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ORIGINAL PAPER

Efficacy of ferric carboxy maltose in treatment of iron deficiency/iron deficiency anaemia during pregnancy

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Abstract

Introduction: To evaluate the efficacy of ferric carboxy maltose (FCM) in the treatment of iron deficiency/iron deficiency anaemia (ID/IDA) during pregnancy.

Material and methods: Pregnant women ≥ 20 years old diagnosed with ID (serum ferritin < 15 µg/l) and moderate IDA were included in this study for correction of their ID/IDA. The participants received an FCM infusion for correction of their ID/IDA. The pre-treatment ferritin, haemoglobin (Hb), and red blood cell (RBC) indices were compared with the 6- and 12-week post-treatment values to evaluate the efficacy of FCM in the treatment of ID/IDA during pregnancy.

Results: The pre-treatment ferritin and Hb significantly increased from 10.3 ±2.3 µg/l and 7.99 ±0.6 g/dl, respectively, to 139.5 ±1.9 and 14.04 ±0.45, respectively, 6-weeks after FCM infusion (p = 0.02 and 0.001, respectively), and to 128.9 ±1.7 and 13.02 ±0.5, respectively, 12-weeks after FCM infusion (p = 0.0008 and 0.02, respectively). In addition, the pre-treatment RBCs mean corpuscular volume and RBCs mean corpuscular haemoglobin (MCH) significantly increased from 72.02 ±3.5 fl and 23.9 ±1.9 pg, respectively, to 90.6 ± 2.8 fl and 29.98 ±1.5 pg, respectively, 6 weeks after FCM infusion (p = 0.01 and p = 0.007, respectively), and to 89.5 ±2.9 fl and 30.2 ±1.5 pg, respectively, 12 weeks after FCM infusion (p = 0.02 and 0.007 respectively).

Conclusions: The ferric carboxy maltose was safe and effective for the treatment of ID/IDA during pregnancy within 6 weeks. The serum ferritin and Hb levels and the RBC indices remained significantly high 12 weeks after FCM infusion compared to the pre-treatment values.

Key words: ferric carboxy maltose (FCM), iron deficiency (ID), iron deficiency anaemia (IDA), pregnancy.

Introduction

Anaemia affects 1.5 billion people worldwide, and 52% of pregnant women in developing countries are anaemic [1–3]. The daily required iron increases during the second and third trimesters [4] for foetal and placental development.

The recommended amount of daily iron during pregnancy is about 27 mg (for singleton pregnancy) [5]. In addition, 7% of vaginal deliveries and 23% of caesarean sections are associated with ≥ 1000 ml blood loss [5–6].

Iron deficiency (ID) and iron deficiency anaemia (IDA) are risks for adverse perinatal outcome [7–10]. Froessler *et al.* found that ID and IDA were associated with adverse perinatal outcome, such as preterm labour, intra-uterine growth retardation, and intra-uterine foetal death [11].

Maternal anaemia increases the need for red blood cell (RBC) transfusion [12–13], but the RBC transfusion corrects the haemoglobin (Hb) only, and not the underlying cause [14].

Treatment of ID/IDA is crucial during pregnancy to avoid the ID/IDA-related perinatal morbidity [15]. Iron salts are an effective treatment option for ID/IDA during pregnancy [16]; however, the oral iron salts are commonly associated with intolerance and gastric discomfort, which adversely affect the compliance and treatment outcome [17–19].

The iron sucrose (IS) was approved in the USA and Europe for treatment of ID/IDA [20]; the multiple infusion sessions are the main disadvantage of IS [21, 22]. Ferric carboxy maltose (FCM) is a new intravenous (IV) iron that can be used for correction of ID/IDA when oral iron preparations are ineffective, contraindicated, or

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when there is clinical need to deliver iron for correction of ID/IDA rapidly [22]. A study of the efficacy of FCM in the treatment of IDA during pregnancy found that the FCM infusion increased the Hb levels significantly in all studied women 3, 6, and 8 weeks after infusion [23]. Therefore, the current study was conducted to evaluate the efficacy of FCM in the treatment of ID/IDA during pregnancy.

Material and methods

This comparative study was conducted during the years 2021 and 2022 after approval of the study by the Obstetrics Department and approval of the FCM for treatment of ID/IDA by the hospital's drug committee (approval number Obs_805_22 on 8 May 2022).

Pregnant women ≥ 20 years old, diagnosed with ID (serum ferritin < 15 µg/l) and moderate IDA, were included in this study after informed consent following the Helsinki Declaration, and after approval of the FCM for treatment of ID/IDA by the hospital's drug committee, they received FCM infusion for treatment of their ID/IDA.

Inclusion criteria included 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).

The iron deficiency diagnosed when the serum ferritin was 15 µg/l, and the moderate IDA diagnosed when serum ferritin was < 15 µg/l, Hb was 7–8.9 g/dl, RBCs-mean corpuscular volume (MCV) was < 80 fl, and RBCs-MCH (mean corpuscular Hb) was < 27 pg [22].

The serum ferritin levels were detected using a UniCel DxI 800 analyser (Beckman Coulter Inc., USA), while the RBCs-MCV and MCH values were detected from the complete blood count using a UniCel DxH 800 haematology analyser (Beckman Coulter Inc., USA).

The iron deficiency anaemia in pregnant women classified according to World Health Organization into severe anaemia when Hb < 7 g/dl, moderate anaemia when Hb 7–8.9 g/dl, and mild anaemia when Hb 9–10.9 g/dl [21–22].

Women with intolerance/hypersensitivity to iron preparations, severe IDA (Hb < 7 gm/dl), or anaemia other than IDA, received blood transfusions, and women who refused to participate were excluded from this study.

The effect of FCM (Ferinject® 50 mg iron/ml solution, Vifor Pharma, UK) on ID/IDA was not assessed before 4 weeks after the last FCM infusion, to allow adequate time for iron utilization and erythropoiesis.

The required iron dose of FCM to correct the ID/IDA was calculated when Hb was < 10 gm/dl, according to participants` body weight: 500 mg iron (< 35 kg), 1500 mg iron (> 35 < 70 kg), and 2000 mg iron (> 70 kg) [11].

The calculated iron dose of FCM was diluted in 100 ml 0.9% normal saline (Gulf Inject, Dubai, UAE) over 6 min when it was ≤ 500 mg, and in 250 ml 0.9% normal saline over 15 min when it was > 500–1000 mg.

It was assumed that the total iron infusion dose of FCM should not exceed 20 mg iron/kg body weight, and 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 (1000 mg in the first session and the remainder in the second session [the 2 sessions scheduled one week apart]).

Participants were observed during the FCM infusion, and for at least 30 min following FCM infusion for signs of anaphylaxis, intolerance, and/or side effects (skin eruption, tachycardia, headache, abdominal or chest pain) to evaluate the safety of FCM (secondary outcome).

In addition, studied women received folic acid tablets for 3 months to avoid folic acid deficiency. The pre-treatment ferritin, Hb, RBCs-MCV, and RBCs-MCH values were compared with the 6- and 12-week post-treatment values to evaluate the efficacy of FCM in the treatment of ID/IDA during pregnancy (primary outcome).

Sample size

The required sample size was calculated using G Power software version 3.1.9.4 for sample size calculation (Heinrich Heine Universität; Düsseldorf; Germany), setting the α error probability at 0.05, power (1-β error probability) at 0.95%, effective sample size (w) at 0.5, and using the t-test for statistical analysis.

Statistical analysis

Collected data were statistically analysed using the Statistical Package for Social Sciences (SPSS) version 20 (Chicago, IL, USA). The mean and standard deviation (±SD) were used to present numerical values, while the number (N) and percentage (%) were used to present categorical values. Student's t-test was used to compare the pre-treatment ferritin, Hb, RBCs-MCV, and RBCs-MCH values with the 6- and 12-week post-treatment values to detect the efficacy of FCM in the treatment of ID/IDA during pregnancy. $P < 0.05$ was considered significant.

Results

A total of 110 pregnant women (14–26 weeks` gestation) with ID (serum ferritin < 15 µg/l), and moderate IDA (Hb 7–8.9 g/dl, RBCs-MCV < 80 fl, and RBCs-MCH < 27 pg) were included in this study and received FCM infusion for treatment of their ID/IDA.

The pre-treatment ferritin, Hb, RBCs-MCV, and RBCs-MCH values were compared with the 6- and 12-week

Table 1. Demographic data of participants, and pre-treatment ferritin, haemoglobin, red blood cells mean corpuscular volume, and red blood cells mean corpuscular values

Parameters	Pregnant participants with ID/IDA (*N* = 110)
Maternal age (years)	24.1 ±4.9
Maternal BMI [kg/m^2]	25.9 ±3.7
Gestational age at inclusion (weeks)	19.7 ±3.0
Pre-treatment ferritin [µg/l]	10.3 ±2.3
Pre-treatment haemoglobin [g/dl]	7.99 ±0.6
Pre-treatment RBCS-MCV [fl]	72.02 ±3.5
Pre-treatment RBCS-MCH [pg]	23.9 ±1.9

BMI – body mass index, ID –iron deficiency, IDA – iron deficiency anaemia, MCH – mean corpuscular haemoglobin, MCV – mean corpuscular volume, *N* – number of patients, RBCs – red blood cells
Data presented as mean ± standard deviation.

post-treatment values to evaluate the efficacy of FCM in the treatment of ID/IDA during pregnancy (primary outcome). Participants were observed during the FCM infusion, and for at least 30 min following FCM infusion for signs of anaphylaxis, intolerance, and/or side effects, to evaluate the safety of FCM (secondary outcome).

Table 1 shows the demographic data of participants (maternal age, body mass index [BMI], and gestational age at inclusion), pre-treatment ferritin, Hb, RBCs-MCV, and RBCs-MCH values.

The pre-treatment ferritin and Hb levels significantly increased from 10.3 ±2.3 µg/l and 7.99 ±0.6 g/dl, respectively, to 139.5 ±1.9 and 14.04 ±0.45, respectively, 6 weeks after FCM infusion (p = 0.02 and 0.001, respectively). Also, the pre-treatment RBCs-MCV and RBCs-MCH significantly increased from 72.02 ±3.5 fl and 23.9 ±1.9 pg, respectively, to 90.6 ±2.8 fl and 29.98 ±1.5 pg, respectively, 6 weeks after FCM (p = 0.01 and 0.007, respectively) infusion (Table 2).

The pre-treatment ferritin and Hb levels significantly increased from 10.3 ±2.3 µg/l and 7.99 ±0.6 g/dl, respectively, to 128.9 ±1.7 µg/l and 13.02 ±0.5 g/dl, respectively, 12 weeks after FCM infusion (p = 0.0008 and 0.02, respectively). Also, the pre-treatment RBCs-MCV and RBCs-MCH significantly increased from 72.02 ±3.5 fl and 23.9 ±1.9 pg, respectively, to 89.5 ±2.9 fl and 30.2 ±1.5 pg, respectively, 12 weeks after FCM infusion (p = 0.02 and 0.007, respectively) (Table 3).

No anaphylaxis and/or intolerance to FCM was reported in this study; the only reported side effect was self-limited burning sensation and itching at the FCM infusion site (1.82% [2/110]).

Discussion

The treatment of IDA during pregnancy reduces the adverse perinatal outcome and the peripartum need for RBC transfusion [24].

Table 2. The pre-treatment ferritin, haemoglobin, red blood cells mean corpuscular volume, and red blood cells mean corpuscular values compared to the 6-week post-treatment values

Parameters	Pre-treatment values (*N* = 110)	6-week post-treatment values (*N* = 110)	*p*-value (95% CI)
Pre-treatment ferritin [µg/l]	10.3 ±2.3	139.5 ±1.9	0.02* (–129.8, –129.2, –128.6)
Pre-treatment haemoglobin [g/dl]	7.99 ±0.6	14.04 ±0.45	0.001* (–6.2, –6.1, –5.9)
Pre-treatment RBCs-MCV [fl]	72.02 ±3.5	90.6 ±2.8	0.01* (–19.4, –18.6, –17.7)
Pre-treatment RBCs-MCH [pg]	23.9 ±1.9	29.98 ±1.5	0.007* (–6.5, –6.1, –5.6)

MCH – mean corpuscular haemoglobin, MCV – mean corpuscular volume, *N* – number of patients, RBCs – red blood cells
*Significant difference when the pre-treatment ferritin, haemoglobin, RBCs-MCV, and RBCs-MCH values were compared with the 6-week post-treatment values. Data presented as mean ± standard deviation.
Student *t*-test used for statistical analysis.

Table 3. The pre-treatment ferritin, haemoglobin, red blood cells mean corpuscular volume, and red blood cells mean corpuscular values compared to the 12-week post-treatment values

Parameters	Pre-treatment values (*N* = 110)	12-week post-treatment values (*N* = 110)	*p*-value (95% CI)
Pre-treatment ferritin [µg/l]	10.3 ±2.3	128.9 ±1.7	0.0008* (–119, –118.6, –118.1)
Pre-treatment haemoglobin [g/dl]	7.99 ±0.6	13.02 ±0.5	0.02* (–6.2, –6.03, –5.9)
Pre-treatment RBCs-MCV [fl]	72.02 ±3.5	89.5 ±2.9	0.02* (–18.3, –17.5, –16.6)
Pre-treatment RBCs-MCH [pg]	23.9 ±1.9	30.2 ±1.5	0.007* (–6.8, –6.3, –5.8)

MCH – mean corpuscular haemoglobin, MCV – mean corpuscular volume, *N* – number of patients, RBCs – red blood cells
*Significant difference when the pre-treatment ferritin, haemoglobin, RBCs-MCV, and RBCs-MCH values were compared with the 12-week post-treatment values. Data presented as mean ± standard deviation.
Student's *t*-test used for statistical analysis.

The oral iron salts are commonly associated with gastric discomfort and intolerance, which adversely affect the compliance and treatment outcome [17–19].

The IS was approved in the USA and Europe for the treatment of ID/IDA [20]. The reported incidence of anaphylaxis with IS is low (0.002%), and there are no hypersensitivity reactions reported with IS [25]. The multiple infusion sessions are the main disadvantage of IS (200 mg IS in each session every other day) [20–22].

Therefore, the current study was conducted to evaluate the efficacy of FCM in the treatment of ID/IDA during pregnancy. The pre-treatment ferritin, Hb, RBCs-MCV, and RBCs-MCH were compared with the 6- and 12-week post-treatment values to evaluate the efficacy of FCM in the treatment of ID/IDA during pregnancy.

In this study, the pre-treatment ferritin and Hb levels significantly increased from 10.3 ±2.3 µg/l and 7.99 ±0.6 g/dl, respectively, to 139.5 ±1.9 µg/l and 14.04 ±0.45 g/dl, respectively, 6 weeks after FCM infusion (p = 0.02 and 0.001, respectively), and to 128.9 ±1.7 µg/l and 13.02 ±0.5 g/dl, respectively, 12 weeks after FCM infusion (p = 0.0008 and 0.02, respectively).

In addition, the pre-treatment RBCs-MCV and RBCs-MCH significantly increased from 72.02 ±3.5 fl and 23.9 ±1.9 pg, respectively, to 90.6 ±2.8 fl and 29.98 ±1.5 pg, respectively, 6 weeks after FCM infusion (p = 0.01 and 0.007, respectively), and to 89.5 ±2.9 fl and 30.2 ±1.5 pg, respectively, 12 weeks after FCM infusion (p = 0.02 and 0.007, respectively).

A systematic review found that the IV iron was an effective option to address the ID problem when rapid replacement of iron was required [26].

A randomized controlled trial (RCT) found the IV iron to be beneficial for the correction of ID/IDA at later gestation [27].

A randomized study comparing FCM and IS for the treatment of IDA during pregnancy found that FCM improved laboratory parameters (Hb, MCV, serum ferritin, and iron-binding capacity) and QoL (quality of life) score in short duration compared with IS [28].

A study of the safety and efficacy of FCM in the treatment of IDA during pregnancy found that FCM infusion increased the Hb levels significantly in all studied women 3, 6, and 8 weeks after infusion and reported minor side effects in 20% of the studied women [23].

No anaphylaxis and/or intolerance to FCM was reported in this study; the only reported side effect was self-limited burning sensation and itching at the FCM infusion site (1.82% [2/110]).

Headache and dizziness were the most common FCM-reported side effects in a previous study (6.5% [3/46]) [29].

A randomized controlled trial conducted to evaluate the effect of FCM infusion (≤ 1000 mg over 15 min) for the treatment of postpartum anaemia found that the FCM was tolerable and effective for rapid correction of postpartum anaemia [30].

Another RCT found that FCM infusion improves the iron stores of pregnant women, with significant elevation of Hb levels within 12 weeks compared to IS. The convenient dosing and fewer infusion sessions result in better patient compliance to FCM infusion [31].

Ferric carboxy maltose improved the iron and quality of life compared to IS in the Korean population, and FCM was suggested as an effective alternative to the current available treatment options for IDA with pregnancy [29].

Overall, there is substantial evidence indicating the efficacy of FCM in the treatment of IDA, with a favourable benefit-risk profile [32].

This study found that pre-treatment ferritin and Hb levels significantly increased 6 and 12 weeks after FCM infusion. In addition, the pre-treatment RBCs-MCV and RBCs-MCH significantly increased 6 and 12 weeks after FCM infusion. The only reported side effect with FCM infusion was self-limited burning sensation and itching at the FCM infusion site (1.82% [2/110]).

This study concluded that the FCM was safe and effective for the treatment of ID/IDA during pregnancy within 6 weeks. The serum ferritin, and Hb levels and the RBC indices remained significantly high 12 weeks after FCM infusion compared to the pre-treatment values.

This study was the first comparative study conducted in Kuwait to evaluate the efficacy and safety of FCM for the treatment of ID/IDA during pregnancy.

Further studies comparing the efficacy and safety of FCM with other IV iron preparation including IS are needed.

Conclusions

Ferric carboxy maltose was safe and effective for the treatment of ID/IDA during pregnancy within 6 weeks. The serum ferritin and Hb levels, and the RBC indices remained significantly high 12 weeks after FCM infusion compared to the pre-treatment values.

Disclosure

The authors report no conflict of interest.

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