




Evaluation of the response and adverse effects of intravenous iron therapy in patients with iron deficiency anemia: a single-center experience

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ABSTRACT

Aims: The present study evaluates the treatment responses and adverse effect profile of intravenous (IV) iron (ferric carboxymaltose) therapy in patients diagnosed with iron deficiency anemia (IDA).

Methods: The medical records of 65 patients diagnosed with IDA and treated with IV iron therapy after presenting to various clinics in our center between 2014 and 2023 were retrospectively reviewed. Pre- and post-treatment hemoglobin (Hb), serum iron, total iron-binding capacity (TIBC), ferritin, and transferrin saturation levels were compared, treatment-related adverse effects were recorded, and improvements in symptoms were noted.

Results: The patients were aged 18–90 years, and 89.2% (n=58) were female. Significant improvements were observed in all laboratory parameters following IV iron therapy. The mean Hb increased from 9.8 g/dl before treatment to 12.7 g/dl after treatment (p<0.001); while the median serum ferritin increased from 4.6 µg/L before treatment to 231 µg/L after treatment, indicating a replenishment of iron stores (p<0.001). All patients experienced an improvement in clinical symptoms, while six (9.2%) developed an allergic reaction to the IV iron therapy.

Conclusion: The present study demonstrated that IV iron therapy rapidly and significantly increases Hb levels and replenishes iron stores, alleviates symptoms, and exhibits an acceptable safety profile in patients with IDA. The incidence of serious adverse effects from IV iron therapy is low, and it can thus be considered an effective treatment approach, particularly in patients who are unresponsive to or intolerant of oral iron therapy.

Keywords: Anemia, ferric carboxymaltose, ferritin, iron-deficiency

INTRODUCTION

According to the World Health Organization (WHO), anemia is defined as a Hb level below 13 g/dl in men, below 12 g/dl in nonpregnant women and below 11 g/dl in pregnant women aged ≥15 years.¹ Globally, approximately 30% of people are affected by anemia, and the underlying cause is iron deficiency anemia (IDA) in half of the cases.² Iron deficiency can lead to clinical problems even in the absence of anemia, including restless leg syndrome and fatigue.^{3,4} Iron replacement therapy is recommended in symptomatic patients with low iron stores, regardless of the presence of anemia.^{3,5}

Oral iron formulations are the first-line treatment for IDA. Oral iron therapy is readily accessible, inexpensive, and efficacious, but is often associated with gastrointestinal adverse effects, particularly at high doses. It has been reported in the literature that approximately 70% of patients receiving oral iron therapy exhibit poor treatment compliance due to

such gastrointestinal adverse effects as nausea, constipation, and abdominal pain.^{6,7} This may adversely affect treatment outcomes by leading many patients to discontinue oral iron therapy or to take inadequate doses. IV iron therapy can be considered an effective alternative for patients who are unresponsive to or cannot tolerate oral iron therapy.⁸ Although anaphylaxis and fatal reactions have been reported with iron dextran in the past, the risk of serious allergic reactions with newer iron formulations is considerably low.⁹ Another advantage of parenteral iron is that the total iron replacement dose can usually be administered in one or two infusions. IV Iron administration thus serves as a practical and effective solution in cases requiring rapid iron replacement or in which oral treatment is ineffective.¹⁰

The present study assesses treatment response and adverse effects in patients diagnosed with IDA who received IV iron therapy. Specifically, it evaluates the efficacy of this

therapeutic approach by analyzing the changes in Hb and iron parameters following IV iron administration. The study further assesses the safety of the treatment by determining the frequency of adverse effects.

METHODS

Ethics

The study was approved by the Non-interventional Clinical Researches Ethics Committee of Van Yüzüncü Yıl University (Date: 20.01.2023, Decision No: 2023/01-13). The study was conducted in accordance with the principles of the Declaration of Helsinki. The identities of the participants were kept confidential.

The medical records of patients diagnosed with IDA and treated with IV iron at Van Yüzüncü Yıl University Faculty of Medicine Hospital between January 2014 and December 2023 were analyzed retrospectively.

Data Collection

The demographic characteristics of the patients, existing comorbidities, presence of malignancy, and potential underlying etiological factors, such as gastrointestinal system pathologies, were retrieved from patient files and the hospital information system. Complete blood count (Hb, hematocrit) and iron panel parameters (serum iron, total iron-binding capacity (TIBC), ferritin, and transferrin saturation) measured prior to IV iron therapy were recorded as baseline values, and the same parameters were re-evaluated in laboratory tests during treatment follow-up. Additionally, patient follow-up notes were reviewed to identify any improvements in symptoms (e.g., fatigue, palpitations, exercise capacity) after treatment and any adverse effects that may have occurred during or after the infusion (e.g., allergic reaction, hypotension).

Study Inclusion Criteria

The study included patients aged 18 years and older who had been diagnosed with IDA according to WHO criteria and who had received intravenous iron therapy with ferric carboxymaltose. Patients with complete laboratory data on hemoglobin (Hb) and iron parameters before and after treatment were included in the evaluation.

Study Exclusion Criteria

Patients under 18 years of age, pregnant women, those with anemia causes other than iron deficiency, those with active infection or acute bleeding, those without sufficient clinical or laboratory data, and patients who did not consent to participate in the study were excluded from the study.

Statistical Analysis

The study data were analyzed using IBM SPSS Statistics, Version 28.0 (IBM Corp., 2011). Descriptive statistics for continuous variables were presented as mean±standard deviation for normally distributed data; and as median and minimum–maximum values for non-normally distributed data. Categorical data were summarized as numbers and percentages. The distribution of quantitative data was evaluated using the Kolmogorov-Smirnov test. Pre-treatment and post-treatment values were compared using a paired t-test for variables meeting the parametric test assumption,

and with a Wilcoxon signed-rank test for non-normally distributed variables. Comparisons of two independent groups (e.g., by sex) were performed using either an Independent samples t-test or the Mann-Whitney U test. Categorical variables were compared using the Chi-square test or Fisher's exact test, as appropriate. In all analyses, a p value of less than 0.05 was considered statistically significant.

RESULTS

Among the 65 patients included in the study, 58 were female (89.2%) and seven were male (10.8%). The median age of the female and male patient groups was 38 and 68 years, respectively. The laboratory and clinical parameters (e.g., symptoms, development of allergies) of the patients before and after treatment were compared. The clinical and demographic characteristics of the patients are presented in **Table 1**.

Table 1. Distribution of patients according to clinical characteristics and demographic features

| Clinical parameters | n (%) or median (min-max) |
|--------------------------------------|---------------------------|
| Age (years) | |
| 18-44 | 33 (50.8) |
| 45-64 | 24 (36.9) |
| ≥65 | 8 (12.3) |
| Sex | |
| Male | 58 (89.2) |
| Female | 7 (10.8) |
| Hemoglobin, g/dl | 9.7 (5.8-16.1) |
| Ferritin, ng/ml | 4.6 (1-198) |
| Serum iron, µg/dl | 23 (9-150) |
| Total iron-binding capacity, µg/dl | 358 (142-527) |
| Transferrin saturation, % | 6.7 (2.6-77) |
| Intravenous iron dose | |
| 500 mg | 3 (4.6) |
| 1000 mg | 45 (69.2) |
| 2000 mg | 17 (26.2) |
| Development of allergy | |
| Yes | 6 (9.2) |
| No | 59 (90.8) |
| Malignancy | |
| Present | 1 (1.5) |
| Absent | 64 (98.5) |
| Abnormal radiological finding | |
| Present | 13 (20) |
| Absent | 52 (80) |
| Regression of symptoms | |
| Present | 65 (100) |
| Absent | 0 (0) |

Min: Minimum, Max: Maximum

The hematological and biochemical profiles of the patients before starting IV iron therapy exhibited a typical profile for IDA. Following IV iron therapy, significant improvements were observed in the Hb levels and iron values of all patients (**Table 2**). An average increase of 2.9 g/dl in Hb levels was observed after treatment. Notably, patients with baseline ferritin levels below 5 ng/ml experienced a pronounced increase in ferritin values following treatment. A comparison of pre- and post-treatment Hb levels and iron parameters is presented in **Table 2**.

The total IV elemental iron dose administered to the majority of patients was 1000 mg in a single session, and the approximately one-quarter of the patients with a greater iron

Table 2. Comparison of hemoglobin and iron parameters before and after treatment

| Laboratory parameters | Pre-treatment value (mean) | Post-treatment value (mean) | p-value |
|------------------------------------|----------------------------|-----------------------------|---------|
| Hemoglobin, g/dl | 9.7 | 12.9 | <0.001 |
| Serum iron, µg/dl | 23 | 91 | <0.001 |
| Total iron-binding capacity, µg/dl | 358 | 175 | <0.001 |
| Transferrin saturation, % | 6.7 | 52.3 | <0.001 |
| Ferritin, ng/ml | 4.6 | 231 | <0.001 |

deficit in the study received total doses of 2000 mg of IV iron. **Table 3** presents the relationship between the administered IV iron doses and the age and sex of the patients, as well as allergic reactions. In the assessment of adverse effects, it was found that six patients (9.2%) developed acute allergic reactions during IV iron infusion. When the etiology of iron deficiency was examined in the study, it was determined that the most common cause, as presented in **Table 4**, was menstrual bleeding in premenopausal women.

Table 3. Comparison of applied parenteral iron treatment doses

| Clinical parameters | IV iron dose <2000 mg | IV iron dose ≤2000 mg | p-value |
|--------------------------------------|-----------------------|-----------------------|---------|
| | n (%) | n (%) | |
| Age (years) | | | |
| 18-44 | 20 (41.7) | 13 (76.5) | 0.048 |
| 45-64 | 21 (43.8) | 3 (17.6) | |
| ≥65 | 7 (14.6) | 1 (5.9) | |
| Sex | | | |
| Female | 43 (89.6) | 15 (88.2) | 1.000 |
| Male | 5 (10.4) | 2 (11.8) | |
| Development of allergy | | | |
| Yes | 5 (10.4) | 1 (5.9) | 1.000 |
| No | 43 (89.6) | 16 (94.1) | |
| Malignancy | | | |
| Present | 1 (2.1) | 0 (0) | 1.000 |
| Absent | 47 (97.9) | 17 (100) | |
| Abnormal radiological finding | | | |
| Present | 9 (18.8) | 4 (23.5) | 0.672 |
| Absent | 39 (81.2) | 13 (76.5) | |

Table 4. Distribution of the etiology of iron deficiency in patients

| Etiology | n (%) | Sex |
|-------------------------------------|------------|--------|
| Premenopausal (menstrual bleeding) | 42 (64.61) | Female |
| Postmenopausal (nutritional causes) | 16 (24.61) | Female |
| Advanced age (nutritional causes) | 4 (6.14) | Male |
| Young age (nutritional causes) | 2 (3.07) | Male |
| Malignancy (stomach cancer) | 1 (1.53) | Male |

DISCUSSION

In this study, the treatment response and adverse effect profile in patients diagnosed with IDA and treated with IV iron using ferric carboxymaltose were retrospectively evaluated using real-world data. WHO defines IDA as the presence of low Hb levels accompanied by low serum ferritin levels (<15 ng/ml, or <50 ng/ml in patients with chronic conditions).¹¹ The present study assessed the treatment outcomes and adverse effect profiles of 65 patients who received IV iron therapy for IDA. The study findings suggest that IV iron therapy is highly effective and well tolerated in patients with IDA, with an acceptable safety profile. A 3 g/dl increase in

Hb levels was noted following treatment, as was expected. Previous studies in the literature suggest that effective iron replacement can be expected to increase Hb levels by 2 g/dl within 2–3 weeks and to restore them to normal levels within 6–8 weeks.¹² In the present study, Hb levels increased by 3 g/dl within 4–6 weeks, noted during the first control visit, achieving the target range. The marked improvement in serum ferritin and iron parameters indicates that IV iron therapy rapidly replenishes iron stores. The increase in mean transferrin saturation from 10% to 70% indicates a substantial rise in functional iron levels. Consequently, all patients showed improvement in clinical symptoms, with a corresponding enhancement in quality of life. Notably, some patients who were asymptomatic at baseline reported improvement after treatment, highlighting that iron deficiency can impair functional capacity even at a subclinical level and emphasizing the benefits of therapy. In a study by Sharma et al.,⁴ IV iron therapy was found to significantly alleviate fatigue in young women with iron deficiency, even when Hb levels were within the normal range. In the present study, restoring iron stores was associated with symptomatic improvement and enhanced overall well-being in patients.

There have been several studies to date reporting IDA to be particularly prevalent among women of reproductive age and those who are pregnant.^{13,14} Consistent with the literature, the majority of patients in the present study were female. In our country (Turkiye), the prevalence of anemia is low among healthy adult males who do not donate blood, whereas higher rates have been reported in women, attributable to such factors as menstruation and pregnancy.^{14,15} Furthermore, studies have shown that ferric carboxymaltose is an effective and safe treatment for patients with IDA associated with hypermenorrhea, menorrhagia, and menometrorrhagia.¹⁶ Although the number of male patients in our study was small, it is worthy of note that the mean age of the male patients was considerably higher than that of female patients, indicating that iron deficiency is particularly prevalent among young women and in older men, likely associated with other comorbid conditions. Half of the male patients in the present study were aged 65 or older, representing an age group in which anemia may be associated with gastrointestinal bleeding or the presence of chronic conditions. The identification of gastric cancer in one male patient in our study underlines the need to thoroughly investigate the underlying pathology in cases of iron deficiency involving older men. When examined alongside the findings of previous studies in the literature, it can be concluded from the present study that all patients diagnosed with IDA, particularly men and postmenopausal women, should be evaluated for sources of gastrointestinal bleeding and underlying malignancy.¹⁷ Although the malignancy rate in our study was low (1.5%), a comprehensive evaluation is advisable to investigate potential sources of occult bleeding that could be detected at an early stage.

In the present study, the adverse effects associated with IV iron therapy were found to be at a tolerable level. Among the observed adverse reactions, none of those related to the IV treatment progressed to anaphylactic shock, and most reactions were managed through such measures as slowing the infusion rate, and the administration of antihistamines and corticosteroids, when necessary. A

review of the literature confirms the low incidence of serious adverse events associated with newer-generation IV iron formulations reported in the present study. In a meta-analysis by Avni et al.¹⁴ involving more than 10,000 patients, IV iron therapy was found not to increase the risk of life-threatening complications, including death, although minor infusion reactions were reported slightly more frequently when compared to a placebo or oral iron treatments.

In this context, the 9% rate of minor reactions observed in our study is consistent with the literature, and no patients experienced any permanent sequelae. The severe reactions historically associated with iron dextran have prompted clinicians to exercise caution; however, the introduction of ferric carboxymaltose has substantially reduced these concerns. In the present study, none of the patients had a known history of allergy to IV iron, and so no test doses were administered for prophylactic purposes.

Although the initial cost of IV iron therapy is higher than that of oral treatment, it may contribute to health economics by rapidly reducing work loss, alleviating symptoms, and decreasing the need for transfusions. Oral therapy should be prioritized as the first-line treatment for patients with mild or uncomplicated anemia who demonstrate good treatment adherence, while IV iron should be considered early in patients with malabsorption (e.g. gastrointestinal intolerance, celiac disease, history of bariatric surgery) or in patients requiring rapid correction, such as those with severe symptomatic anemia or as a preoperative preparation.⁸

Based on studies in the literature, there is consensus that correcting Hb levels with IV iron therapy in patients diagnosed with IDA is associated with better outcomes in terms of reduced hospital admissions and improved quality of life. Achieving target Hb levels plays an important role in reducing anemia-related morbidity and ultimately improving patient-centered outcomes in these various clinical settings.¹⁹

Limitations

The retrospective design of the study may lead to gaps in the data, and some measurements may not have been performed at the defined time points. Furthermore, there may have been variations in the timing of the post-treatment laboratory follow-up, introducing heterogeneity to the assessment of treatment response. Finally, the data on symptoms and adverse effects came from patient records, and assessments may have been influenced by subjective reporting.

The study is based on real-world data, and so provides insight into the outcomes of IV iron therapy in routine clinical practice. The administration of ferric carboxymaltose to all patients in the study has ensured homogeneity in treatment response and safety assessments, thereby enhancing the reliability of the results.

CONCLUSION

The findings of the present study indicate that patients should receive appropriate replacement therapy upon the detection of iron deficiency, regardless of whether or not symptoms are present. It can further be concluded that IV iron therapy is an effective and reliable option in patients who cannot

tolerate oral iron therapy or whose response to oral treatment is inadequate. The patients in the present study experienced a rapid increase in laboratory parameters following IV iron therapy, including Hb and ferritin levels, and the treatment was noted to have a well-tolerated safety profile and to spur a rapid improvement in symptoms.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was approved by the Non-interventional Clinical Researches Ethics Committee of Van Yüzüncü Yıl University (Date: 20.01.2023, Decision No: 2023/01-13).

Informed Consent

As this was a retrospective study, formal written informed consent was not required and was therefore not obtained.

Peer Review Process

This manuscript was subject to external peer review.

Conflict of Interest

The authors declare no conflicts of interest related to this study.

Financial Disclosure

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Author Contributions

Concept: G.A., R.E.; Design: G.A., A.D.; Control: G.A., R.E.; Data Collection and/or Processing: G.A., R.E., A.D.; Analysis and/or Interpretation: G.A., A.D.; Literature Review: G.A., A.D.; Article Writing: G.A., R.E., A.D.; Critical Review: All authors.

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