Experimental
&
Clinical Article

Effectiveness of Intravenous Ferric Carboxymaltose in the Management of Anemia of Varying Severity in Pregnant Women

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ABSTRACT

OBJECTIVES: To evaluate the effectiveness and safety of intravenous ferric carboxymaltose (FCM) in pregnant women with iron deficiency anemia (IDA), comparing outcomes between those with baseline hemoglobin (Hb) levels <8.5 g/dL and ≥8.5 g/dL. The study aimed to assess hematologic response, postpartum anemia rates, and obstetric and neonatal outcomes.

STUDY DESIGN: This retrospective observational study included 161 pregnant women with IDA who received FCM treatment (Hb 7-10 g/dL) between January 2020 and October 2024. Patients were divided into two groups based on initial Hb levels (Group 1: Hb<8.5 g/dL and Group 2: Hb ≥8.5 g/dL). Hematologic parameters were evaluated at baseline, 2 and 4 weeks post-treatment, and postpartum day 1. Obstetric and neonatal outcomes were also compared.

RESULTS: Both groups demonstrated significant increases in Hb levels post-treatment (p <0.001). The increase was more pronounced at 2 and 4 weeks in the group with Hb <8.5 g/dL. At the fourth week after treatment, the increase in hemoglobin levels was 3.36±1.14 g/dL in Group 1, compared to 2.40±0.93 g/dL in Group 2 (all p <0.001). Postpartum anemia was more common in Group 1 (36.8% vs. 20.3%, p = 0.044), although the absolute Hb gain was greater. There were no serious adverse events, and no statistically significant differences were found in adverse maternal or neonatal outcomes between the groups.

CONCLUSION: Intravenous FCM is an effective and well-tolerated treatment for anemia during pregnancy, providing a rapid rise in Hb levels. The therapy is particularly beneficial for those with more severe anemia, helping to reduce postpartum anemia and potentially improving maternal health outcomes.

Keywords: Anemia; Ferric carboxymaltose; Intravenous iron; Iron deficiency; Pregnancy

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Introduction

Anemia is a significant public health issue worldwide, complicating 38% of all pregnancies globally and approximately 50% of pregnancies in developing countries (1,2). Iron deficiency anemia (IDA) represents the leading cause of anemia during pregnancy, which accounts for approximately 50-75% of cases (2,3). Due to increased fetal demands, maternal erythropoiesis, and blood loss during delivery, iron requirements significantly rise during pregnancy (4).

Although various cut-off values have been proposed for anemia in pregnancy, the most widely accepted thresholds are Hb <11 g/dL in the first and third trimesters and Hb <10.5 g/dL in the second trimester (5-7). The World Health Organization defines severe anemia as Hb <7 g/dL (6). Anemia during pregnancy is associated with increased adverse obstetric outcomes such as postpartum depression, postpartum hemorrhage (PPH), the need for transfusion, sepsis,

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and preeclampsia (5,8). In addition, anemia has been associated with unfavorable perinatal outcomes, including low birth weight, preterm delivery, intrauterine growth restriction, and neonatal death (5,9,10).

Although oral iron therapy is generally recommended as the first-line treatment, intravenous (IV) iron therapy is preferred in cases of severe anemia, inadequate response to oral treatment, or when a rapid increase in hemoglobin is required in late pregnancy (11-13), IV iron preparations containing ferric carboxymaltose (FCM) are notable for their ability to be administered in high doses in a single session, their rapid increase in hemoglobin levels, and their favorable safety profile (12-15). Additionally, IV FCM has been shown to provide higher maternal Hb levels at delivery, more effectively increase ferritin stores, and cause fewer side effects (11). Improvement of anemia during the antenatal period reduces maternal morbidity, the risk of PPH, and the need for postpartum transfusion (8,16). Moreover, preventing postpartum anemia improves the mother's overall health by reducing fatigue, depression, and the negative effects on maternal-infant bonding (5,8,16).

Current literature supports the use of IV FCM as a beneficial and safe method for the rapid improvement of anemia during pregnancy. The objectives of this study were to compare obstetric and neonatal outcomes between pregnant women with anemia who received ferric carboxymaltose treatment and had hemoglobin (Hb) levels <8.5 g/dL and those with Hb levels≥8.5 g/dL; to evaluate the treatment's efficacy at weeks 2 and 4; and to determine postpartum anemia rates. The aim was to demonstrate the clinical effects of intravenous FCM treatment in pregnant women with varying degrees of anemia.

Material and Method

In this retrospective observational study, pregnant women with anemia who received intravenous ferric carboxymaltose (FCM) treatment between January 2020 and October 2024 were analyzed. Prior to the study, approval was obtained from the Ethics Committee of Bilkent City Hospital (TABED 1-24-627). Written informed consent was obtained from all participants, and the study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients diagnosed with iron deficiency anemia during the second or third trimester, classified as having moderate anemia based on the WHO definition (hemoglobin levels <10 g/dL and >7 g/dL), and treated with FCM were included in the study (6). Indications for intravenous FCM administration included intolerance to oral iron, insufficient increase in hemoglobin levels, or the need for rapid correction of anemia due to limited time. Pregnant women with placental invasion anomalies or fetuses with diagnosed anomalies were excluded. The study population consisted of 161 patients who met the eligibility criteria.

Although the threshold for severe anemia is generally consistent (Hb <7 g/dL), different sources have reported varying cut-off values for moderately severe anemia in pregnant women (14,17-19). This cut-off, which is clinically relevant for predicting adverse obstetric and perinatal outcomes and for guiding treatment decisions, has been reported as 8 g/dL in some studies, 8.5 g/dL in others, and 9 g/dL in certain references (14,17-19). In the present study, considering the overall literature, the study population was divided into two groups according to baseline hemoglobin levels: Group 1 (Hb <8.5 g/dL) and Group 2 (Hb ≥8.5 g/dL).

During the study period, FCM was the institutionally preferred intravenous iron preparation. The required IV FCM dose was calculated based on patients' body weights and hemoglobin levels (15). A maximum weekly dose of 1000 mg was administered as a single infusion. For patients whose required FCM dose exceeded 1000 mg, a second dose was given one week later (15). Sociodemographic characteristics, obstetric history, obstetric outcomes, pre-treatment hemogram parameters, iron, ferritin, total iron-binding capacity, and transferrin saturation levels were recorded, along with hemogram parameters measured at the second and fourth weeks after treatment and on postpartum day 1.

The groups were compared in terms of sociodemographic characteristics, obstetric outcomes (mode of delivery, preterm birth, postpartum hemorrhage, need for transfusion), neonatal outcomes (birth weight, gestational age, Apgar scores, NICU admission), and laboratory parameters. The effect of intravenous FCM at different hemoglobin levels was also evaluated.

Statistical analyses were performed using SPSS software version 26.0 (IBM Corp., Chicago, IL, USA). The Kolmogorov-Smirnov test was applied to evaluate the normality of data distribution. Continuous variables were expressed as mean ± standard deviation for normally distributed data and compared using the Student's t-test. For non-normally distributed data, results were presented as median (minimum-maximum), and comparisons were made using the Mann-Whitney U test. Categorical variables were presented as frequencies and percentages, and intergroup comparisons were conducted using the chi-square test. Paired t-tests were employed to evaluate changes in hematological parameters before and after treatment. A p-value of <0.05 was considered statistically significant.

Results

There were 84 anemic pregnant women in Group 1 (Hgb < 8.5 g/dL) and 77 in Group 2 (Hgb ≥ 8.5 g/dL). There were no significant differences between the groups in terms of age, gravidity, parity, rate of multiple pregnancies, gestational week, and trimester at the time of treatment, obstetric complications, gestational age at delivery, time interval between treatment and

delivery, mode of delivery, or neonatal outcomes (all p-values >0.05). The rate of postpartum anemia was significantly higher in Group 1 compared to Group 2 (36.8% vs. 20.3%, respectively; p= 0.044). The majority of patients in both groups received treatment during the third trimester (Group 1: 79.8%, Group 2: 81.3%). No serious adverse events related to the treatment were observed in either group. A comparison of the sociodemographic features and obstetric and neonatal outcomes of the groups is summarized in Table I.

The groups were then compared in terms of laboratory values at baseline, at the second and fourth weeks post-treatment, and on postpartum day 1. Although the difference in hemoglobin levels decreased by the second week after treatment, it remained statistically significant (p <0.001); however, the difference in MCV levels was reduced and not statistically significant (p= 0.088). At the fourth week post-treatment, hemoglobin levels in Group 1 became comparable to those in Group 2, with no statistically significant differences observed between the groups regarding hemoglobin and MCV values (p= 0.384 and p= 0.239, respectively). In Group 1, postpartum hemoglobin levels were significantly lower than those in Group 2 (10.50 ± 1.74 vs. 11.06±1.35; p= 0.030). Comparisons of baseline laboratory parameters and post-treatment values at weeks 2 and 4, as well as postpartum day 1, between the groups are shown in Table II.

Table I: *Comparison of sociodemographic and clinical characteristics of the treatment groups*

	Hb<8.5 (84)	**Hb ≥8.5 (77)**	**p**
Age, years	28.3 ± 5.4	29.3 ± 5.4	0.300
Gravidity	2 (1 - 8)	2 (1 - 9)	0.122
Parity	1 (0 - 4)	1 (0 - 5)	0.184
Multiple pregnancy	9/84 (10.7%)	6/76 (7.9%)	0.541
GA at treatment, weeks	31.9 ± 5.6	31.5 ± 4.8	0.337
Period of gestation at treatment			0.803
Second trimester	17/84 (20.2%)	14/75 (18.7%)	
Third trimester	67/84 (79.8%)	61/75 (81.3%)	
GA at delivery, weeks	38 (31 - 41)	38 (30 - 41)	0.302
Time between treatment and delivery, weeks	4.5 (1 - 20)	5 (1 - 20)	0.195
Preeclampsia	1/76 (1.3%)	2/75 (2.7%)	0.552
FGR	4/76 (5.3%)	3/75 (4.0%)	0.712
Preterm birth	15/76 (19.7%)	12/75 (16.0%)	0.549
Postpartum anemia	28/76 (36.8%)	15/74 (20.3%)	**0.044**
Mode of delivery, caesarean	23/76 (30.3%)	29/75 (38.7%)	0.277
1st minute Apgar	7 (3-8)	7 (3 - 9)	0.776
5th minute Apgar	9 (6-10)	9 (6 - 10)	0.092
Birth weight, grams	3026.7 ± 535.3	3161 ± 483.7	0.075
NICU	20/74 (27.0%)	11/70 (15.7%)	0.099

GA: Gestational age, FGR: Fetal growth restriction, NICU: Neonatal intensive care unit, Hb: Hemoglobin
Data presented as mean ± SD, median (min-max), or n (%). A p-value of <0.05 was considered statistically significant.

Table II: *Comparison of baseline laboratory values and post-treatment results at the 2nd, 4th weeks, and postpartum between the groups*

		Hb<8.5 (84)	**Hb ≥8.5 (77)**	**P value**
Baseline				
	Hb (g/dL)	7.81 ± 0.40	9.00 ± 0.41	**<0.001**
	MCV (fl)	71.38 ± 9.87	76.20 ± 8.26	**<0.001**
	Serum ferritin (µg/dL)	7.73 ± 9.93	11.80 ± 41.30	0.573
	Serum iron (µg/dL)	35.28 ± 45.71	27.11 ± 16.72	0.381
	TIBC (µg/dL)	479.92 ± 110.61	498.30 ± 66.08	0.466
	Transferrin saturation (%)	7.50 ± 10.70	5.19 ± 2.98	0.281
Post-treatment				
2nd week	Hgb (g/dL)	9.73 ± 1.11	10.47 ± 0.92	**<0.001**
	Mcv (fl)	79.28 ± 10.36	82.0 ± 7.09	0.088
4th week	Hgb (g/dL)	11.17 ± 1.17	11.36 ± 0.81	0.384
	MCV (fl)	82.87 ± 6.97	84.64 ± 7.06	0.239
Postpartum				
	Hgb (g/dL)	10.50 ± 1.74	11.06 ± 1.35	**0.030**
	MCV (fl)	83.02 ± 9.69	84.62 ± 8.02	0.274

Hb: Hemoglobin, MCV: Mean corpuscular volume, TIBC: Total iron binding capacity; Data presented as mean ± SD; A p-value of <0.05 was considered statistically significant.

When each group was evaluated individually, statistically significant differences were observed between baseline hemoglobin levels and those measured at weeks 2, 4, and postpartum (all p-values <0.001). In both treatment groups, hemoglobin levels measured after treatment and in the postpartum period were significantly elevated compared to baseline levels. At the fourth week after treatment, the increase in hemoglobin levels was 3.36 ± 1.14 g/dL in Group 1, compared to 2.40 ± 0.93 g/dL in Group 2 (all p <0.001) (Table III).

When the increase in hemoglobin levels was evaluated between the groups, both the 0-2 week and 0-4 week increments were significantly higher in Group 1 (p= 0.022 and p <0.001, respectively). When postpartum hemoglobin levels were compared with baseline levels, the increase in Hgb in Group 1 was significantly higher than in Group 2 (2.69 ± 1.76 vs. 2.04 ± 1.40; respectively, p= 0.014). The comparison of hemoglobin increases between groups is presented in table 4.

Discussion

This study investigated the efficacy of ferric carboxymaltose treatment for different hemoglobin levels and its impact on postpartum anemia rates. Our results demonstrate a significant increase in Hb and a reduction in postpartum anemia rates in both groups. Group 1 exhibited a more prominent Hb increase over the two-week period. By the fourth week, Hb levels in Group 1 had caught up with those in Group 2. Although postpartum Hb levels remained statistically lower in Group 1, the absolute increase in Hb in this group was more substantial.

The contribution of iron deficiency anemia during pregnancy to maternal and fetal morbidity has long been recognized. Severe anemia, in particular, is associated with serious complications such as postpartum hemorrhage, need for transfusion, and preterm birth (1,8).

Several studies in the literature have reported that FCM is safe in both early and late pregnancy, with no serious adverse events observed (20,21). In our study, although no first-trimester administrations were performed, the safety of the treatment and the favorable neonatal outcomes are noteworthy.

In a randomized controlled trial by Breymann et al., FCM was found to result in a faster and more effective increase in Hb than oral iron, with fewer gastrointestinal side effects (15). Their study included pregnant women with Hgb between 8-10.4 g/dL and reported a mean increase of 1.2 g/dL by the third week (15). In the study by Christoph et al. comparing FCM and iron sucrose, FCM was found to improve patient comfort due to its ability to be administered in higher doses with fewer sessions (12). The average Hb increase in the FCM group was 1.5 g/dL (12). Similarly, in our study, the one- or two-dose regimen achieved good patient compliance, with minimal side effects and effective, rapid improvement in Hb levels.

In a prospective observational study, significant increases in Hb and ferritin levels were observed in pregnant women receiving FCM, along with a reported 65% improvement in quality of life (13). Smith and Young's literature review emphasized that effective correction of anemia during the antenatal period reduces maternal morbidity and the risk of postpartum anemia (4). A review by Breymann et al. highlighted that intravenous iron therapy effectively and rapidly replenishes maternal iron stores before delivery, reduces the need for postpartum iron, and improves maternal health (14). In our

Table III: *Analysis of the increase in hemoglobin levels in treatment groups*

	Groups	Number of patients	Rise in Hb (g/dL)	p
Baseline to 2 weeks	Hgb <8.5	n: 65	1.90 ± 1.09	<0.001
	Hb ≥8.5	n: 60	1.46 ± 1.00	<0.001
Baseline to 4 weeks	Hgb <8.5	n: 40	3.36 ± 1.14	<0.001
	Hb ≥8.5	n: 50	2.40 ± 0.93	<0.001
2 to 4 weeks	Hgb <8.5	n: 38	1.02 ± 1.02	<0.001
	Hb ≥8.5	n: 43	0.85 ± 0.77	<0.001
Baseline to postpartum	Hgb <8.5	n: 76	2.69 ± 1.76	<0.001
	Hb ≥8.5	n:74	2.04 ± 1.40	<0.001

Hb: Hemoglobin; Data presented as mean ± SD, p value calculated using paired t-test; A p-value of <0.05 was considered statistically significant.

Table IV: *Comparison of changes in hemoglobin levels between groups*

	Hb<8.5 g/dL	Hb ≥8.5 g/dL	p
Baseline to 2 weeks	1.90 ± 1.09	1.46 ± 1.00	0.022
Baseline to 4 weeks	3.36 ± 1.14	2.40 ± 0.93	<0.001
2 to 4 weeks	1.02 ± 1.02	0.85 ± 0.77	0.388
Baseline to postpartum	2.69 ± 1.76	2.04 ± 1.40	0.014

Hb: Hemoglobin; Data presented as mean ± SD; A p-value of <0.05 was considered statistically significant.

study as well, the post-treatment increase in Hb and higher postpartum Hb levels support improved maternal well-being. The significant decrease in postpartum anemia rates and the absence of significant maternal morbidity in the current study are consistent with these results.

In another study in 2018, patients were grouped by anemia severity, and the most pronounced increase in Hb was observed in the group with the most severe anemia (22). In the randomized controlled trial by Pasricha et al., FCM administration in late pregnancy reduced the prevalence of anemia from 62.7% to 46.7%, and the increase in Hb was found to be statistically significant (16). Similarly, in a study involving 1,191 pregnant women, an average Hb increase of 2.8 g/dL and a 30 μg/L increase in ferritin at week 4 were reported; in the subgroup with severe anemia, the average Hb increase was 3.6 g/dL (23). In the study by Gupte et al., FCM treatment resulted in an increase in Hb of approximately 4.2 g/dL in women with severe anemia (24). Consistent with these studies, our study found a 3.3 g/dL increase in Hb at week 4 in Group 1 and a 2.4 g/dL increase in Group 2.

In the current study, FCM was not compared with other intravenous iron formulations. However, in the literature, it appears advantageous, particularly due to its ability to be administered in high doses in a single session (12,25). Additionally, some studies have demonstrated that FCM is more effective than other IV iron preparations in terms of hemoglobin increase (25,26).

Strengths and Limitations: The most important limitation of our study is the retrospective design, which resulted in missing laboratory data. In particular, post-treatment ferritin and other iron deficiency parameters were not monitored, so changes in these parameters could not be evaluated. Hemogram values at weeks 2 and 4, as well as postpartum, were not available for all patients; analyses involving these values were performed using the available data. Additionally, data regarding minor adverse events could not be retrieved from patient records and thus were not reported.

Conclusion

This study demonstrates that ferric carboxymaltose (FCM) is an effective and safe treatment option for pregnant women with varying degrees of anemia. While a more pronounced increase in hemoglobin was observed in the group with Hb <8.5 g/dL, both groups exhibited a rapid and effective rise in Hb levels. These findings support the advantages of FCM in providing a prompt response and maintaining a favorable safety profile in the management of anemia during pregnancy.

In conclusion, our study provides up-to-date clinical data and supports the findings of similar large-scale studies in the literature. FCM ensures a rapid increase in Hb and stands out particularly in pregnant women with severe anemia, providing a more pronounced improvement in Hb. This, in turn, contributes to the reduction of maternal morbidity and the improvement of maternal and neonatal health.

Declarations

Ethics approval and consent to participate: All participants signed informed written consent before being enrolled in the study. The study was reviewed and approved by the ethics committee of Bilkent City Hospital (Ethics approval reference number: TABED: 1-24-627, date 09.10.2024). All procedures were performed according to the Declaration of Helsinki.

Availability of data and materials: The data supporting this study are available through the corresponding author upon reasonable request.

Competing interests: The authors declare that they have no competing interests.

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