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ORIGINAL RESEARCH

Impact of Intravenous Ferric Carboxymaltose on Quality of Life in Patients with Iron Deficiency Anemia: A Prospective Observational Study

Rıfat Bozkuş, Emin Gemcioğlu, Şeyma Sarışen

Department of Internal Medicine, Ankara Etlik City Hospital, Ankara, Turkey

Correspondence: Rıfat Bozkuş, Department of Internal Medicine, Ankara Etlik City Hospital, Varlık Mahallesi, Halil Sezai Erkut Caddesi, Yenimahalle, Ankara, Turkey, Tel +90 505 799 17 45, Email rifatbozkus@gmail.com

Purpose: Iron deficiency anemia (IDA) is a major public health concern. Intravenous (IV) iron supplementation serves as an effective alternative when oral iron therapy fails or is not tolerated. This study aimed to evaluate the efficacy, safety, and impact on quality of life of ferric carboxymaltose in the treatment of IDA.

Methods: In this prospective observational study conducted between June 2023 and February 2025, a total of 528 patients with IDA—unresponsive or intolerant to oral iron—received IV ferric carboxymaltose. Doses were calculated using the Ganzoni formula. Hematological parameters and quality of life were assessed pre- and 30 days post-treatment using laboratory tests and the WHOQOL-BREF questionnaire. Adverse events were recorded during a 30-day follow-up.

Results: The mean age was 41.56 ± 12.33 years, with 92.4% female participants. Hemoglobin increased from 9.17 ± 1.36 to 13.12 ± 0.82 g/dL, and ferritin exhibited a substantial rise from 6.23 ± 4.38 to 178.91 ± 123.99 ng/mL (both $p < 0.001$). Mild side effects occurred in 11.36% of cases; no serious adverse events were observed. Significant improvements were recorded in physical and psychological domains of quality of life ($p < 0.001$). Hypophosphatemia was more frequent in patients receiving > 1750 mg of iron and with pre-treatment phosphorus levels < 3.05 mg/dL.

Conclusion: IV ferric carboxymaltose is a safe and effective therapy for IDA, offering rapid hematological recovery and improved quality of life. However, hypophosphatemia remains a concern at higher doses, warranting close monitoring and further investigation.

Plain Language Summary: Iron deficiency anemia is a common condition, especially among women, and it can cause tiredness, poor concentration, and lower quality of life. Some people cannot tolerate iron pills or do not respond to them, so they need iron treatment through a vein.

In this study, we looked at the effect of a specific type of intravenous iron treatment, called ferric carboxymaltose, in people with Iron deficiency anemia. We wanted to find out whether this treatment improves blood iron levels and also whether it helps people feel better in their daily lives.

Our results demonstrate that this treatment effectively improves hemoglobin and iron levels within one month. They also reported feeling physically and mentally better, with fewer symptoms of fatigue and discomfort. The treatment caused only mild side effects in a small number of people. However, some patients developed low blood phosphorus levels, especially when they received higher doses of the treatment or had lower phosphorus before treatment. This can lead to health problems if not monitored.

In summary, ferric carboxymaltose is a safe and effective treatment for iron deficiency anemia that can improve patients' quality of life. But doctors should monitor phosphorus levels, especially in patients at higher risk.

Keywords: iron deficiency anemia, ferric carboxymaltose, hypophosphatemia, quality of life

Introduction

Iron deficiency anemia (IDA) is one of the most common hematological disorders worldwide. It is particularly prevalent among women, children, the elderly, and individuals with chronic diseases.[1] According to the World Health Organization

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(WHO), approximately one-third of the global population is affected by anemia, with a substantial proportion of cases attributed to iron deficiency.[2] In Turkey, the prevalence of IDA among adults is estimated to be around 20%, with the highest incidence observed in women of reproductive age.[3]

Iron deficiency is not merely a hematological condition; it has multisystemic implications, contributing to impaired cognitive function, reduced physical performance, compromised immune response, and an overall decline in quality of life.[4]

Although oral iron supplementation is typically the first-line treatment for iron deficiency, it may be inadequate or poorly tolerated in certain populations due to gastrointestinal side effects, malabsorption syndromes, prior gastrointestinal surgeries, or inflammatory bowel diseases.[5] In such cases, intravenous (IV) iron preparations, particularly ferric carboxymaltose, offer an effective alternative. Recent advancements in IV formulations have facilitated the administration of higher iron doses with improved safety and tolerability profiles.[6]

While several studies have demonstrated the efficacy and safety of IV iron therapy, the expanding use of these treatments underscores the need for further research—particularly regarding adverse events and patient-reported outcomes. Notably, there is a lack of studies evaluating the impact of IV iron on quality of life using validated tools such as the WHOQOL-BREF, especially within the Turkish population. Standardized instruments like WHOQOL-BREF, endorsed by the WHO, enable a patient-centered approach to assessing quality of life and provide valuable insights into treatment effectiveness.[7,8]

To our knowledge, this is the first prospective observational study to evaluate changes in quality of life using the WHOQOL-BREF scale among Turkish patients with IDA treated with intravenous ferric carboxymaltose. The primary objectives were to assess the treatment's hematologic efficacy, safety profile, and impact on quality of life.

Materials and Methods

Study Design

This prospective, single-center, open-label observational study was conducted between June 2023 and February 2025 in the Internal Medicine Clinic of Ankara Etlik City Hospital. A total of 615 patients diagnosed with IDA who were either intolerant to oral iron therapy or unable to use it due to comorbid conditions and were therefore candidates for IV iron treatment were initially considered for inclusion.

Patients were excluded if they had known intolerance or hypersensitivity to iron preparations, hepatic failure, were receiving immunosuppressive therapy, had an existing hematological disorder, active gastrointestinal bleeding, or malignancy. Patients with active malignancy were excluded, as cancer and its treatments may independently alter hematological parameters and quality of life, thereby confounding the study outcomes. Additionally, patients with incomplete data were excluded from the final analysis.

After applying these exclusion criteria and accounting for missing data, a total of 528 patients were included in the final study cohort. Ethical approval was obtained prior to study initiation and granted by the Ethics Committee of Ankara Etlik City Hospital (Approval No: AESH-EK1-2023-751).

Treatment Protocol

All patients included in the study received ferric carboxymaltose as IV iron therapy. The drug was diluted in 0.9% isotonic saline and administered via IV infusion over 15–20 minutes.

Dosage was individualized for each patient based on pre-treatment hemoglobin (Hb) level, body weight (kg), and target Hb level. The total iron requirement was calculated using the Ganzoni formula: Total iron dose (mg) = [Target Hb − Actual Hb (g/dL)] × Body weight (kg) × 2.4 + 500 mg (iron stores).[9,10]

Administration protocol was as follows: doses of 500 mg or 1000 mg were delivered in a single session; 1500 mg was administered in two sessions—1000 mg initially and 500 mg one week later; and 2000 mg was administered as two separate infusions of 1000 mg, one week apart.

Following each infusion, patients were monitored in the hospital for 6 hours to observe for any immediate adverse reactions, including anaphylaxis or drug intolerance. After discharge, patients were instructed to record any side effects in a daily log over a 30-day period. Delayed and long-term adverse events were assessed based on these patient-reported

records. During the 30-day follow-up, patients were monitored for biochemical and clinical changes, including musculoskeletal symptoms such as myalgia or arthralgia potentially related to hypophosphatemia.

Patient Data

Sociodemographic and clinical characteristics—including age, sex, height, weight, body mass index (BMI), etiology of anemia, and total administered iron dose—were recorded for all participants.

Laboratory parameters, including Hb, white blood cell count (WBC), platelet count, folate, ferritin, vitamin B12, transferrin saturation, creatinine, calcium, phosphorus, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), and gamma-glutamyl transferase (GGT), were measured at baseline and at 30 days post-treatment.

Adverse events occurring from the start of treatment through day 30 were documented based on patient self-reports and clinical observations. The severity of these events was classified according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

Quality of Life Assessment

Patients' quality of life was evaluated using the WHOQOL-BREF scale both before and 30 days after intravenous iron therapy. The questionnaire was administered through face-to-face interviews, with each session taking approximately 20 minutes.

The WHOQOL-BREF instrument measures quality of life across four domains: physical health, psychological well-being, social relationships, and environmental factors. Domain scores were calculated and compared pre- and post-treatment.[7] The Turkish validation and reliability of the scale were previously established by Eser et al.[8]

Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize patient characteristics, with continuous variables presented as mean ± standard deviation (SD) and categorical variables as frequencies and percentages.

Paired t-tests were applied to compare laboratory parameters and WHOQOL-BREF scores before and after treatment. A two-sided p-value of <0.05 was considered statistically significant.

Receiver Operating Characteristic (ROC) curve analysis was conducted to evaluate the predictive value of total treatment dose and baseline serum phosphorus levels for the development of hypophosphatemia. The area under the curve (AUC) was calculated to assess model performance, and statistical significance was determined accordingly.

Results

A total of 528 patients were included in the study. The mean age of the participants was 41.56 ± 12.33 years, and 92.42% were women. The mean BMI was calculated as 26.31 ± 4.91 kg/m^2. The mean administered dose of ferric carboxymaltose was 1,258.52 ± 405.05 mg.

The most common etiologic factor for IDA was polymenorrhea, observed in 380 patients (72.0%). This was followed by atrophic gastritis in 42 patients (8.0%), history of bariatric surgery in 40 patients (7.6%), celiac disease in 21 patients (4.0%), gastrointestinal (GI) operations in 20 patients (3.8%), previous GI bleeding in 14 patients (2.6%), and inflammatory bowel diseases in 11 patients (2.1%).

A total of 60 patients (11.36%) reported mild treatment-related adverse effects. The most frequently observed side effects were headache (n = 18, 3.4%) and local irritation at the IV administration site (n = 18, 3.4%). These were followed by myalgia and arthralgia (n = 15, 2.84%), elevated blood pressure (n = 9, 1.7%), low back pain (n = 5, 0.94%), mild allergic reactions (n = 3, 0.56%), and palpitations (n = 2, 0.5%). Importantly, no serious allergic or anaphylactic reactions were observed during the 6-hour hospital monitoring period or within the 30-day post-treatment follow-up period (Table 1).

When the WHOQOL-BREF scores before and 30 days after treatment were compared, a statistically significant improvement was observed in general health status, physical health, and psychological health domains ($p < 0.001$ for all).

Table 1 Sociodemographic and Clinical Characteristics of the Patients (N:528)

Characteristic	Value/n (%)
General Characteristics	
Age (years, mean ± SD)	41.56 ± 12.33
BMI (kg/m^2, mean ± SD)	26.31 ± 4.91
Treatment Drug Dose (mg, mean ± SD)	1,258.52 ± 405.05
Gender (Female/Male)	488/40 (92.42%/7.58%)
Etiological Distribution	
Polymenorrhea	380 (72.0%)
Bariatric surgery	40 (7.6%)
Atrophic gastritis	42 (8.0%)
Celiac disease	21 (4.0%)
GIS operation	20 (3.8%)
IBD	11 (2.1%)
GIS bleeding	14 (2.6%)
Adverse Effects Observed After Treatment	
Headache	18 (3.4%)
Local injection site irritation	18 (3.4%)
Myalgia/Arthralgia	15 (2.84%)
Increased blood pressure	9 (1.7%)
Back pain	5 (0.94%)
Allergic reaction	3 (0.56%)
Palpitations	3 (0.5%)
Patients with ≥1 adverse effect	60 (11.36%)

Abbreviations: BMI, Body Mass Index; GIS, Gastrointestinal System; IBD, Inflammatory Bowel Disease; SD, Standard Deviation; kg/m^2, kilogram per square meter; mg, milligram; %, percentage.

Specifically, the general health status score increased from 30.9 ± 31.78 to 44.32 ± 37.01, physical health from 36.88 ± 33.53 to 43.22 ± 37.55, and psychological health from 45.08 ± 37.82 to 47.61 ± 40.07. However, no statistically significant changes were noted in the social health domain ($p = 0.260$) or the environmental health domain ($p = 0.354$).

Laboratory findings also revealed significant improvements after treatment. Hb levels increased from 9.17 ± 1.36 g/dL at baseline to 13.12 ± 0.82 g/dL post-treatment ($p < 0.001$). Ferritin levels demonstrated a substantial rise from 6.23 ± 4.38 ng/mL to 178.91 ± 123.99 ng/mL ($p < 0.001$). The wide standard deviation in post-treatment ferritin levels is likely due to dose heterogeneity, with baseline deficiency severity. Similarly, transferrin saturation increased from 5.51 ± 2.50% to 35.46 ± 17.11% ($p < 0.001$).

In contrast, statistically significant decreases were observed in vitamin B12 and folate levels (both $p < 0.001$). WBC counts decreased from 6,738.85 ± 1,699.96 to 6,540 ± 3,664.76 ($p < 0.001$), and platelet counts decreased from 347.04 ± 98.75 to 258.95 ± 66.48 ($p < 0.001$). Among liver function parameters, ALT, GGT, and ALP levels increased

significantly after treatment ($p < 0.001$ for all). Additionally, serum creatinine levels increased from 0.66 ± 0.61 to 0.72 ± 0.61, and although the absolute change was small, it was statistically significant ($p = 0.047$).

Serum phosphorus levels showed a significant decrease from 3.37 ± 2.05 mg/dL to 2.59 ± 0.82 mg/dL ($p < 0.001$), whereas the increase in serum calcium levels did not reach statistical significance ($p = 0.275$) (Table 2).

On day 30 post-treatment, the majority of patients achieved target values in key hematological parameters. Specifically, 95.26% of the cohort reached the target hemoglobin level, 98.11% reached the target ferritin level, and 93.18% reached the target transferrin saturation level (Figure 1).

With regard to phosphorus status, serum levels on day 30 revealed that 53.0% of patients had phosphorus concentrations above 2.5 mg/dL (within normal limits), 34.1% had levels between 1.51–2.5 mg/dL (mild to moderate hypophosphatemia), and 12.9% had levels below 1.5 mg/dL (severe hypophosphatemia) (Figure 2).

Receiver Operating Characteristic (ROC) curve analysis was used to determine the predictive value of total iron dose and baseline phosphorus level for the development of hypophosphatemia. The area under the curve (AUC) for iron dose was 0.599 ($p = 0.000$), suggesting a statistically significant but modest predictive ability. Based on this, a cut-off value of 1750 mg was identified as the threshold dose associated with increased risk (Figure 3).

Table 2 WHOQOL-BREF Questionnaire and Laboratory Results of Patients Before and 30 Days After Treatment (N:528)

Parameter	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	P-value
General Health Status	30.9 ± 31.78	44.32 ± 37.01	0.000
Physical Health	36.88 ± 33.53	43.22 ± 37.55	0.000
Psychological Health	45.08 ± 37.82	47.61 ± 40.07	0.000
Social Health	45.47 ± 39.48	47.05 ± 41.92	0.260
Environmental Health	46.98 ± 38.23	47.82 ± 39.25	0.354
Hemoglobin (g/dL)	9.17 ± 1.36	13.12 ± 0.82	0.000
Hematocrit (%)	31.63 ± 3.49	42.20 ± 2.72	0.000
Ferritin (ng/mL)	6.23 ± 4.38	178.91 ± 123.99	0.000
Platelet Count 10^9/L	347.04 ± 98.75	258.95 ± 66.48	0.000
White Blood Cell Count 10^9/L	6738.85 ± 1699.96	6540 ± 3664.76	0.000
Folate (ng/mL)	7.96 ± 3.39	6.54 ± 3.12	0.000
Vitamin B12 (pg/mL)	422.15 ± 202.68	402.05 ± 228.91	0.000
ALT (IU/L)	14.34 ± 6.65	19.67 ± 12.02	0.000
GGT (IU/L)	16.88 ± 12.69	22.34 ± 18.75	0.000
ALP (IU/L)	70.34 ± 19.77	75.35 ± 23.14	0.000
Calcium (mg/dL)	9.15 ± 0.36	9.34 ± 3.93	0.275
Phosphorus (mg/dL)	3.37 ± 2.05	2.59 ± 0.82	0.000
Creatinine (mg/dL)	0.66 ± 0.61	0.72 ± 0.61	0.047

Notes: Data are presented as mean ± standard deviation. P-values represent comparisons between baseline and 30 days post-treatment using paired statistical tests. Values of $p < 0.05$ were considered statistically significant. **Abbreviations**: WHOQOL-BREF, World Health Organization Quality of Life–BREF; ALT, Alanine aminotransferase; GGT, Gamma-glutamyl transferase; ALP, Alkaline phosphatase; SD, Standard deviation; g/dL, grams per deciliter; ng/mL, nanograms per milliliter; pg/mL, picograms per milliliter; IU/L, international units per liter; mg/dL, milligrams per deciliter; 10^9/L, billions per liter; %, percentage.

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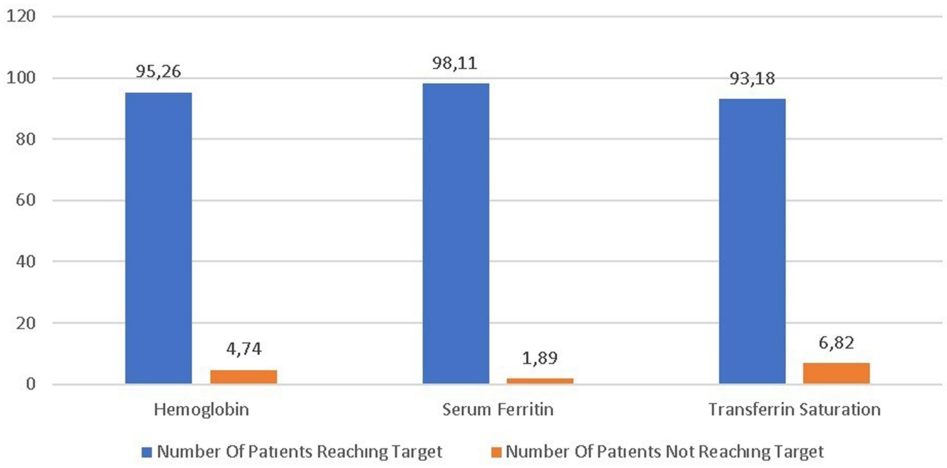

Figure 1 Target value reaching rates of patients on the 30th day after treatment.

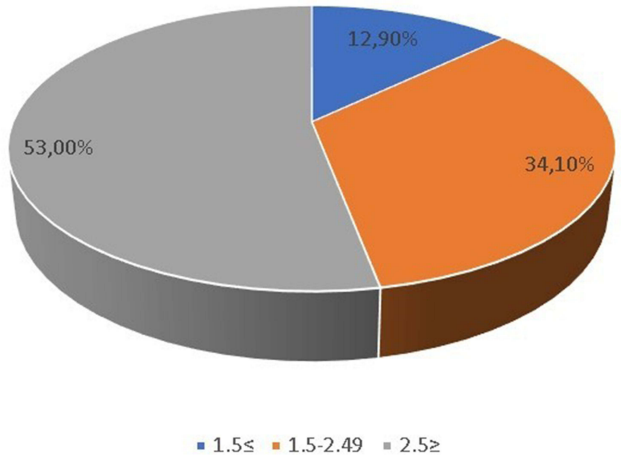

Figure 2 Phosphorus values of patients on the 30th day after treatment.

A separate ROC analysis showed that the AUC for baseline phosphorus level was 0.761 ($p < 0.001$), indicating a stronger predictive capacity. The optimal cut-off value for pre-treatment serum phosphorus level was determined to be 3.05 mg/dL (Figure 4).

Discussion

This prospective observational study evaluated the efficacy, safety, and impact on quality of life of IV ferric carboxymaltose therapy in patients with IDA. The findings demonstrated that ferric carboxymaltose administration resulted in significant improvements in hematological parameters as well as in multiple domains of quality of life, and was generally well tolerated by the study population.

Assessment of etiological factors revealed that polymenorrhea was the most common underlying cause of IDA, underscoring the ongoing public health burden of iron deficiency among women of reproductive age. Other identified etiologies included atrophic gastritis, previous bariatric surgery, celiac disease, and gastrointestinal surgical history, indicating that the study cohort was clinically diverse and representative of real-world IDA populations.[11,12] In our study, subgroup analyses comparing hematologic responses between patients with polymenorrhea and those with other

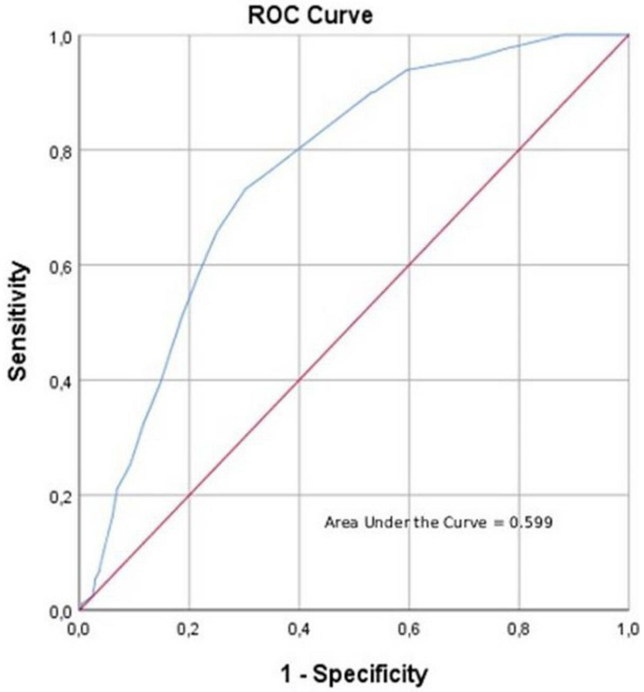

Figure 3 ROC analysis of the effect of treatment dose on hypophosphatemia in patients.

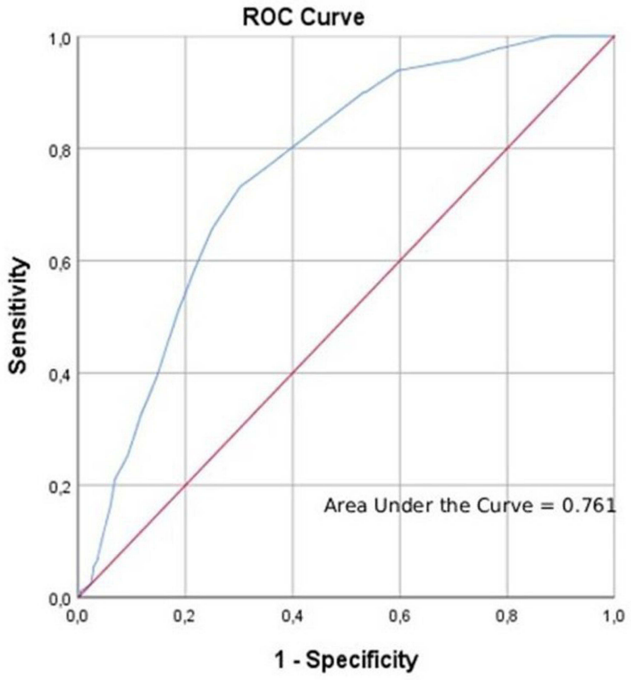

Figure 4 ROC analysis of the relationship between hypophosphatemia and pre-treatment phosphorus level on the 30th day after treatment.

etiologies were not performed. This decision was primarily driven by the observational design and the unequal distribution of etiologic subgroups. However, future studies using subgroup designs could provide valuable insight into whether ongoing loss of menstrual bleeding affects hemoglobin increase and treatment response differently than non-gynecologic causes of IDA.

The high proportion of patients who achieved target levels of Hb, ferritin, and transferrin saturation by day 30 post-treatment underscores the hematological efficacy of ferric carboxymaltose. This aligns with prior studies demonstrating its rapid and effective action in patients intolerant to or unresponsive to oral iron therapy.[13–15] The robust post-treatment increases observed in hematologic parameters in our study further support its high bioavailability and therapeutic potency. These findings contribute to the growing body of evidence on the effectiveness and tolerability of ferric carboxymaltose.

The incidence of mild adverse events in our cohort was 13.34%, consistent with previously reported rates,[16–18] thereby reaffirming its favorable safety profile. The most frequently reported side effects included headache, localized injection site irritation, myalgia, arthralgia, and transient elevations in blood pressure. Importantly, no serious allergic or anaphylactic reactions were observed. Overall, these results indicate that ferric carboxymaltose is well tolerated and comparable in safety to other modern IV iron formulations.

In our study, IV ferric carboxymaltose therapy led to significant improvements in patients' quality of life. According to the WHOQOL-BREF assessment, statistically significant increases were observed in the domains of general health status, physical health, and psychological well-being. These findings support the view that iron deficiency is not merely a hematologic abnormality, but a systemic condition that plays a central role in various physiological processes, including energy metabolism, neurotransmitter synthesis, muscle function, and immune system regulation.[19]

The marked improvement in general health scores suggests an overall enhancement in patients' perceived well-being following treatment. Improvements in physical health are likely attributable to the resolution of hallmark symptoms of iron deficiency such as fatigue, weakness, and reduced exercise tolerance. Likewise, the observed improvement in psychological health may reflect the amelioration of cognitive dysfunction, irritability, and mood disturbances commonly associated with anemia.

In contrast, no statistically significant changes were detected in the domains of social relationships or environmental health. This may be due to the fact that these domains are more strongly influenced by stable external factors—such as socioeconomic status, environmental conditions, and social support systems—which tend to change more gradually. It is also plausible that improvements in these domains require longer follow-up periods to become evident. Therefore, future studies with extended follow-up are warranted to investigate potential delayed changes in social and environmental aspects of quality of life. Our findings are in line with previous reports demonstrating that intravenous iron therapy can have a positive impact on quality of life in patients with IDA.[20–22] Collectively, these observations emphasize that IDA is a multisystem disorder and highlight the importance of a multidisciplinary treatment approach to achieve optimal patient-centered outcomes.

In addition, our study identified statistically significant reductions in serum vitamin B12 and folate levels following IV ferric carboxymaltose administration. This finding highlights the importance of monitoring not only iron indices but also associated micronutrient levels during the management of IDA. Although previous studies have not consistently reported significant changes in vitamin B12 or folate following iron replacement, it has been suggested that iron therapy may increase the metabolic consumption of these vitamins by stimulating erythropoiesis.[23,24] This mechanism raises the possibility of post-treatment deficiencies, particularly in individuals with marginal B12 or folate status prior to therapy. Accordingly, pre-treatment evaluation and appropriate supplementation when indicated may enhance treatment outcomes and prevent potential micronutrient imbalances. However, routine posttreatment vitamin B12 and folate monitoring in patients within the normal range before treatment may not be cost-effective or clinically necessary because the changes observed were minimal and likely to be of limited clinical significance.

Statistically significant reductions in WBC and platelet counts were observed in the laboratory assessments performed on the 30th day following intravenous ferric carboxymaltose administration. Although the decrease in WBC count remained within physiological limits, it may reflect a reduction in systemic inflammatory activity or a modulation of immune function induced by the treatment. The significant decline in platelet count, which has also been documented in previous studies, may be attributed to regulatory effects of iron therapy on the thrombopoietic system.[25,26] Importantly, all values remained within reference ranges, and no cases of clinically significant leukopenia or thrombocytopenia were observed in the study population.

Elevations in liver enzyme levels—including ALT, GGT, and ALP—were also detected at day 30 post-treatment. These findings suggest potential pharmacological effects of intravenous iron administration on hepatocellular function. Our results are consistent with earlier reports indicating that ferric carboxymaltose may cause transient, subclinical increases in hepatic enzyme levels.[27,28] Although these elevations did not reach clinical significance, they underscore the importance of monitoring liver function tests before and after treatment, particularly in patients with pre-existing liver disease.

Regarding renal parameters, a statistically significant yet clinically negligible increase in serum creatinine levels was observed. This modest change is likely attributable to transient alterations in renal perfusion or fluid homeostasis following intravenous iron administration.[28] However, the long-term clinical relevance of this finding remains unclear and warrants further investigation through prospective studies with extended follow-up durations focused on renal safety.

A significant reduction in serum phosphorus levels observed on day 30 following treatment in this study is consistent with hypophosphatemia, a well-recognized adverse effect associated with ferric carboxymaltose administration.[29] Previous reports in the literature have highlighted that ferric carboxymaltose may pose a greater risk of inducing hypophosphatemia, with a potentially prolonged recovery period compared to other IV iron formulations.[30] Despite the decline in phosphorus levels, no statistically significant changes were noted in serum calcium levels.

In most cases, hypophosphatemia is clinically asymptomatic and remains within tolerable limits. However, the observation of phosphorus levels below 1.5 mg/dL—classified as severe hypophosphatemia—in some patients by day 30 post-treatment underscores the potential clinical relevance of this adverse effect. Persistently low phosphorus levels may lead to serious complications, including osteomalacia, osteoporosis, and cardiovascular dysfunction. These findings reinforce the need for prospective research to evaluate the long-term clinical implications of treatment-induced hypophosphatemia. In our study, a small number of patients—mostly women with severe hypophosphatemia—reported mild, transient musculoskeletal symptoms such as myalgia or arthralgia, which resolved without intervention. No severe or disabling manifestations were observed during the 30-day follow-up period. However, as the follow-up did not extend beyond 30 days, late-onset clinical consequences could not be evaluated.

Receiver Operating Characteristic curve analysis in our study revealed that both the total administered dose of ferric carboxymaltose and baseline phosphorus levels were statistically significant predictors of post-treatment hypophosphatemia. A ferric carboxymaltose dose of 1750 mg or higher was associated with increased hypophosphatemia risk (AUC=0.599; p=0.000), while a baseline phosphorus level of ≤3.05 mg/dL emerged as a strong predictive factor (AUC=0.761; p<0.001). These results suggest that individuals receiving high-dose intravenous iron and exhibiting low pre-treatment phosphorus levels may benefit from prophylactic phosphorus supplementation. Conducting a baseline phosphorus evaluation may be a clinically prudent strategy to mitigate potential complications.

This study has several limitations that should be acknowledged. Primarily, its single-center and observational design may restrict the generalizability of the findings. Furthermore, the absence of a control group limits the ability to directly compare the efficacy and safety of ferric carboxymaltose against other available treatment modalities. Moreover, it is not possible to completely exclude the possible confounding effects of concomitant diseases and medications used on both biochemical results and quality of life. Another limitation of this study is the lack of follow-up beyond 30 days, which may have prevented the detection of late-onset clinical signs of hypophosphatemia. Lastly, the assessment of quality of life was restricted to a 30-day follow-up period, which may not fully capture the long-term impact of therapy.

Conclusion

This prospective observational study demonstrated that IV ferric carboxymaltose is an effective and well-tolerated treatment option for patients with IDA. In addition to its strong hematologic efficacy, it improved patients' quality of life. More importantly, the absence of serious adverse events during the follow-up period supports the favorable safety profile of this treatment in routine clinical use. However, our study also revealed a significant risk of hypophosphatemia in individuals receiving high cumulative ferric carboxymaltose doses and those with low baseline phosphorus levels. This finding supports the need for careful monitoring of phosphorus levels before and after treatment and replacement if deficiencies are detected.Given the potential for both acute and long-term complications of hypophosphatemia, including osteomalacia and cardiovascular effects, further studies are needed to clarify its clinical consequences and identify preventive and therapeutic strategies for high-risk patients.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request. However, due to privacy and ethical considerations, the data are not publicly available.

Ethics Approval and Informed Consent

All procedures involving human participants were conducted in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments. This study was approved by the Etlik City Hospital Research Ethics Committee (Approval No: AESH-EK1-2023-751).

Acknowledgment

The authors have no acknowledgments to declare.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Consent for Publication

This study does not contain any individual person's data in any form (including images, videos, or recordings).

Consent to Participate

Written informed consent was obtained from all individual participants included in the study.

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Disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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