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Intravenous Ferric Carboxymaltose for Treatment of Postpartum Anemia

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Intravenous Ferric Carboxymaltose for Treatment of Postpartum Anemia

Abstract

Objective: This study aimed to evaluate Ferric Carboxymaltose (FCM) effectiveness in postpartumiron deficiency anemia (PP-IDA) treatment.

Methods: One hundred fifteen (115) women with PP-IDA (serum ferritin <15 μ g/L, hemoglobin <11 g/dL after delivery or at 1st postpartum week, and <12 g/dL at 8th postpartum week) were included in the current comparative study following STROBE Checklist.

Studied women received FCM (Ferinject[®]) infusion to treat their PP-IDA. Studied women mean levels of serum ferritin, hemoglobin, and mean RBCs-indices were compared both before (pre-treatment), and 8-weeks after (post-treatment) receiving Ferinject[®] to determine the effectiveness of Ferinject[®] in PP-IDA treatment.

Results: Studied women mean level of serum ferritin statistically elevated from 10.02 ± 2.4 before (pre-treatment) Ferinject[®] to 140.7 ± 8.9 ug/L after (post-treatment) Ferinject[®] (p<0.0001). Studied

women mean hemoglobin level statistically elevated from 8.03 ± 0.6 before (pre-treatment) Ferinject[®] to 14.06 ± 0.45 g/dL after (post-treatment) Ferinject[®] (p<0.0001).

Studied women mean RBCs-volume statistically elevated from 71.9 ± 3.5 before (pre-treatment) Ferinject[®] to 90.3 ± 2.6 fL after (post-treatment) Ferinject[®] (p<0.0001). Studied women mean RBCs-hemoglobin statistically elevated from 24.2 ± 1.8 before (pre-treatment) Ferinject[®] to 30.03 ± 1.6 pg after (post-treatment) Ferinject[®] (p<0.0001).

Conclusion: Studied women mean levels of serum ferritin, hemoglobin and mean RBCs-indices (volume and hemoglobin) were statistically elevated after Ferinject[®]. This study suggests rapid correction of postpartum-IDA using Ferinject[®] to improve postpartum maternal physical performance, and to enhance mothers' ability to take care of their babies.

Key words: Ferinject, FCM, postpartum-IDA.

Introduction

Postpartum anemia (PPA) is a worldwide health problem (1). Most guidelines define PPA as hemoglobin (Hb) <11 g/dL after delivery or at 1st postpartum week, and <12 g/dL at 8th postpartum week (2).

PPA defined according to WHO as Hb <11 g/dL at 1st postpartum week, and <12 g/dL at 1st postpartum year. The prevalence of PPA is about 22-50% in developed, and 50-80% in developing countries (3). Main causes of PPA include undiagnosed antenatal iron deficiency anemia (IDA), and excess blood loss during labor or during cesarean sections (4,5).

Untreated PPA affects the maternal as well as child well-being. PPA negatively impair the physical ability, and quality of life (QoL) (6). Froessler et al (7), found an association between IDA and both maternal cognitive functions and depressive disorders.

A significant relation between iron stores, and maternal QoL was previously reported (8). Moya et al (9), found the iron replacement tremendously improved fatigue, and depression symptoms.

Iron salts are effective for the treatment of postpartum-IDA. Common oral iron salts side effects (i.e., gastric upset, and constipation) (10), and multiple infusion sessions of iron sucrose (IS) affect the treated women compliance and treatment outcome (11-13). Hence, this study aimed to evaluate Ferric Carboxymaltose (FCM) effectiveness in postpartum-iron deficiency anemia (PP-IDA) treatment.

Aim: To evaluate Ferric Carboxymaltose (FCM) effectiveness in postpartum-iron deficiency anemia (PP-IDA) treatment.

Materials and Methods

One hundred fifteen (115) women with PP-IDA (serum ferritin <15 µg/L, hemoglobin <11 g/dL after delivery or at 1st postpartum week, and <12 g/dL at 8th postpartum week) were included in the current prospective comparative study, during the year 2024, following STROBE Checklist, after approval of West Kazakhstan Medical University (Protocol No. 10; dated January 10, 2024), and informed written consents.

FCM (Ferinject®) approved for treatment of IDA by Ministry of Health Republic of Kazakhstan (Approval No. 931; dated December 8, 2017).

Inclusion criteria: Women with PP-IDA, ≥20 years and agreed to receive Ferinject[®] infusion to treat their PP-IDA.

Most guidelines define PPA as hemoglobin <11 g/dL after delivery or at 1st postpartum week, and <12 g/dL at 8th postpartum week (2).

PPA defined according to WHO as Hb <11 g/dL at 1st postpartum week, and <12 g/dL at 1st postpartum year (3)

The UniCel DxI and DxH analysers (Beckman International SA, Dubai, UAE) were used to detect the studied women serum ferritin, hemoglobin and RBCs-indices (volume and hemoglobin).

Exclusion criteria: Hypersensitivity or allergy to iron, women with severe PPA (hemoglobin <7 gm/dL), with pre-existing disorders in phosphate homeostasis (i.e., low serum vitamin D (14) and hyperparathyroidism (15), received blood transfusions, PPA due to other causes of anemia (i.e., hemoglobinopathy), and/or refused to participate.

FCM effect (Ferinject[®], Vifor, UK) on PP-IDA should be detected after ≥4 weeks following last FCM (Ferinject[®]) dose (i.e., time needed to utilize FCM for erythropoiesis) (16).

Required FCM (Ferinject®) dose for correction of anemia was calculated according to manufacturer's instructions and participants' body weight as follow: 500 mg FCM when participants' body weight <35 kg, 1500 mg FCM when participants' body weight >35 and <70 kg, and 2000 mg FCM when participants' body weight >70 kg (13).

Calculated Ferinject[®] dose was diluted and given by intravenous infusion (≤500 mg Ferinject[®] over 6 min. and >500-1000 Ferinject[®] over 15 min.)

Total Ferinject[®] dose should not exceed 1000 mg/infusion. FCM dose >1000 mg was given over 2 infusion sessions one week apart (15,16).

Studied women were monitored during, and for 30 min. after Ferinject[®] infusion to detect Ferinject[®] related adverse effects including skin eruptions, hypertension, nausea, headache, tachycardia, and/or pains, and hypophosphatemia (i.e., muscle pain, and fatigue in mild cases and muscle weakness,

confusion, numbness, weak reflexes, and seizures in severe cases), and to identify FCM (Ferinject®) safety (secondary outcome). Folic acid was given to studied women in form of oral tablets for 2 months (i.e., to avoid folate deficiency).

Studied women mean levels of serum ferritin, hemoglobin, mean RBCs-indices (volume and hemoglobin) were compared both before (pre-treatment), and 8-weeks after (post-treatment) receiving Ferinject® to determine the effectiveness of Ferinject® in PP-IDA treatment (primary outcome).

The G Power 3.1.9.4 (Düsseldorf; Germany) with 0.05 α -error probability, and 0.95% power was used to calculate the sample size for this study (4,17).

Studied women mean levels of serum ferritin, hemoglobin, mean RBCs-indices (volume and hemoglobin) were compared both before (pre-treatment), and 8-weeks after (post-treatment) receiving Ferinject® to determine the effectiveness of Ferinject® in PP-IDA treatment.

Results

One hundred fifteen (115) women with PP-IDA (serum ferritin <15 μ g/L, hemoglobin <11 g/dL after delivery or at 1st postpartum week, and <12 g/dL at 8th postpartum week, with RBCs-indices including volume and hemoglobin <80 fl and <27 pg, respectively), agreed to participate in the current study and received Ferinject[®] infusion to treat their PP-IDA. **Figure 1**

Studied women were monitored during, and for 30 min. after Ferinject® infusion to detect Ferinject® related adverse effects and Ferinject® safety. Studied women mean levels of serum ferritin, hemoglobin, mean RBCs-indices (volume and hemoglobin) were compared both before (pretreatment), and 8-weeks after (post-treatment) receiving Ferinject® to determine the effectiveness of Ferinject® in PP-IDA treatment.

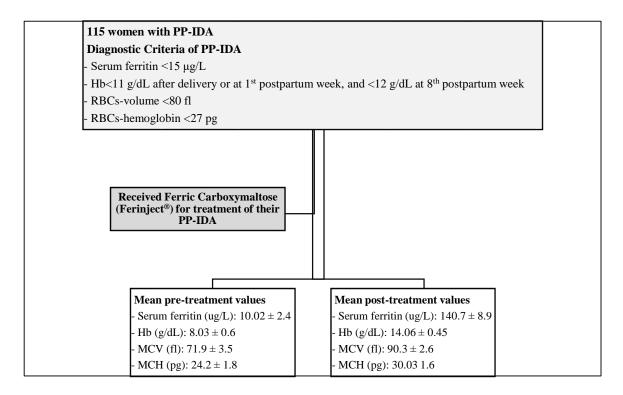


Figure 1: Flow diagram summarizing intervention and results

Hb: Hemoglobin. MCH: Mean corpuscular hemoglobin. MCV: Mean corpuscular volume.

PP-IDA: Postpartum anemia-iron deficiency anemia. RBCs: Red blood cells

Table 1 shows studied women age, BMI, postpartum duration at inclusion, serum ferritin, hemoglobin, and RBCs-indices (volume and hemoglobin) before (pre-treatment) Ferinject[®].

Table 1: Studied women characteristics and pre-treatment ferritin, Hb, MCV and MCH

Variables	Studied women with PP-IDA (N = 115)
Maternal age (Years)	25.8 ± 4.95
Maternal BMI (Kg/m²)	26.1 ± 3.6
Postpartum duration at inclusion (Weeks')	2.5 ± 1.3
Pre-treatment serum ferritin (ug/L)	10.02 ± 2.4
Pre-treatment Hb (g/dL)	8.03 ± 0.6
Pre-treatment MCV (fl)	71.9 ± 3.5
Pre-treatment MCH (pg)	24.2 ± 1.8

BMI: Body mass index. Data presented as mean ± SD (Standard deviation). Hb: Hemoglobin. IDA: Iron deficiency anemia.

MCV: Mean corpuscular volume. N: Number of studied women. MCH: Mean corpuscular hemoglobin. PP: Postpartum.

Studied women mean level of serum ferritin statistically elevated from 10.02 ± 2.4 before (pretreatment) Ferinject® to 140.7 ± 8.9 ug/L after (post-treatment) Ferinject® (p<0.0001). Studied women mean hemoglobin level statistically elevated from 8.03 ± 0.6 before (pre-treatment) Ferinject® to 14.06 ± 0.45 g/dL after (post-treatment) Ferinject® (p<0.0001). **Table 2**

Studied women mean RBCs-volume statistically elevated from 71.9 ± 3.5 before (pre-treatment) Ferinject® to 90.3 ± 2.6 fL after (post-treatment) Ferinject® (p<0.0001). Studied women mean RBCs-hemoglobin statistically elevated from 24.2 ± 1.8 before (pre-treatment) Ferinject® to 30.03 ± 1.6 pg after (post-treatment) Ferinject® (p<0.0001). **Table 2**

No cases of severe adverse effects to FCM were reported in this study. One case (1.7%) of headache, and another case (1.7%) of mild skin rash around the infusion site were the reported Ferinject® side effects.

Table 2: The pre-treatment versus post-treatment ferritin, Hb, MCV and MCH

Variables	Pre-treatment	Post-treatment	p-value
	(N = 115)	(N = 115)	(95% CI)
Serum ferritin (µg/L)	10.02 ± 2.4	140.7 ± 8.9	<0.0001* (-132.4 to -128.9)
Hb (g/dL)	8.03 ± 0.6	14.06 ± 0.45	<0.0001* (-6.2 to -5.9)
MCV (fL)	71.9 ± 3.5	90.3 ± 2.6	<0.0001* (-19.2 to -17.6)
MCH (pg)	24.2 ± 1.8	30.03 ± 1.6	<0.0001* (-6.3 to -5.4)

^{*:} Significant difference. CI: Confidence interval. Data presented as mean ± SD (Standard deviation).

Discussion

Most guidelines define PPA as Hb <11 g/dL after delivery or at 1st postpartum week, and <12 g/dL at 8th postpartum week (2). PPA defined according to WHO as Hb <11 g/dL at 1st postpartum week, and <12 g/dL at 1st postpartum year. The prevalence of PPA is about 22-50% in developed, and 50-80% in developing countries (3).

A randomized controlled trial (RCT) found PPA impair maternal QoL and negatively affect mothers' wellbeing (18). Iron salts are effective for the treatment of postpartum-IDA. Common oral iron salts side effects (i.e., gastric upset, and constipation) (10), and multiple infusion sessions of iron sucrose (IS) affect the treated women compliance and treatment outcome (12,13). Hence, this study aimed to evaluate Ferinject® effectiveness in PP-IDA treatment.

Studied women mean level of serum ferritin statistically elevated from 10.02 ± 2.4 before (pretreatment) Ferinject® to 140.7 ± 8.9 ug/L after (post-treatment) Ferinject® (p<0.0001). Studied women mean hemoglobin level statistically elevated from 8.03 ± 0.6 before (pre-treatment) Ferinject® to 14.06 ± 0.45 g/dL after (post-treatment) Ferinject® (p<0.0001).

Studied women mean RBCs-volume statistically elevated from 71.9 ± 3.5 before (pre-treatment) Ferinject® to 90.3 ± 2.6 fL after (post-treatment) Ferinject® (p<0.0001). Studied women mean RBCs-hemoglobin statistically elevated from 24.2 ± 1.8 before (pre-treatment) Ferinject® to 30.03 ± 1.6 pg after (post-treatment) Ferinject® (p<0.0001).

Network of Advanced Patient Blood Management, Hemostasis, and Thrombosis (NATA) recommends administration of IV iron for treating women with Hb <9.0 g/dL following IDA (19).

A systematic review found the 6-weeks postpartum-Hb was 1.0 g/dL higher after receiving IV iron versus oral iron (20).

Hb: Hemoglobin. MCH: Mean corpuscular hemoglobin. MCV: Mean corpuscular volume.

N: Number of studied women. t-test used for statistical analysis.

IV iron increases postpartum Hb in women with PP-IDA (Hb <8 g/dL) by 1.9 and 3.1 g/dL in 7 and 14 days, respectively (21). Holm et al (22), found IV iron to correct PPA was associated with significant reduction of postpartum maternal physical fatigue within 12-weeks compared to oral iron. Van Wyck et al (23), randomized trial found total postpartum maternal fatigue statistically improved after IV iron versus oral iron at 4, 8 and 12-weeks postpartum.

Shim et al (24), found FCM (Ferinject®) was an effective, well-tolerable for IDA treatment, it improved the iron stores and QoL compared to IS.

A retrospective study compared pregnant participants treated with IV iron for their IDA versus oral iron, and found odds of maternal morbidities (i.e., blood transfusion, hysterectomy, and ICU admission) was similar with no statistical difference between two studied groups (25).

The same study found the peripartum blood transfusion risk was less in IV iron treated participants (35 women) versus oral iron treated participants (114 women) (25).

No cases of severe adverse effects to FCM were reported in this study. One case (1.7%) of headache, and another case (1.7%) of mild skin rash around the infusion site were the reported FCM side effects. Shim et al (24), reported headache and dizziness as FCM-side effects in 3 cases [6.5% (3/46)]. Van Wyck et al (23), reported the FCM as a well-tolerable option for IDA treatment with minimal side effects.

A RCT found the Ferinject[®] improves both iron stores and Hb levels, and concluded that the convenient Ferinject[®] doses, and infusions were associated with improved studied patients' compliance (26). Evidence supports the use of FCM (Ferinject[®]) as a safe, tolerable and an effective option for IDA treatment (27).

Conclusion: Studied women mean levels of serum ferritin, hemoglobin and mean RBCs-indices (volume and hemoglobin) were statistically elevated after Ferinject[®]. This study suggests rapid correction of postpartum-IDA using Ferinject[®] to improve postpartum maternal physical performance, and to enhance mothers' ability to take care of their babies.

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