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Systematic Review

Efficacy and safety of ferric carboxymaltose for the management of iron deficiency anemia in women

Narayanan Palaniappan[1]*, Mehul V. Sukhadiya[2]

[1]Department of Obstetrics and Gynecology, Sri Ramachandra University, Chennai, Tamil Nadu, India
[2]Department of Obstetrics and Gynecology, Sumiran Women's Hospital, Ahmedabad, Gujarat, India

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***Correspondence:**
Dr. Narayanan Palaniappan,
E-mail: npalaniappan@hotmail.com

ABSTRACT

Iron deficiency anemia (IDA) remains the most common nutritional deficiency across the world with about1in four people suffering from anemia. Iron deficiency anemia spans across the life of a female. Healthy females absorb 5.6% of iron in diet. The efficacy of oral iron is diminished when uptake through the gut is impaired or when iron losses are large and/or continuous (eg, menorrhagia, gastrointestinal bleeding, or post-surgery). Dose-dependent gastrointestinal side effects hinder compliance and result in poor patient compliance in upto 50% of patients. For patients who are diagnosed with IDA during 2nd or 3rd trimesters, intravenous iron replacement therapy (IRT) is recommended. One of the commonly used parenteral iron formulations include ferric carboxymaltose (FCM). Iron supplied as FCM is quickly distributed to different tissues. In randomized trials in pregnant women with IDA, postpartum women with anemia and women with heavy menstrual bleeding, treatment with FCM significantly improved hemoglobin levels compared with oral iron treatment. Ferric carboxymaltose can be used at high doses and allows rapid administration (up to1000 mg in a single dose infused in 15 min). Since FCM is a dextran-free, it does not react with dextran antibodies, thus resulting in a lower risk for hypersensitivity reaction. The novel iron formulation ferric carboxymaltose (FCM) has a better potential for restoring the iron stores. It reduces the dosage frequency which is the chief drawback of parenteral preparations and there is minimal drug related adverse effects. Hence FCM can be the drug of choice for the management of iron deficiency anemia in women.

Keywords: Iron deficiency Anemia, Women, Ferric carboxy maltose

INTRODUCTION

Iron deficiency remains the most common nutritional deficiency across the world with about 1 in four people suffering from anemia.[1] Globally, 1.5 billion people worldwide, and 52% of pregnant women in developing countries are anemic.[2] The 2019–2021 National Family Health Survey-5 data from India reported that 57.0% of reproductive-age women, and 52.2% of pregnant women in India were anemic.[1] Almost 50% of the burden of anemia is contributed by iron deficiency anemia.[1] The World Health Organization (WHO) defines iron deficiency anemia (IDA) as hemoglobin <12.0 g/dl in women who are not pregnant and <11.0 g/dl in women who are pregnant (WHO; IDA presents as hemoglobin concentration (Hb≥8 and <12 g/dl), serum ferritin (<30 µg/l), transferrin saturation <20%, red blood cell (RBC) mean corpuscular volume (MCV<80 fl), and RBC mean corpuscular hemoglobin (MCH<27 pg).[3]

The causes of iron deficiency anemia in Indian women include poor nutrition, pregnancy, menstruation, dysfunctional uterine bleeding, malaria, infestations and chronic infections.

Iron deficiency anemia spans across the life of a female. In the neonatal period, if the mother is anemic, the neonate

would also be anemic.[4] In adolescence and reproductive age group, menstruation and nutritional deficits contribute to IDA. About 20% of women suffer excessive menstrual blood loss.[5] In pregnancy, multiparity which is common in India leads to IDA.[4]

Several reasons have been cited for IDA in Indian women such as nutritional deficiency, poor intake of iron rich food stuff, worm infestations, repeated pregnancies in a short interval of time, absence of replenishing of the iron stores lost due to menstrual loss.[6]

Data from Indian Council of Medical Research (ICMR), National Nutrition Monitoring Bureau (NNMB) and District Level Household Survey (DLHS) have shown that prevalence of anemia is extremely high (ranging between 80% and 90%) in adolescent girls, preschool children, pregnant and lactating women.[4] Postpartum anemia reportedly affects up to 27% of women.[7]

Consequences of IDA

Iron deficiency (ID) and IDA may lead to adverse pregnancy and fetal outcomes.[1] Iron deficiency is associated with fatigue, restless legs syndrome (RLS), reduced work productivity, impaired quality of life, impaired cognitive function, and infertility.[3] Frequent infections, preterm labor, fetal growth restriction (FGR), post-partum hemorrhage, cardiac failure and puerperal sepsis have been found frequently in women who were anemic during antenatal period.[4]

Consequences of IDA during pregnancy

Pregnancy is associated with an increased demand for iron throughout pregnancy. Iron requirement during pregnancy is about 4–6 mg/day. ID and IDA are linked to increased risks of thyroid dysfunction, preterm labor, placental abruption, pre-eclampsia, eclampsia, cesarean delivery, postpartum anemia and need for blood transfusion, postpartum depression and fatigue.[8] A significant prolongation of total hospital stays and ICU stay have also been observed in pregnant women with IDA.

The adverse fetal outcomes include stillbirths, low birth weights, and small-for-gestational-age (SGA) babies. The adverse outcomes in children include increased rates of stunting; impairment in both short-term and long- term brain development (brain growth, myelination, neurotransmitters, and brain programming), including significant (likely non-reversible) motor and neurocognitive changes; anxiety and depression; and an increased risk of autism spectrum disorder.[1,9]

Objectives

The objective of this study was to assess the efficacy of the IV iron formulations, ferric carboxymaltose for the management of IDA in women, especially during pregnancy in the real-world setting.

METHODS

This systematic review was performed using the PRISMA method using PubMed, Web of science, google scholar databases and WHO and CDC recommendations. 362 records were screened and 226 records were retrieved. 106 records were excluded due to no access to full text of the papers. The search words included iron deficiency anemia, women, pregnancy, dysfunctional uterine bleeding, oral iron, parenteral iron, ferric carboxymaltose, iron sucrose and iron dextran. Case report and non-randomized studies were excluded.

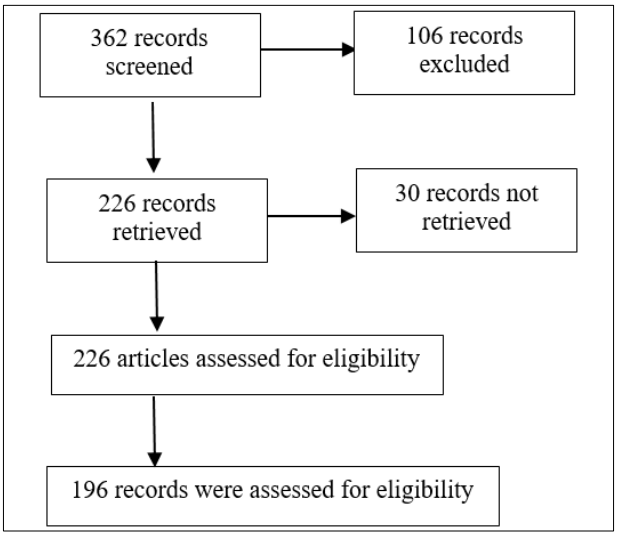

Figure 1: PRISMA checklist.

Management of IDA

Iron therapy for IDA has been shown to reduce morbidity by improving physical activity and reducing fatigue and cognitive deficits.[3,7,10] Iron therapy can be administered orally or parenterally.[3,5,11] Globally, oral iron has been the first line of treatment and standard of care to address the prevention and treatment of anemia in pregnancy.[3,5,11]

Oral iron therapy and parenteral iron therapy

Healthy females absorb 5.6% of iron in diet. The maximum rate of absorption of 100 mg of oral iron is 20% to 25% and is reached only in the late stage of iron deficiency. In latent iron deficiency and iron deficiency anemia, the mean absorption rates of iron are 10% and 13%, respectively.[3]

Oral iron is readily available, inexpensive, and convenient, making it a commonly used treatment option.[3] However, the use of oral iron must be limited to patients with mild anemia (Hb 11.0-11.9 g/dl in non-pregnant women) because repletion occurs slowly.[3] The Hb level should increase by 2 g/dl within 4 to 8 weeks. Depending on the severity of the deficiency and underlying cause, normalization of the Hb level may take up to 3 months, and

it may take longer to replace iron stores (ferritin >100 µg/l).[3]

Oral iron can often lead to gastrointestinal side effects, such as nausea, diarrhea or vomiting, that can adversely impact patient adherence to treatment and, ultimately, the efficacy of the iron treatment.

The efficacy of oral iron is diminished when uptake through the gut is impaired or when iron losses are large and/or continuous (e.g., menorrhagia, gastrointestinal bleeding, or post-surgery). Dose-dependent gastrointestinal side effects hinder compliance and result in poor patient compliance in up to 50% of patients.[3]

Parenteral iron therapy

For patients who are diagnosed with IDA during 2nd or 3rd trimesters, intravenous iron replacement therapy (IRT) is recommended.[8] Compared to oral iron, pregnant women treated with IV iron have consistently shown a more rapid and robust response in raising and maintaining hemoglobin concentrations and ferritin during pregnancy and after delivery. Parenteral iron administration is also preferred for patients who are unable to tolerate oral iron therapy, or are unresponsive to oral iron treatment and for patients who are unable to absorb sufficient iron in the gastrointestinal tract or for whom blood transfusions should be avoided.[3,11] Four to six weeks after IRT initiation, testing for serum ferritin is recommended.[8]

The commonly used parenteral iron formulations include ferric carboxymaltose (FCM), iron sucrose and iron dextran.[3]

Ferric carboxy maltose

FCM is a type I polynuclear iron (III)-hydroxide carbohydrate complex. It produces a slow and controlled delivery of the complexed iron to endogenous iron binding sites.[12,13]

Iron supplied as FCM is quickly distributed to different tissues, such as the bone marrow, liver, and spleen, the volume of distribution being approximately 3 l. Following the administration of an i.v. dose of FCM, the level of total serum iron is reduced between 24 hours and 72 hours. Serum ferritin increases in a dose dependent manner within 48–120 hours post FCM dose, with maximum levels of a 23–210-fold increase above baseline level.[13]

In randomized trials in pregnant women with IDA, postpartum women with anemia and women with heavy menstrual bleeding, treatment with FCM significantly improved hemoglobin levels compared with oral iron treatment (Tables 2-4).[14,15]

Table 1: Simple scheme for the estimation of total iron need.[3]

Degree of iron deficiency	Hemoglobin level (g/dl)	Dose for body weight <70 kg, (mg)	Dose for body weight ≥70 kg, (mg)
No anemia	Normal	500	1000
Moderate	10-12 (women), 10-13 (men)	1000	1500
Severe	7-10	1500	2000
Critical	<7	2000	2500

Table 2: Efficacy of FCM in pregnant women with IDA.

Study	Study design	Patient population	Treatment	Observations
Li et al[16]	Retrospective study	127 women, mean age: 31.2 years (range: 18 to 42 years old).	Intravenous ferric carboxymaltose	The median Hb at delivery - FCM: 10.7 g/dl, ontrol: 8.9 g/dl; increase in Hb - FCM: +2.3 g/dl, control: +0.35 g/dl
Obaid et al[2]	Prospective study	Pregnant women between 14-26 weeks gestation, ≥20 years old, with ID (serum ferritin <15 µg/l), and moderate, IDA (Hb 7–8.9 g/dl) (n=110)	The total iron infusion dose of FCM did not exceed 20 mg iron/kg body weight. The maximum recommended iron infusion dose of FCM was 1000 mg of iron/week. More than 1000 mg of iron was given in 2 infusion sessions	Serum ferritin - pretreatment: 10.3±2.3 µg/l, post treatment: 139.5±1.9, p=0.02; Hb – pretreatment: 7.99±0.6 g/dl, post treatment after 6 weeks: 14.04±0.45, p<0.001; RBC mean corpuscular volume (MCV) - pretreatment: 72.02±3.5 fl, posttreatment: 90.6±2.8 fl, p=0.02; RBC mean corpuscular haemoglobin (MCH) - pretreatment: 23.9±1.9 pg, posttreatment: 29.98±1.5 pg, 6 weeks after FCM infusion (p<0.01)

Continued.

Study	Study design	Patient population	Treatment	Observations
			(1000 mg in the first session and the remainder in the second session [the 2 sessions scheduled one week apart]).	
Froessler et al[17]	Prospec-tive obser-vational study	65 anemic pregnant women	Ferric carboxymaltose up to 15 mg/kg between 24 and 40 weeks of pregnancy	Mild anemia (95-116 g/l) - preinfusion: 102.1 g/l, 3 weeks post infusion: 108.3 g/l, 6 weeks post infusion: 120.6 g/l, 8 weeks post-partum post infusion: 113.1 g/l; moderate anemia (90-94 g/l) - preinfusion: 92.6 g/l, 3 weeks post infusion: 105.8 g/l, 6 weeks post infusion: 108.4 g/l, 8 weeks post- partum post infusion: 92.7 g/l; severe anemia (<90 g/l) - preinfusion: 83.7 g/l, 3 weeks post infusion: 100.2 g/l; 6 weeks post infusion: 110.0 g/l, 8 weeks pos partum post infusion: 93.3 g/l; serum ferritin - preinfusion ferritin values: 6.5 mcg/l, post infusion ferritin values: 194 mcg/l, 65.5% women reported an improvement in their well-being, no serious adverse effects
Jose et al[18]	Randomi-zed clinical trial	Pregnant women diagnosed with moderate to severe iron deficiency anemia	Ferric carboxymaltose, iron sucrose	Mean rise in Hb at 12 weeks was significantly higher in FCM group (29 g/l versus 22 g/l; p value <0.01); FCM was associated with greater improvement in fatigue scores. Number of visits were significantly less in FCM group. No serious adverse events were noted in either group. Treatment with FCM resulted in rapid replenishment of iron stores in pregnant women with significantly higher Hb rise over a 12-week period.
Chawla et al[4]	Randomise d control trial	Pregnant anemic women with IDA were enrolled between 18 and 34 weeks of pregnancy.	1000 mg of FCM i.v. as single dose or FS tablets twice daily (120 mg iron daily).	FCM group women showed 2.6 gm% rise in Hb compared to 1.7 gm% of FS group. No difference was observed in the neonatal outcome. No major side effects were observed in the either group. 166 (96.5) women achieved Hb >11% in FCM group. 81 (49.7) women achieved Hb >11% in FS group. FCM was more effective than oral FS in increasing Hb in women with IDA during pregnancy.
Breymann et al[19]	Prospec-tive randomi-zed study	Pregnant women (n=252; gestational weeks 16-33) with IDA	FCM (1000-1500 mg iron) or FS (200 mg iron/day) for 12 weeks.	Hb levels improved at comparable rates across both treatments. Significantly more women achieved anemia correction with FCM versus FS [Hb ≥11.0 g/dl; 84% versus 70%]. FCM treatment significantly improved vitality (p=0.025) and social functioning. Treatment-related adverse events were experienced by 14 (FCM; 11%) and 19 women (FS; 15%). Markedly higher rates of gastrointestinal disorders reported with FS (16 women) than with FCM (3 women). During late-stage pregnancy, FCM may be a more appropriate option than first- line oral iron for rapid and effective anemia correction, with additional benefits of vitality and social functioning.
Pels et al[20]	Retrospecti ve case	All women who received at least one	128 patients (FCM: 64; control: 64).	Age at the time of first treatment was 34 weeks and 6 days. Median Hb increased from

Continued.

Study	Study design	Patient population	Treatment	Observations
	control study	administration of FCM during their pregnancy were eligible for the case group	FCM dose was 1000 mg	8.4 g/dl at the first FCM administration to 10.7 g/dl (9.8; 11.5 g/dl; n=46) at the time of delivery, achieving levels similar to those in the control group (10.8 g/dl; n=48)
Maitri et al[21]	Prospecti-ve study	100 women with severe anemia during pregnancy	Single parenteral administration of FCM, vitamin B12, and folic acid	Compared to baseline, absolute increase in hemoglobin was 2.9 g/dl (p<0.001) and 5.4 g/dl (p<0.001) after 6 weeks of infusion and at delivery respectively. 63.9% of women achieved anemia correction

Table 3: Efficacy of FCM in postpartum anemia.

Study	Study design	Patient population	Treatment	Observations
Rathod et al[22]	Randomi-zed, double blinded study	366 women with post-partum anemia	Oral iron or IV ferric carboxy-maltose or iron sucrose.	Ferric carboxymaltose increased Hb level and restored iron stores faster than IV iron sucrose and oral iron, without any severe adverse reactions. Patients in the ferric carboxymaltose group reported greater treatment satisfaction
Van Wyck et al[14]	Randomi-zed, controlled trial	Women enrolled within 10 days postpartum	IV ferric carboxymaltose (n=174), oral ferrous sulphate (n=178)	Patients assigned to IV ferric carboxymaltose compared with those assigned to oral ferrous sulphate achieved a Hb rise greater than or equal to 2.0 g/dl earlier (7.0 compared with 14.0 days, p<0.001), FCM treated patients were more likely to achieve a Hb rise greater than or equal to 3.0 g/dl at any time (86.3% compared with 60.4%, p<0.001), FCM treated patients were more likely to achieve a Hb greater than 12.0 g/dl (90.5% compared with 68.6%, p<0.001). Proportion of patients who achieved a Hb rise greater than or equal to 2.0 g/dl (96.4% compared with 94.1%, IV compared with oral, p=0.443). There were no serious adverse drug reactions.
Mishra et al[23]	Open, single arm study	595 women with post-partum IDA anemia and Hb levels between 4 gm% and 11 gm%	Single intravenous ferric carboxy-maltose (500-1500 mg)	After three weeks of total dose infusion, mean hemoglobin levels significantly increased over a period of three weeks after ferric carboxy-maltose. Other parameters like total iron binding capacity, ferritin and iron levels also had a significant improvement
Damineni et al[24]	Prospective compara-tive study	90 women with Hb between 7-10 g/dl and peripheral smear showing microcytic hypochromic anaemia on the first post-partum day	IV FCM (single dose 1000 mg) or oral ferrous ascorbate (100 mg twice daily for 6 weeks).	Significant rise in Hb was observed in subjects treated with FCM compared to oral iron. FCM treated subjects were more likely to achieve an Hb rise greater than or equal to 3.0 g/dl. FCM was better tolerated with complete adherence to treatment as compared to oral ferrous ascorbate

Table 4: FCM in dysfunctional uterine bleeding.

Study	Study design	Patient population	Treatment	Observations
Hagras et al[25]	Prospectiv e study	Women with moderate IDA due to abnormal uterine bleeding (AUB).	The total iron infusion dose of FCM should not exceed 20 mg iron/kg body weight, and the maximum recommended iron	At 6 weeks post treatment - ferritin levels: pre-treatment: 13.2±7.4 µg/l, post treatment: 111.5±5.6 µg/l; Hb levels - pre-treatment: 8.8±0.8 g/dl

Continued.

Study	Study design	Patient population	Treatment	Observations
			infusion dose of FCM was 1000 mg of iron/week. More than 1000 mg of iron was given in two infusion sessions [1000 mg in the first session, and the remaining amount in the second session (the two sessions scheduled one week apart)].	(p=0.0009), post treatment: 13.9±0.6 g/dl (p=0.001); at 12 weeks post treatment; ferritin levels - post treatment: 98.7±6.1 µg/l (p=0.01), Hb levels – post treatment: 12.9±0.65 g/dl (p=0.01). FCM was safe and effective for correction of ID/IDA caused by chronic AUB within 6 weeks

Special features of FCM observed in clinical trials

In the study by Breymann et al, 252 pregnant women (gestational weeks 16–33) with IDA were randomized 1:1 to FCM (1000–1500 mg iron) or FS (200 mg iron/day) for 12 weeks.19 Pregnant women treated with FCM were twice as likely to achieve anemia correction (Hb≥11.0 g/dl) than those treated with FS (84% versus 70%) and the median time to achieving this correction was shorter with FCM treatment (3.4 versus 4.3 weeks) (Figure 2).

Significantly greater increase in serum ferritin levels with FCM treatment compared with FS were observed (Figure 3). During late-stage pregnancy, FCM may be a more appropriate option than first-line oral iron for rapid and effective anaemia correction (Table 5).[19]

FCM had a dramatically reduced burden of treatment: comparable improvements in Hb levels were achieved with a 12-fold lower total dose and a 12-fold lower duration of exposure to FCM compared with FS. This improved patient compliance to treatment.[19]

FCM has been compared with other Parenteral iron formulations and has been found to have better efficacy and tolerability features (Tables 6 and 7).

Table 5: Comparison of change in hemoglobin levels. between FCM versus FS groups.

Variables	Week 3 (g/dl)	Week 6 (g/dl)
FCM	1.23±0.95	1.75±1.18, p=0.032
FS	0.96±1.38	1.32±1.54

Table 6: Comparison of FCM with iron sucrose.

S. no.	Parameters	Result with clinical evidence
1	Efficacy	FCM was found to be superior to iron sucrose (IS) in correction of anemia. In a study by Christoph et al, the mean hemoglobin rise was 15.4 g/l and 11.7 g/l in the group receiving FCM and iron sucrose respectively.[26]
2	Rate of rise of Hb	More rapid rise in Hb levels with FCM as compared to IS. The mean Hb levels increased by 1.03 g/dl in FCM group compared with 0.81 g/dl in IS group after 4 days of treatment. FCM seemed to have a better and presumably more sustained effect on the hemoglobin value compared to IS. Mean increase in Hb levels 1.5 versus 1.1 g/dl after 5 days and 1.8 versus 0.5 g/l after 8 days of treatment in FCM vs IS groups respectively.[27]
3	Dosing	Injection FCM is becoming a molecule of choice also due to its favorable characteristic of administration at a higher dose (up to 1000 mg) in a single infusion over a short period of time (15–20 minutes). Iron sucrose can be infused 200 mg in a day and needs repeated injections. In a study by Lee et al, 900 mg of ferric carboxymaltose was administered in a single visit, while same dose of IS required over three to eight visits.[28]
4	Durationof treatment	Duration of treatment is shorter with FCM as compared to IS. In a study by Lee et al., it was noted that time required to achieve Hb levels ≥10 g/dl was 7.7 days and 10.5 days with FCM and IS respectively.[28]
5	Improvement in fatigue	FCM provides comparable relief in fatigue as compared to IS. Treatment with FCM and iron sucrose improved fatigue levels by 11 points on the functional assessment of chronic illness therapy (FACIT) scale after 8 weeks of treatment.[29,30]
6	Quality of life	FCM provides better improvement in quality of life as compared to Iron sucrose. In a study by Lee et al, it was observed that health-related quality of life using the short form-12 health survey (SF 13) score increased by 3.7 versus 2.3 in FCM and IS group respectively in physical component summary and by 4.5 versus 1.6 in FCM and IS group respectively in mental component summary.[28]

Continued.

S. no.	Parameters	Result with clinical evidence
7	Adverse effects	Lesser incidence of adverse effects by FCM as compared to Iron sucrose. In a study by Joshi et al, minor adverse effects like urticaria, injection site reactions, nausea, hypotension occurred in 7.2% patients in iron sucrose group whereas nausea, rash and chest discomfort occurred in 3.3% patients of FCM group.[30]
8	Compliance	Compliance is better with FCM as compared to IS because of lesser number of total doses hence less number of needle pricks and reduced number of visits to hospital translating to better patient compliance to treatment. In a study by Sanavelli et al, it was noted that 6-8 doses of Iron Sucrose were required in IS group whereas in FCM group, 1-2 doses of FCM were required for each patient. Hence the number of doses required to correct anemia was significantly less with FCM.[31]

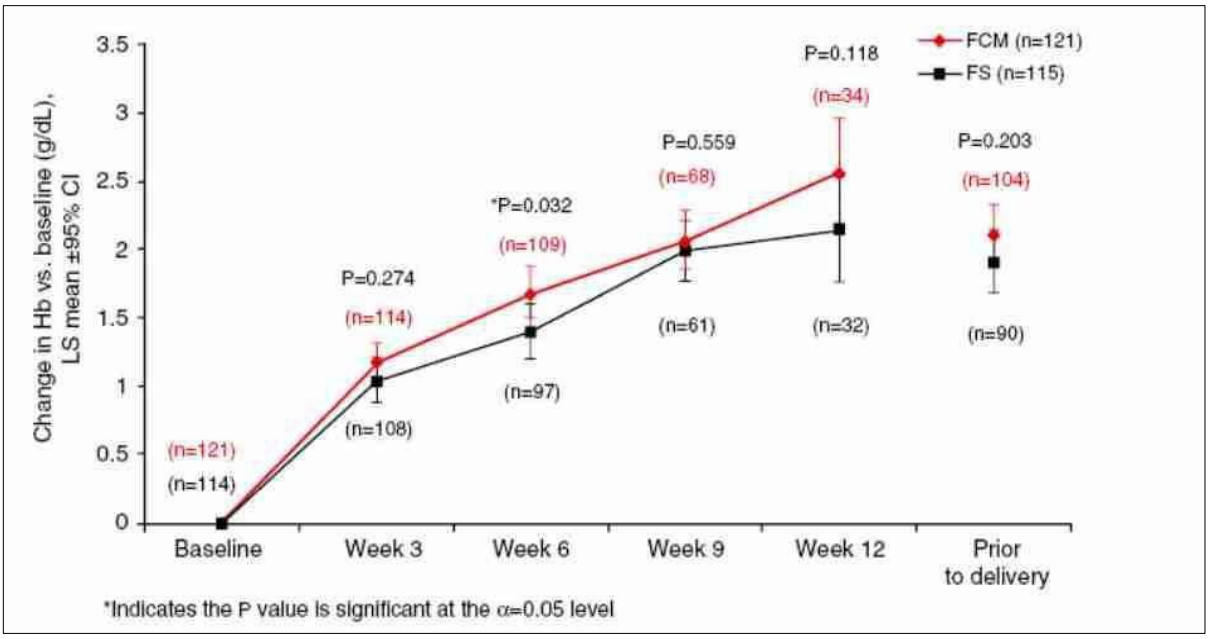

Figure 2: Change in hemoglobin levels.

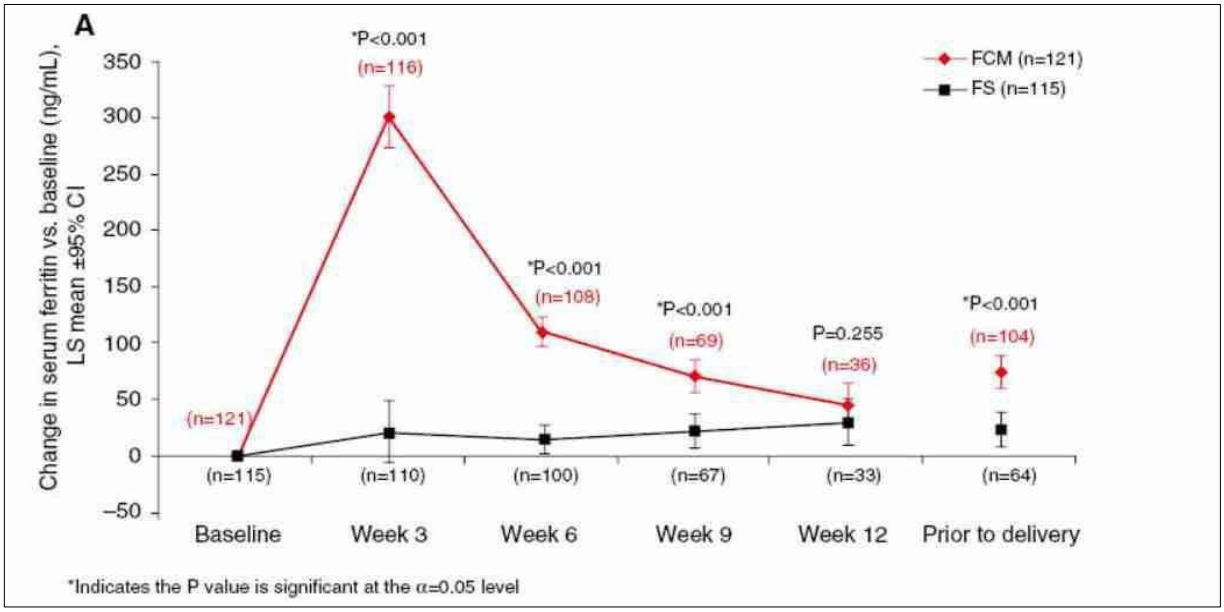

Figure 3: Change in ferritin levels.

Table 7: FCM versus iron dextran.

S. no.	Parameter	Result with clinical evidence
1	Efficacy	FCM was found superior to iron dextran in correction of anemia. In a study by Dillon et al., mean increase in hemoglobin after 6 weeks of treatment with iron dextran and FCM was 1.4 g/dl and 2.7 g/dl respectively.[32]
2	Rate of rise of Hb	More rapid and persistently higher rise in Hb with FCM as compared to iron dextran.[32,33]
3	Allergic reactions	Allergic reactions occur due to development of antibodies to the dextran moiety. Iron dextran has been associated with an incidence of anaphylaxis or anaphylactoid reactions as high as 1.7%.[34] FCM does not contain dextran components thus does not trigger reactions with anti-dextran antibodies. FCM poses a significantly lower risk of hypersensitivity reactions than iron dextran.3[5]
4	Test dose	Test dose is not required before administering FCM as compared to Iron dextran which requires test dose due to frequent allergic reactions.

DISCUSSION

Oral iron is readily available, inexpensive, and convenient treatment option to treat iron deficiency anemia. The limitations of oral iron formulations when used to treat iron deficiency anemia include slow rise of hemoglobin and gastrointestinal adverse effects which can adversely affect patient adherence to treatment.[3] In women who are diagnosed with IDA during 2nd or 3rd trimester, intravenous IRT is recommended.[8] FCM is a parenteral iron formulation that produces a slow and controlled delivery of the complexed iron to endogenous iron binding sites.[12,13] FCM is an i.v. iron formulation which can be used at high doses and allows rapid administration (up to 1000 mg in a single dose infused in 15 min). Since FCM is a dextran-free, it does not react with dextran antibodies, thus resulting in a lower risk for hypersensitivity reactions.[36] Clinical trials have proven the efficacy of FCM in significantly improving hemoglobin levels compared with oral iron treatment.[14,15] FCM provides better improvement in quality of life as compared to Iron sucrose.[28] Compliance is better with FCM as compared to IS because of lesser number of total doses hence less number of needle pricks and reduced number of visits to hospital translating to better patient compliance to treatment.[31]

Limitations

This a review paper based on published studies.

CONCLUSION

IDA has been proved to be associated with increased morbidity and mortality in pregnancy and post-partum period. Over the past few decades' oral iron supplementation has been utilized as the standard of care in treating and preventing ID and IDA. But the results of oral iron supplementation in pregnant women with moderate to severe iron deficiency are often suboptimal due to limited intestinal absorption and poor patient adherence to treatment. Parenteral iron supplements are associated with faster normalization of iron in pregnant women and also overcomes the drawbacks of oral iron supplements. Amongst the IV iron formulations, FCM is associated with robust and rapid increase in iron and improved outcomes of pregnancy in women with IDA. Another important benefit of FCM is the better tolerability profile as compared to other parenteral iron formulations. FCM is an i.v. iron formulation which can be used at high doses and allows rapid administration (up to 1000 mg in a single dose infused in 15 min). Since FCM is a dextran-free, it does not react with dextran antibodies, thus resulting in a lower risk for hypersensitivity reactions. The novel iron formulation FCM has a better potential for restoring the iron stores. It reduces the dosage frequency which is the chief drawback of parenteral preparations and there is minimal drug related adverse effects. Hence, FCM can be the drug of choice for the management of iron deficiency anemia in women, especially during pregnancy when rapid and robust increase in iron is required.

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