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Oral iron versus intravenous ferric carboxymaltose in the treatment of iron deficiency anemia in pregnancy: a retrospective study

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Abstract

Objective: Pregnant women with iron deficiency and severe anemia are at increased risk of preterm delivery, prematurity, and small for gestational age. Increased iron requirement necessitates iron replacement during pregnancy. While oral iron supplements are the common first choice, up to two-thirds of women experience dose-limiting gastrointestinal side effects. Hence, intravenous iron can be an alternative method for iron replacement. We aimed to compare women who were given oral iron with women who received ferric carboxymaltose during pregnancy with regard to change in hemoglobin (Hb) and hematocrit (Hct) levels, mean corpuscular volume (MCV), weight gain during pregnancy, gestational age at birth, delivery method and birthweight.

Methods: A total of 120 pregnant women, 60 in the oral iron group and 60 in the ferric carboxymaltose group were included in this retrospective study. All pregnant women underwent a baseline measurement for Hb, MCV, and Hct levels at their first antepartum care visit in the first trimester. Women in the oral iron group were started supplementation between the 16 and 20 weeks of gestation. Women in the ferric carboxymaltose group underwent 1000 mg of iron infusion between 20 and 28 weeks of gestation.

Results: Women in the oral iron group have shown a significant decrease in Hb levels which was 12.2 (range: 11.5–13) g/dL at baseline and 12.1 (range: 11.2–12.5) g/dL before delivery (p=0.034). However, ferric carboxymaltose group did not show any difference between baseline Hb levels and Hb levels before delivery (p=0.60). Likewise, Hct levels have shown a significant decrease in the oral iron group which were 36.7 (range: 34–39) and 35.8 (range: 34–38) at baseline and before delivery, respectively (p=0.006). There was no significant difference between Hct levels in the ferric carboxymaltose group.

Conclusion: Intravenous ferric carboxymaltose administration seems an effective, easy-to-use option for iron supplementation during pregnancy.

Keywords: Intravenous ferric carboxymaltose; oral iron; iron deficiency in pregnancy, anemia in pregnancy.

Özet: Gebelikte demir eksikliği anemisinin tedavisinde oral demire karşı intravenöz ferrik karboksimaltoz: Retrospektif çalışma

Amaç: Demir eksikliği ve şiddetli anemisi olan gebeler, preterm doğum, prematürite ve gebelik haftasına göre küçük olma yönünden artmış risk altındadır. Artmış demir gereksinimi, gebelikte demir replasmanını gerekli kılmaktadır. Oral demir takviyeleri yaygın ilk tercihken, kadınların üçte ikisine kadar olan kısmı doz sınırlayıcı gastrointestinal yan etkiler yaşamaktadır. Bu nedenle, demir replasmanı için intravenöz demir alternatif bir yöntem olabilir. Çalışmamızda, hemoglobin (Hb) ve hematokrit (Hct) seviyelerinde değişim, ortalama eritrosit hacmi (MCV), gebelikte kilo alma, doğumda gestasyonel yaş, doğum yöntemi ve doğum ağırlığı yönünden gebelik süresince oral demir alan kadınlarla ferrik karboksimaltoz alan kadınları karşılaştırmayı amaçladık.

Yöntem: Bu retrospektif çalışmaya, altmışı oral demir grubu ve altmışı ferrik karboksimaltoz grubunda olmak üzere toplam 120 gebe dahil edildi. Tüm gebelere, birinci trimesterdeki ilk antepartum bakım ziyaretlerinde Hb, MCV ve Hct seviyeleri için referans ölçümü yapıldı. Oral demir grubundaki kadınlara 16. ve 20. gebelik haftaları arasında takviye başlandı. Ferrik karboksimaltoz grubundaki kadınlara 20. ve 28. gebelik haftaları arasında 100 mg demir infüzyonu uygulandı.

Bulgular: Oral demir grubundaki kadınlarda Hb seviyelerinde anlamlı bir azalma görüldü; referans ölçümünde 12.2 (aralık: 11.5–13) g/dL ve doğumdan önce 12.1 (aralık: 11.2–12.5) g/dL idi. Ancak ferrik karboksimaltoz grubunda referans Hb seviyeleri ile doğumdan önceki Hb seviyeleri arasında herhangi bir fark görülmedi (p=0.60). Benzer şekilde Hct seviyelerinde de oral demir grubunda anlamlı azalma görüldü; referans ölçümünde ve doğumdan önce sırasıyla 36.7 (aralık: 34–39) ve 35.8 (aralık: 34–38) idi (p=0.006). Ferrik karboksimaltoz grubunda Hct seviyeleri arasında anlamlı fark yoktu.

Sonuç: İntravenöz ferrik karboksimaltoz uygulamasının, gebelik süresince demir takviyesi olarak verimli ve kullanımı kolay bir seçenek olduğu görülmektedir.

Anahtar sözcükler: İntravenöz ferrik karboksimaltoz; oral demir; gebelikte demir eksikliği, gebelikte anemi.

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Introduction

Hemoglobin (Hb) concentration <11 g/dL in the first trimester or <10 g/dL in the second and third trimesters are defined as significant anemia in pregnancy.[1,2] Iron deficiency is the most common cause of anemia in pregnancy and affects 2–26% of pregnant women depending on the population screened.[1,3,4] Iron deficiency can be diagnosed by serum ferritin-level measurement (threshold value <30 µg/L).[5]

Patients with iron deficiency may present with fatigue, headache, low physical and mental capacity, vertigo, leg cramps, pagophagia, cold intolerance, koilonychia, mucosal paleness, and angular stomatitis.[6] Besides, pregnant women with iron deficiency and severe anemia are at increased risk of preterm delivery, prematurity, and small for gestational age.[7]

Increased iron requirement necessitates iron replacement in pregnant women. The American College of Obstetricians and Gynecologists (ACOG) recommends low-dose iron supplementation with 27 to 30 mg iron during pregnancy.[8] While oral iron supplements are the common first choice, up to two-thirds of women experience dose-limiting gastrointestinal side effects. Hence, intravenous iron can be an alternative method for iron replacement.[9]

Ferric carboxymaltose solution comprises a polynuclear iron (III)-(oxyhydr)oxide core stabilized by carboxymaltose.[10] While former intravenous iron preparations had the risk of serious side effects such as anaphylactic shock, ferric carboxymaltose is safer with carbohydrate shells ensuring the slower release of iron.[11] Different studies comparing different intravenous iron formulations have suggested that when high molecular weight iron dextran is avoided intravenous iron seems safe with a risk of serious events <1:200,000.[12] A recent clinical trial comparing ferric carboxymaltose and oral iron in patients with iron deficiency anemia following childbirth has suggested that ferric carboxymaltose is a safe and effective option.[13]

In this study, we aimed to investigate whether single intravenous ferric carboxymaltose administration was as effective as 6-month oral iron supplementation in pregnant women with iron deficiency anemia.

Methods

This retrospective study was conducted in accordance with the Declaration of Helsinki Ethical Principles and Good Clinical Practices and the protocol of this retrospective study was approved by Koç University Clinical Research Ethics Committee (2021.280.IRB1.098).

In our unit, either oral Fe^{+2} iron or intravenous ferric carboxymaltose is prescribed for women with ferritin levels <30 ng/ml at the discretion of the physician in charge. For our study, we screened our electronic patient records and included all women who were given intravenous ferric carboxymaltose at Koç University Hospital Department of Obstetrics and Gynecology, between January 2020 and May 2020. These were matched according to their baseline Hb levels with 60 women who were supplemented with oral Fe^{+2} iron during the same period. We excluded women with other causes of anemia, vitamin B12 or folate deficiency, multiple pregnancy, or preterm birth.

All pregnant women underwent a baseline measurement for Hb, mean corpuscular volume (MCV), and hematocrit (Hct) levels at their first antepartum care visit in the first trimester. Also, we evaluated serum ferritin levels immediately before iron supplementation in both groups. Iron deficiency is defined with ferritin levels <30 ng/mL.[14] Women in the oral iron group were started Fe^{+2} iron supplementation between 16 and 20 weeks of gestation if ferritin levels <30 ng/mL or Hb level <11 g/dL at their visit. Women in the ferric carboxymaltose group underwent 1000 mg of iron infusion between the 20 and 28 weeks of gestation with ferric carboxymaltose.

The primary outcome was the change in Hb and Hct levels before and after iron supplementation. We recorded body mass index (BMI), weight gain during pregnancy, serum ferritin levels before iron treatment, Hb, MCV, and Hct levels before and after iron treatment, gestational age at birth, delivery method, and fetal weight at birth in both groups.

The distribution of each variable was evaluated with a histogram. Continuous variables were defined with median (25th and 75th percentiles) and compared between the groups using Mann-Whitney U or unpaired t-test depending on the distribution assumptions. Categorical variables were presented as numbers and percentages. Comparisons were made with Chi-squared or Fisher's exact test for categorical variables. A two-sided p-value <0.05 was considered statistically significant.

Statistical analysis was performed with Statistical Package for Social Sciences (SPSS) software Version 28.0 (IBM SPSS Statistics, Armonk, NY, USA).

Results

A total of 120 pregnant women, 60 in the oral iron treatment group and 60 in the ferric carboxymaltose treatment group were included. Baseline characteristics are shown in **Table 1**. The median age was 30 (range: 28–34.8) years in the oral iron treatment group and 34 (range: 30–37) years in the ferric carboxymaltose group (p<0.01). Median BMI levels were 21.9 (range: 19.2–24.7) kg/m^2 in oral iron treatment group and 22.9 (range: 20.8-–26.1) kg/m^2 in ferric carboxymaltose group (p=0.12).

Baseline Hb levels were 12.2 (range: 11.5–13) mg/dL and 12.5 (range: 11.9–13.2) mg/dL in oral iron and ferric carboxymaltose treatment groups, respectively (p=0.22). However, Hb levels at delivery were significantly higher in ferric carboxymaltose group with 12.5 (range: 11.9–13.7) g/dL compared to oral iron group with 12.1 (range: 11.2–12.5) g/dL (p=0.002). Likewise, baseline Hct levels did not show any difference 36.7 (range: 34–39) vs. 37.6 (range: 35.4–39.7) (p=0.29) between the groups. Median Hct levels at delivery were significantly higher in ferric carboxymaltose group which was 37 (range: 35.6–39) compared to oral iron group which was 35.8 (range: 34–38) (p=0.005).

Ferritin levels before iron treatment in both groups are shown in **Table 2**. There was no significant difference between ferritin levels immediately before treatment (p=0.08). We compared baseline Hb levels and Hb levels before delivery in both groups. Women in the oral iron group have shown a significant decrease in Hb levels which was 12.2 (range: 11.5–13) g/dL at baseline and 12.1 (range: 11.2–12.5) g/dL before delivery (p=0.034). However ferric carboxymaltose group did not show any difference between baseline Hb levels and Hb levels before delivery (p=0.60). Likewise, Hct levels have shown a significant decrease in the oral iron group which were 36.7 (range: 34–39) and 35.8 (range: 34–38) at baseline and before delivery, respectively (p=0.006). There was no significant difference between Hct levels in the ferric carboxymaltose group (**Table 3**).

Weight gain during pregnancy was 14 (range: 12–17) kg in the oral iron group and 14 (range: 10–16) kg in the ferric carboxymaltose group (p=0.26). Hence BMI levels at delivery did not show a difference (p=0.13) same as baseline BMI levels.

Median birth weight was 3260 (range: 2983–3550) g in the oral iron group and 3090 (range: 3390–3550) g in the ferric carboxymaltose group (p=0.20). Median gestational age at birth was 273 (range: 267–278) days and 272.5 (range: 266–275.8) days in the oral and ferric carboxymaltose group, respectively (p=0.28). Method of delivery in oral iron group was 50% vaginal (n=30) and 50% cesarean section (n=30). However, vaginal birth constituted 28.3% (n=17) of the deliveries in the ferric carboxymaltose group.

Women who had ferric carboxymaltose did not experience severe side effects after the treatment. Specifically, anaphylactic reaction during ferric carboxymaltose administration did not occur. Only one woman

Table 1. Baseline characteristics of pregnant women in oral iron and ferric carboxymaltose groups.

	Oral iron group	Ferric carboxymaltose group	p-value
Age (years)	30 (28–34.8)	34 (30–37)	<0.01
Gravida			
1	29	33	
2	25	16	0.16
>2	6	11	
Parity			
0	36	43	
1	23	15	0.27
>1	1	2	
Baseline BMI levels (kg/m^2)	21.9 (19.2–24.7)	22.9 (20.8–26.1)	0.12
Baseline Hb levels (g/dL)	12.2 (11.5–13)	12.5 (11.9–13.2)	0.22
Baseline MCV levels	88 (84.9–90.3)	86 (83.1–88.6)	0.05
Baseline Hct levels (%)	36.7 (34–39)	37.6 (35.4–39.7)	0.29

Table 2. Post-treatment characteristics of pregnant women in oral iron and ferric carboxymaltose groups.

	Oral iron group	Ferric carboxymaltose group	p-value
Ferritin levels before iron replacement	12 (10–20)	10 (8–18.5)	0.08
BMI levels at delivery (kg/m^2)	27.3 (25.4–29.4)	28.7 (26–31.2)	0.13
Hb levels at delivery (g/dL)	12.1 (11.2–12.5)	12.5 (11.9–13.7)	**<0.01**
MCV levels at delivery	88.5 (85–91)	88.8 (86.5–91)	0.21
Hct levels at delivery	35.8 (34–38)	37 (35.6–39)	**<0.01**
Difference in Hb levels (g/dL)*	-.3 (.4, -.9)	-.05 (-.6, .7)	0.06
Difference in Hct levels†	-1 (-3.5, 1)	-.2 (-1.9, 1.9)	0.09
Difference in MCV levels‡	1 (-1.63, 3)	3 (0.75-5.1)	**<0.01**
Weight gain during pregnancy (kg)	14 (12–17)	14 (10–16)	0.26
Birthweight (kg)	3260 (2983–3550)	3090 (3390–3550)	0.20
Gestational age at birth (days)	273 (267–278)	272.5 (266–275.8)	0.28
Method of delivery Vaginal birth (n) Cesarean section (n)	 50% (30) 50% (30)	 28.3% (17) 71.7% (43)	**0.02**

Note: Values are median (25th and 75th percentiles) or % (n). *Difference between Hb levels at delivery and baseline Hb levels; †Difference between Hct levels at delivery and baseline Hct levels; ‡Difference between MCV levels at delivery and baseline MCV levels.

reported a mild allergic reaction during the treatment which disappeared after the treatment.

Discussion

Our results suggest that intravenous ferric carboxymaltose is a good alternative iron supplementation for pregnant women who cannot tolerate oral iron or who have severe anemia in pregnancy. According to our findings, median Hb and Hct levels at delivery decreased significantly compared with baseline Hb and Hct levels in the oral iron group. However, in the intravenous iron group, Hb and Hct levels at delivery did not show a significant difference when compared to baseline Hb levels. One of the explanations could be that Hb and Hct levels are decreasing in both groups around 20–24 weeks of gestation. From a practical point of view, patients are eventually anemic compared to their basal levels if they use oral iron during pregnancy. However, Hb and Hct levels of women who were administered ferric carboxymaltose around 24 weeks of gestation increase until delivery and therefore we do not see that decrease in the ferric carboxymaltose group.

Intravenous iron carries a risk of anaphylaxis.[15] In a study the risk for anaphylaxis was 68 per 100,000 persons for iron dextran (95% CI, 57.8–78.7 per 100,000) and 24 per 100,000 persons for all nondextran intravenous iron products (95% CI, 20.0–29.5 per 100,000) (adjusted odds ratio [OR] of 2.6 [95% CI, 2.0–3.3; p<0.001]).[15] However ferric carboxymaltose is an agent which can be considered safe and practical, as it does not

Table 3. Comparison of Hb and Hct levels before and after treatment in oral iron and ferric carboxymaltose groups.

	Baseline Hb levels (g/dL)	Hb levels at delivery (g/dL)	p-value
Oral iron	12.2 (11.5–13)	12.1 (11.2–12.5)	0.03
Ferric carboxymaltose	12.5 (11.9–13.2)	12.6 (11.9–13.2)	0.60
	Baseline Hct levels (%)	**Hct levels at delivery (%)**	**p-value**
Oral iron	36.7 (34–39)	35.8 (34–38)	**<0.01**
Ferric carboxymaltose	37.6 (35.4–39.7)	37 (35.6–39)	0.58

require a test dose or premedication prior to administration, and can be administered in 15 minutes without serious side effects.[11] We also did not observe any severe adverse effects in our patients following intravenous ferric carboxymaltose treatment.

Intravenous iron supplementation has been shown to improve iron-deficiency anemia and restore iron stores effectively in previous studies.[16,17] Based on clinical trials and real patient data ferric carboxymaltose is an effective and well-tolerated agent for treating anemia in pregnant women who have iron deficiency.[18–21] A randomized study including 90 women with hemoglobin levels between 8 and 10.5 g/dL and ferritin values less than 13 mcg/L compared oral iron polymaltose complex (300 mg elemental iron per day) with intravenous iron sucrose in pregnant women. Their results have shown that intravenous iron restored iron stores faster and more effectively than oral iron in iron-deficiency anemia of pregnancy, with no serious adverse reactions.[16] Another randomized study including 100 anemic antenatal women with hemoglobin 7–9 g/dL and serum ferritin <15 ng/mL, compared ferrous sulfate with intravenous iron sucrose infusion. They also have reported a statistically significant difference in the increase of hemoglobin levels (p=0.002) and ferritin levels on day 30 in the intravenous iron group compared to the oral iron group (p=0.005).[22] On the other side, a randomized study comparing two different doses of intravenous iron with 80 mg ferrous sulfate daily in 260 pregnant women did not find clinically significant benefit for the parental route in iron prophylaxis of anemia. In the first intravenous iron group, 75 women received two doses of 200 mg iron sucrose and in the second intravenous iron group, 55 women received three doses of 200 mg iron sucrose. Only in the second intravenous iron group with three doses a significant rise in serum ferritin levels were reported. However, they did not use a standard dose and timing of oral iron prophylaxis. Besides, women included in this study were non-anemic by the time of the recruitment opposite to the former studies mentioned above.

A disadvantage of ferric carboxymaltose is its cost. In Turkey, it is 6 times more expensive than six-month oral iron supplementation. Moreover, intravenous iron infusion requires a hospital setting. Therefore, it is not possible to advocate the routine use of intravenous iron for all pregnant women. The advantage of ferric carboxymaltose is its efficiency and quick response.

The main limitations of our study are its retrospective design and small sample size. In order to minimize selection bias, we included all the women who were given intravenous iron supplementation within the study period. Another limitation of our study is that we were not able to measure patients' compliance with oral supplements.

Although ferric carboxymaltose seems efficient, cost-effectiveness analysis, risk analysis, and randomized controlled trials are required before suggesting routine use instead of oral iron in pregnancy.

Conclusion

Intravenous ferric carboxymaltose administration seems an effective, easy-to-use option for iron supplementation during pregnancy. From a practical point of view, intravenous iron supplementation seems to be an acceptable alternative especially for pregnant women who cannot tolerate oral iron treatment or who have very low ferritin levels and severe anemia.

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Compliance with Ethical Standards: The authors stated that the standards regarding research and publication ethics, the Personal Data Protection Law and the copyright regulations applicable to intellectual and artistic works are complied with and there is no conflict of interest.

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