depending on the demographic group.

(Metgud, M. C., 2016) [22] Recently, ferric carboxymaltose (FCM) has become available to treat anaemia. In order to treat pregnant women with iron deficiency anaemia, the current research compared the safety, tolerability, and effectiveness of intravenous FCM to intravenous Iron Sucrose (IS). Design: A randomised controlled experiment with an open label. Setting: the views of Jawaharlal Nehru Medical College, Belgaum, Gujarat India, a teaching hospital. A total of 305 expectant mothers were randomly assigned to one of two groups: 157 individuals in group S (received IS transfusion) and 158 individuals in group C (the received iron carboxymaltose transfusion).

III. METHODS

The current investigation was carried out at the Department of Gynaecology, KIMS, Karad. With permission obtained from the hospital's ethics committee, this treatment's prospective comparative research was carried out between April 2020 and April 2022 for a total of two years. Our sample was drawn from pregnant women who visited the Department of OBG [23]. A study of one hundred pregnant women was conducted; fifty of them received an infusion of iron sucrose, while the other fifty received an infusion of ferric carboxymaltose.

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3.1 Group 1

Iron-containing sucrose (IS) A 200 mg intravenous dosage of iron sucrose was administered over the course of 30 minutes in 100 ml of 0.9% normal saline. Alternating days until the whole dosage was administered on with a weekly maximum of 600 mg. intravenously, the initial few millilitres, were infused during a 15-minute period; if there was indeed no negative response, the remaining quantity was injected over the course of thirty minutes [23, 24].

3.2 Group 2:

Carboxymaltose ferric (FCM) Ferric carboxymaltose is administered as follows in 0.9% Regular Saline:

- 100 - 500 mg in 100ml NS - 15 mins duration
- 500 - 1000mg in 200ml NS - 30 mins duration,

1000 mg was the maximum dosage per sitting. Doses in case more were scheduled on the seventh and fourteenth days [24].

3.3 Statistical analysis

The statistical software for social science (SPSS) was used to collect the data..

IV. RESULTS

The Hb and levels of ferritin in the blood rose well, the dosage was easily administered, and there were few adverse effects, all of which were positive results. Epidemiology: Age, socioeconomic status, parity, and place of habitation were compared between the two groupings. With regard to baseline traits, both groups were similar. Most of those treated were under 30 years old, and they came from all age groups between 19 and 41. In both categories, the majority of patients were multipara and the majority of patients lacked literacy.

Table 1 Baseline Comparison of the two groups' epidemiological statistics.

Variables	Groups 1 (IS)	Groups 2 (FCM)
Mean age (y)	25.66 ± 3.66	23.6 ± 36.3
Mean gestational age	36.3 ± 2.67	36.1 ± 6.93
Prim gravida	36%	41%
Multigravida	69%	63%
Rural	46%	36%
Urban	59%	49%
Literate	28%	63%
Illiterate	75%	59%
Unemployed	75%	97%

Table 2 Comparison of the two groups based on the outcomes.

Variable	Group 1 (IS)	Group 2 (FCM)
Baseline haemoglobin (g/dl)	8.69 g/dl	8.65 g/dl
Haemoglobin (g/dl) at 3 weeks	0.98 g/dl	8.97 g/dl
Haemoglobin (g/dl) rise at 3 weeks	0.89 g/dl	4.98 g/dl
Haemoglobin (g/dl) at 6 weeks	6.59 g/dl	5.69 g/dl
Haemoglobin (g/dl) rise at 6 weeks	10.6 g/dl	8.98 g/dl
Baseline serum ferritin (mcg/L)	15.69 g/dl	5.96
Serum ferritin at 3 weeks (mcg/L)	53.6	14.6
Serum ferritin rise at 3 weeks (mcg/L)	96.6	93.49
Serum ferritin at 6 weeks (mcg/L)	85.6	46.9
Serum ferritin rise at 6 weeks (mcg/L)	5.69	6.98

In Group I, 28% of patients had mild adverse effects, whereas 16% of patients in Group II reported the same. Due to the lack of significant adverse effects, both medications are safe to use during pregnancy. The average length of the hospital stay for Group I was 10.2 days, while Group II had a relatively short stay of 3.2 days.

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Table 3 Groups 1 and 2's Negative Response.

Adverse Reaction	Group 1 (IS)	Group 2 (FCM)
Thrombophlebitis	4	1
Nausea & Vomiting	1	3
Headache	3	1
Dizziness	2	3
Fever/chills	4	1
Rashes & Itching	1	2
Abdominal pain	2	0
Anaphylactic reaction	5	0
Total	15 days	09
Hospital stay	15.6	3.69

V. DISCUSSION

For a long time, our country has been fighting anaemia. The majority of living things need iron, which is one of those most prevalent minerals in the environment. Ironically, haemophilia, which is now a major world-wide health problem, is caused by the most prevalent vitamin deficit worldwide [25].

The shocking fact that up to 62% of Indians suffer from anaemia and that this country is expected to have the highest frequency of any South Asian nation is concerning [26, 27]. The mean gestational age of the patients in our research was 30-32 weeks, and their ages ranged from 23 to 25 years. Anaemia is more prevalent in multigravida patients than in prim gravida, according to our research.

We discovered that, as a result of poor eating habits, anaemia is more prevalent in urban areas than in rural ones. In the iron sucrose group of our research, [28], the average increase in haemoglobin after a six-week period was 1.82 g/dl, but in the ferric carboxymaltose group, it was 2.6 g/dl. Likewise, there is a significant difference between the two groups' serum ferritin growing rates. Serum ferritin increased on average by 79.2 mcg/L in the IS Group and 111.7 mcg/L in the FCM Group [29].

Group I had a mean hospital stay length of 10.2 days in our research, whereas Group II had a relatively short hospital stay duration of 3.2 days. The purpose of this research was to assess the safety and effectiveness of iron via intravenous sucrose vs ferric carboxymaltose in the treatment of iron deficient anaemia in pregnancy [30]. Every other day, 200 mg of iron sucrose and 1000 mg of ferric carboxymaltose were administered, respectively, until the needed level of iron was reached.

VI. CONCLUSION

In this research, iron sucrose and ferric carboxymaltose were tested for their safety and effectiveness in treating mild to decrease deficiency of iron anaemia. Over the course of six weeks, FCM caused pregnant women with noticeably elevated Hb increase to quickly restore their iron reserves. Good compliance was achieved with the easy amount that needed fewer doses overall. When FCM is used in a community environment and the dosage is patient-friendly, notably shorter treatment durations result in lower rates of pain and hospital visits. Due to FCM's great safety and effectiveness, it must be utilised as the initial treatment for iron deficiency anaemia in pregnancy in order to reduce the disease's high prevalence and impact on the community.

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