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Evaluation of Clinical Characteristics and Treatment Appropriateness in Patients Receiving Intravenous Iron Therapy

Mert Tokatli,[1] Neslihan Nisa Gecici,[2] Eray Peker,[2] Ezgi Aysu Sahin Mavi,[1] Berat Baran,[1] Oguz Abdullah Uyaroglu[3]

[1]Department of Internal Medicine, Hacettepe University Faculty of Medicine, Ankara, Türkiye
[2]Hacettepe University Faculty of Medicine, Ankara, Türkiye
[3]Department of General Internal Medicine, Hacettepe University Faculty of Medicine, Ankara, Türkiye

ABSTRACT

Objective: Intravenous (IV) iron is frequently used to treat iron deficiency. While IV therapy offers several benefits, it also has drawbacks, including high costs, potential allergic reactions, and the need for hospitalization. This study aimed to assess patient- and disease-related factors in IV iron therapy and to re-evaluate treatment appropriateness using an algorithm developed from current guideline recommendations.

Materials and Methods: This retrospective, single-center study included patients receiving IV iron at a tertiary care hospital between May 2 and October 15, 2023. Threshold values for iron deficiency, based on a review of current guidelines, were defined as ferritin <30 µg/L or, when C-reactive protein (CRP) ≥5 mg/L, ferritin <100 µg/L and transferrin saturation (TSAT) <20%.

Results: A total of 264 patients were re-evaluated. IV iron therapy was deemed inappropriate in 81 patients (31%). The primary reason for inappropriateness in 74 patients (28%) was the lack of preference for oral iron therapy as the first-line option. Inappropriate treatment was significantly more frequent in the group without anemia (p<0.001) and among patients over 65 years old (p=0.03).

Conclusion: Developing treatment algorithms that integrate evidence, patient factors, and clinical experience may help reduce unnecessary costs and improve prescription quality.

Keywords: Anemia, iron deficiency, intravenous iron.

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Address for correspondence:
Mert Tokatli.
Department of Internal Medicine, Hacettepe University Faculty of Medicine, Ankara, Türkiye
Phone: +90 544 205 54 00
E-mail:
merttokatli17@gmail.com

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INTRODUCTION

Iron deficiency (ID) and iron deficiency anemia (IDA; low hemoglobin or hematocrit resulting from iron deficiency) are significant public health problems affecting a large portion of the population.[1] The underlying causes include malnutrition, malabsorption, and gastrointestinal or gynecologic bleeding. Iron treatment recommendations may vary according to comorbid diseases. Oral iron is generally recommended as the first-line treatment for ID, with a few exceptions, such as in patients with heart failure (HF) with reduced ejection fraction, chronic kidney disease (CKD), malabsorption syndromes (e.g., celiac disease, inflammatory bowel disease [IBD]), or following bariatric surgery.[2]

In recent years, intravenous (IV) iron therapy has become more common for ID/IDA due to its advantages, including rapid clinical response, avoidance of gastric mucosal irritation, and fewer side effects with an improved safety profile. However, IV iron therapy can only be administered in a hospital setting, requires venous access, may cause allergic reactions, and can lead to complications such as hypophosphatemia. It also increases the risk of infection and, most importantly, is expensive. Therefore, IV iron should be used judiciously in appropriate patients.

In this study, we developed an algorithm (Fig. 1) based on current guidelines to evaluate the appropriateness of IV iron therapies administered in the daily treatment unit of a tertiary care university hospital.

KEY MESSAGES

- A real-life, retrospective evaluation of intravenous iron therapy use was conducted in a tertiary care hospital.
- Intravenous iron therapy was found to be inappropriate in 31% of patients, primarily due to not preferring oral iron as the first-line treatment.
- The study underscores the need to rationalize IV iron use, reduce unnecessary healthcare costs, and improve prescription quality.

MATERIALS AND METHODS

Population

This retrospective, single-center, observational study was conducted among outpatients who received IV iron therapy in the Daily Treatment Unit of a tertiary care university hospital between May 2 and October 15, 2023. All patients over 18 years of age receiving IV iron therapy were included in the study. Participants who provided informed consent were eligible. The study was approved by the University Health Sciences Research Ethics Committee (Approval Date: 15/12/2023, Approval Number: SBA 23/415). This study was conducted in accordance with the ethical standards outlined in the Declaration of Helsinki.

Relevant patient information was obtained from the electronic hospital database. The patient's age, sex, comorbid diseases, routine medications, symptoms, history of oral iron therapy or intolerance, and hematologic laboratory parameters were recorded. As a retrospective study, no formal sample size calculation was performed; all eligible patients were included.

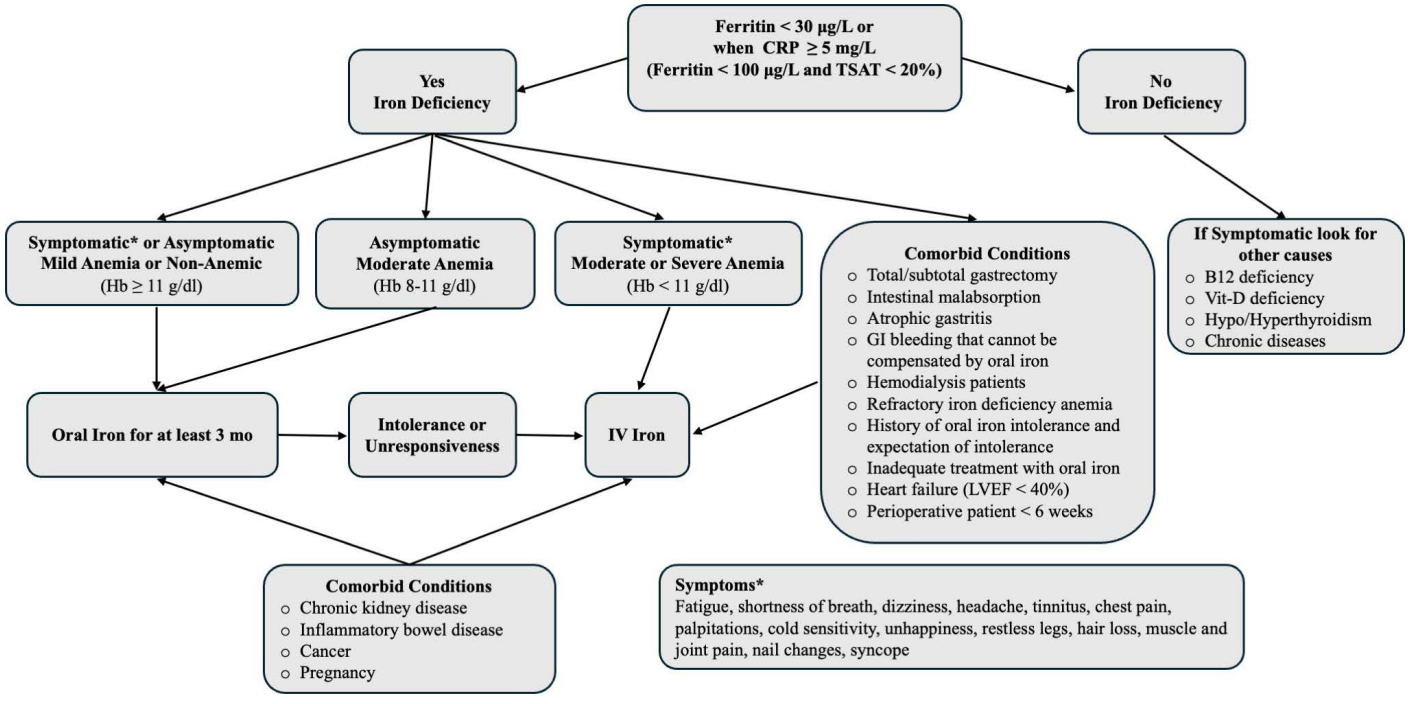

Figure 1. Iron treatment algorithm for the general population.

Hb: Hemoglobin; CRP: C-reactive protein; TSAT: Transferrin saturation; Mo: Month. Iron deficiency treatment recommendations for comorbid conditions are provided in Table 1.

Table 1. Iron deficiency treatment recommendations from current guidelines

Morbidity	Guideline	Iron deficiency treatment recommendations
Heart failure	ESC (2021)[20]	• Ferritin <100 µg/L, or ferritin <300 µg/L with TSAT <20% • LVEF <45% • LVEF <50% with recent cardiac decompensation and hospitalization
CKD	NICE (2021)[21]	• TSAT ≤20% and ferritin ≤800 µg/L, or ferritin ≤100 µg/L • Hemodialysis patients with Hb <11g/dL or receiving ESA • Oral iron recommended for CKD patients not on hemodialysis or ESA
IBD	ECCO (2015)[22]	• Ferritin <30 µg/L, or with inflammation, ferritin <100 µg/L • IV iron recommended in patients with active IBD, prior oral iron intolerance, Hb <10 g/dL, or ESA use • Oral iron recommended for inactive IBD
Cancer	ESMO (2018)[23]	• Ferritin <100 ng/mL • Hb ≤11 g/dL, or Hb drop ≥2 g/dL from a baseline ≤12 g/dL
Pregnancy	IDA Working Group Consensus Report (2015)[24]	• Minimum Hb threshold in pregnancy: <11 g/dL in the 1st and 3rd trimesters; <10.5 g/dL in 2nd trimester • Oral iron therapy is first-line for IDA • IV iron therapy may be preferred, when rapid iron replacement is required

Hb: Hemoglobin; ESA: Erythropoiesis-stimulating agent; CKD: Chronic kidney disease; IBD: Inflammatory bowel disease; TSAT: Transferrin saturation; IDA: Iron deficiency anemia.

Searching and Screening for Eligible Guidelines

We searched various English-language sources, including databases and websites (Pubmed, SCOPUS, Google, Yandex, Trip Medical Database, and the World Health Organization) for relevant Clinical Practice Guidelines (CPGs) related to the topic. The following keywords were used: iron, iron deficiency, iron deficiency anemia, anemia, iron treatment, iron replacement, oral iron, and intravenous iron. The final search date was April 1, 2024.

Assessment and Definitions

By compiling the most current and valid guidelines for the general population, we determined the definitions of anemia, ID, and IDA as follows. According to the World Health Organization (WHO) definition, anemia was defined as a blood hemoglobin (Hb) level below 13 g/dL in men (15-65 years), below 12 g/dL in women (15-65 years, nonpregnant), and below 11 g/dL in pregnant women.[3] ID was defined as ferritin <30 µg/L or ferritin <100 µg/L when C-reactive protein ≥5 mg/L and transferrin saturation (TSAT) <20%.[4,5] Anemic patients whose iron parameters were consistent with ID were classified as having IDA.

Following the definitions, we determined ID and IDA treatment recommendations according to the most current and valid guidelines from relevant societies for the general population and for different clinical scenarios (HF, IBD, CKD, cancer, and pregnancy). These recommendations are presented in Table 1.

Algorithm for Reassessment of IV Iron Therapy

We created an algorithm based on these definitions and treatment recommendations, taking into account symptom severity, anemia level, history of oral iron use, response to oral iron treatment, oral iron intolerance, and other comorbid conditions (Fig. 1). All patients were evaluated for compliance with this algorithm. The appropriateness of all treatments was assessed by all authors, who thoroughly reviewed each patient's clinical condition according to the algorithm. In cases of disagreement, a consensus was reached by majority agreement. Inter-rater reliability of the algorithm was evaluated in a random sample of 50 cases independently assessed by two authors, showing substantial agreement (Cohen's κ=0.82).

Statistics Analysis

All statistical analyses were performed using SPSS version 27 (IBM, Armonk, NY, USA). For descriptive statistics, numbers and percentages were reported for categorical variables. For continuous variables with a normal distribution, the mean and standard deviation (SD) were used; for non-normally distributed continuous variables, the interquartile range (IQR) was reported. The Pearson chi-squared test or Fisher's exact test was used to evaluate categorical variables. The suitability of variables for normal distribution was assessed using both visual and analytical methods.

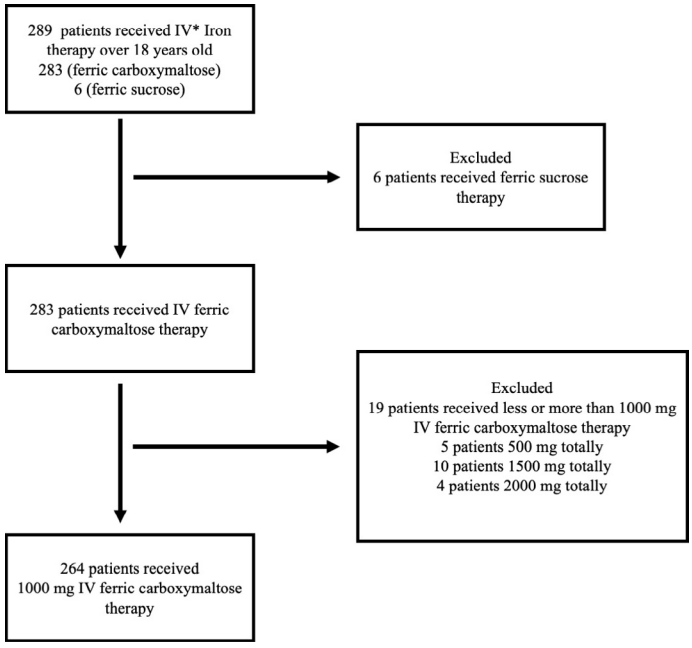

Figure 2. Flow chart of the patients receiving intravenous iron included in the study.

*: Intravenous.

Non-normally distributed numerical data were analyzed using the Mann-Whitney U test or Kruskal-Wallis test. The paired Student's t-test was used to compare pre- and post-treatment Hb levels, while the Wilcoxon test was used for ferritin and phosphate levels. The McNemar test was applied to compare the proportions of anemic patients before and after treatment. To identify independent predictors of inappropriate intravenous iron use, a multivariable logistic regression analysis was performed. For all comparisons, a p value <0.05 was considered statistically significant.

RESULTS

The study included 289 patients who received IV iron therapy between May 2 and October 15, 2023. Two main iron preparations were used: ferric carboxymaltose (98%) and ferric sucrose (2%). For statistical comparison, we evaluated only the patient population that received ferric carboxymaltose. Due to the unavailability of patient weight data, we could not determine whether the intravenous iron replacement dose was appropriate based on weight. To ensure consistency, we included only patients who received a single dose of 1,000 mg ferric carboxymaltose, as prescribed by their physician. Consequently, the final study population comprised 264 patients over 18 years of age who received a 1,000 mg IV ferric carboxymaltose replacement (Fig. 2).

Table 2. Clinical and demographic characteristics of the patients

	All patients (n=264)
Age, median (IQR)	49 (37.5–69.5)
Sex, n (%)	
Male	49 (18.6)
Female	215 (81.4)
Comorbid conditions related to iron treatment, n (%)	
Chronic kidney disease	26 (9.8)
Heart failure (LVEF <50%)	14 (5.3)
Active cancer	11 (4.1)
History of bariatric surgery	11 (4.1)
Gastrointestinal bleeding	9 (3.4)
Inflammatory bowel disease	8 (3)
Atrophic gastritis	6 (2.3)
Celiac disease	4 (1.5)
Perioperative patient	3 (1.1)
Refractory iron deficiency anemia	1 (0.4)
Routine medications, n (%)	
Antiplatelet	54 (20.5)
Anticoagulant	27 (10.2)
Steroid/NSAIDs	35 (13.2)
PPIs/H2RA	68 (25.8)
History of oral iron therapy, n (%)	
Yes	105 (40)
No	159 (60)
Anemia, n (%)	
Yes	213 (80.7)
No	51 (19.3)
Anemia status by sex, n (%)	
Female (Hb <12 g/dL)	174 (80.9)
Male (Hb <13 g/dL)	39 (79.6)
Iron deficiency, n (%)	
Yes	257 (97.3)
No	7 (2.7)
Iron deficiency anemia, n (%)	
Yes	207 (78.4)
No	57 (21.6)

NSAID: Non-steroidal anti-inflammatory drug; IQR: interquartile range; LVEF: Left ventricular ejection fraction; PPI: Proton pump inhibitor; H2RA: Histamine-2 receptor antagonist. Percentages may not sum to 100% as some patients were taking more than one medication

Table 3. Hematologic parameters before intravenous (IV) treatment

Laboratory parameter	
Hemoglobin, g/dL, mean (SD)	10.5 (1.8)
MCV, fL, median (IQR)	81.2 (74.7–86.5)
MCH, g/L, median (IQR)	25.6 (22.1–27.8)
Ferritin, g/dL, median (IQR)	6.2 (3.6–12.2)
Serum iron, µg/dL, median (IQR)	27 (18–43.7)
TSAT, %, median (IQR)	7 (4–11)

MCV: Mean corpuscular volume; MCH: Mean corpuscular hemoglobin; TSAT: Transferrin saturation; SD: Standard deviation; IQR: Interquartile range.

Table 4. Multivariate logistic regression analysis of factors associated with treatment appropriateness

Variable	OR	95% CI	p
Age >65 years	2.04	1.08–3.86	0.029
Female sex	0.89	0.41–1.91	0.755
Absence of anemia	7.31	3.7–14.29	<0.001

OR: Odds ratio; CI: Confidence interval. Statistically significant associations are indicated in bold.

Patient Characteristics

The demographic and clinical characteristics of the 264 patients included in the study are presented in Table 2. The median age was 49 years (IQR: 37-69), and most patients, 215 (81.4%), were female. Women were more commonly in the younger age group (53% of women were aged 18-45 years), whereas men were predominantly older than 65 years (63.3% of men; p<0.001).

Anemia was present in 213 patients (80.7%). A total of 257 patients (97.3%) were diagnosed with ID, while 207 patients (78.4%) had IDA. One patient had neither ID nor anemia. There was no statistically significant difference between sexes in the prevalence of ID, IDA, or anemia. Hematologic parameters before IV treatment are shown in Table 3. The mean hemoglobin level before IV iron therapy was 10.5 g/dL (SD 1.82), and the median ferritin level was 6.25 µg/L (IQR 3.6-12.2).

CKD, HF, IBD, and celiac disease were the main comorbid conditions. Among women, 34 patients (15.81%) reported heavy menstrual bleeding. No drug reaction or anaphylaxis occurred that required stopping the infusion.

Appropriateness of IV Iron Treatment According to the Algorithm

In 81 patients (30.7%) who received IV iron therapy, treatment was considered inappropriate according to our algorithm (Fig. 3). This group included 19 males (23.5%) and 62 females (76.5%), with no statistically significant difference between sexes (p=0.392). The rate of inappropriate treatment was higher among patients aged ≥65 years (33 [40.2%] vs 48. [26.4%], p=0.03). Inappropriate treatment was also more frequent in patients without anemia (62.7% vs. 23%, p<0.001), without IDA (66.7% vs. 20.8%, p<0.001), and without ID (100% vs. 28.8%, p<0.001).

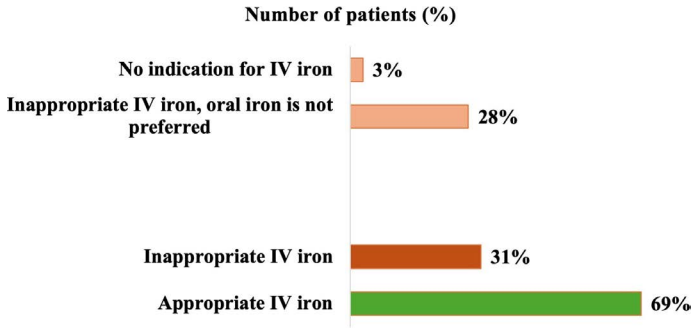

Figure 3. Appropriateness rates of IV iron treatment according to the algorithm.

Anemia was absent in 32 patients (39.5%) in the inappropriate treatment group. Additionally, 38 patients (46.8%) had no IDA, and seven patients (2.6%) had no ID at all. The main reason for inappropriateness was the failure to prefer oral iron therapy as the first-line treatment in 74 patients (91.4%). In the remaining seven patients (8.6%), the reason was the absence of ID. In this group, the mean Hb level was 11.64 g/dL (SD 1.52), the median ferritin level was 7.5 µg/L (IQR 4.3-20.6), and the median TSAT was 10.0% (IQR 6-20). Multivariable logistic regression analysis revealed that age ≥65 years and absence of anemia were independently associated with inappropriate intravenous iron use (Table 4).

Follow-Up After Intravenous Iron Therapy

After receiving IV iron treatment, anemia parameters were re-examined in 77 patients (29.1%) within three months. Hb was checked in all patients, but data on other iron parameters were not available. The pre-treatment mean Hb value was 10.1 g/dL (SD 1.78), and the post-treatment mean Hb value was 11.73 g/dL (1.87) in these 77 patients. The increase of 1.6 g/dL in Hb values was statistically significant (p<0.001).

Before treatment, 66 patients (85.7%) had anemia; after treatment, 39 patients (50.6%) had anemia (p<0.001, McNemar test). Anemia persisted in 37 (56.1%) of the 66 initially anemic patients, but the 1.0 g/dL increase in Hb value in this group was also statistically significant (p<0.001). Ferritin levels were measured in only 57 patients (21.5%) in this follow-up group.

Table 5. Comparison of laboratory parameters before and after treatment

Parameter	Time-point	Value	Difference	p
		Mean±SD/Median (IQR)		
Hemoglobin (g/dL)	Before	10.1 (1.8)	+1.6↑	<0.001
	After	11.7 (1.9)		
Phosphorus (mg/dL)	Before	3.76 (0.79)	-0.47↓	0.002
	After	3.29 (0.87)		
Ferritin (ng/mL)	Before	5.80 (5.20)	+116.50↑	<0.001

IQR: Interquartile range; SD: Standard deviation. Analysis was performed only in patients with available laboratory parameters at follow-up visits.

The median ferritin value before treatment was 5.80 g/dL (IQR 5.20), and after treatment it increased to 122.30 g/dL (IQR 178.35), a change that was statistically significant (p<0.001). This group also showed a significant rise in mean hemoglobin levels (pre-treatment: 10.2 vs. post-treatment: 11.9, p<0.001). Phosphate levels were reassessed in only 49 patients. The pre-treatment median phosphate level was 3.76 g/dL (IQR 0.79), and the post-treatment median level was 3.29 g/dL (IQR 0.87) (Table 5). This decrease was statistically significant (p=0.002). Hypophosphatemia developed in 10 (20.4%) of 49 patients. Due to missing follow-up data, not all parameters could be evaluated statistically.

DISCUSSION

By systematically evaluating the appropriateness of IV iron therapy, this study provides insights into current prescribing practices and highlights opportunities for optimization. Our findings support the notion that while IV iron therapy is effective, its use should be carefully targeted to appropriate patients to prevent unnecessary healthcare costs. In 81 patients (31%) who received IV ferric carboxymaltose therapy, treatment was deemed inappropriate according to the algorithm we developed, which was based on definitions and treatment recommendations and considered symptom severity, anemia level, history of oral iron use and treatment response, oral iron intolerance, and other comorbid conditions. The research confirms that IV iron replacement effectively increases hemoglobin levels and reduces the number of patients with anemia. However, it also highlights the growing prevalence of inappropriate IV therapy use in daily practice.

A recent study among inpatients in Switzerland found that 37% of IV iron therapy use was inappropriate,[6] with the main reason being the lack of preference for oral iron. In our study, 5.3% of patients receiving IV iron therapy had HF, and all of these cases were appropriate. Previous studies have demonstrated that IV iron therapy reduces hospitalization and cardiovascular mortality in patients with HF with reduced ejection fraction and ID.[7,8] However, in a recent randomized study of 3,065 HF patients with reduced ejection and ID, there was no significant difference in hospitalization, 6-minute walk test, or mortality.[9]

Treating anemia in CKD patients can be both clinically and economically beneficial.[10] Studies have shown that IV iron therapy achieves target hemoglobin values faster than oral iron.[11,12] However, oral iron therapy has also been proven effective in producing a statistically significant and sustained increase in hemoglobin levels while being well tolerated in patients with stage 3 or 4 CKD.[13] In our study, 22 patients (8.3%) had CKD, and 40.9% of IV iron therapy in this group was deemed inappropriate according to our algorithm. Among these, seven patients (31.8%) had not received oral iron therapy as a first-line treatment, and two patients (9.1%) did not have ID at all.

ID is a common condition that often occurs in individuals with IBD. Malabsorption, intestinal bleeding, or dietary choices can lead to iron deficiency in these patients. Studies suggest that IV iron therapy is often a better option than other treatments for iron deficiency in patients with IBD.[14]

Intravenous iron therapy containing dextran has been associated with increased rates of anaphylaxis and has been discontinued due to unfavorable safety profiles.[15] Infusion-related reactions are rare with modern IV iron preparations, such as ferric carboxymaltose, which was used in this study. However, hypersensitivity and infusion reactions are more common than with oral iron or placebo.[16] In our study, no cases of anaphylaxis were observed. The development of hypophosphatemia in 10 of 49 patients (20.4%) was significant. Hypophosphatemia has been reported with all parenteral iron preparations, and although it occurs more frequently with ferric carboxymaltose than with other formulations, its clinical significance is unclear.[17] According to the 2020 recommendations from the Medicines and Healthcare Products Regulatory Agency, serum phosphate levels should be monitored in patients receiving long-term or multiple high-dose ferric carboxymaltose infusions.

Although IV iron replenishes body iron stores more rapidly than oral iron therapy, several studies indicate that both approaches produce similar increases in hemoglobin

levels.[18] IV iron can be considered first-line therapy in certain exceptional cases, but oral iron should remain the preferred option in most cases of ID/IDA, which are highly prevalent in the general population.

Just as the Choosing Wisely campaigns of the American Society of Hematology and the American Association of Blood Banks recommend avoiding red blood cell transfusion for ID in the absence of hemodynamic instability,[19] it would also be prudent to advise against using IV iron as the first option for the general population. The high rate of inappropriate IV iron use may be explained by several factors. Clinicians may prioritize rapid improvement in symptoms such as fatigue or dizziness, particularly in patients with complex comorbidities or when a quick clinical response is desired. In addition, some patients may request IV treatment due to prior intolerance to oral iron or the perception that IV formulations are more effective and faster-acting.

Another contributing factor may be limited awareness or inconsistent application of guideline recommendations, which generally advocate oral iron as the first-line treatment in most cases. Although reimbursement policies do not necessarily promote or facilitate IV iron use over oral alternatives, clinical habits and patient expectations may still drive its overuse in inappropriate settings.

Our study has some limitations. The use of other iron preparations was very low, likely due to physician familiarity and preference for ferric carboxymaltose, as well as institutional protocols favoring its use because of shorter administration times and fewer required doses. For statistical analysis, only patients receiving ferric carboxymaltose were included in the study. Due to the retrospective design and variability in clinical follow-up practices, post-treatment ferritin and iron indices were unavailable for many patients, limiting our ability to fully assess iron store replenishment.

Although iron deficiency is a common clinical condition, there are no universally accepted thresholds for iron parameters or clear guidelines for the choice of iron preparations, both in the general population and in certain unique clinical scenarios. Therefore, based on patients' clinical conditions and current recommendations, we developed an algorithm for the rational selection of iron replacement therapy. This algorithm reflects international guidelines while also incorporating Turkish Social Security Institution (SSI) reimbursement rules, which in some cases allow IV iron use without prior oral therapy. By integrating patient-specific factors and prioritizing oral iron whenever possible, our algorithm aims to reduce unnecessary IV iron use and associated costs.

CONCLUSION

This study highlights the importance of rational utilization of health resources and evidence-based treatments for iron deficiency, a significant public health concern. To enhance the treatment of iron deficiency, new algorithms should be developed that incorporate current literature and guidelines, patient-related factors, and clinical experience.

In this study, IV iron therapy was inappropriately used in 31% of patients based on current guidelines. The primary reason for this inappropriate use was the lack of preference for oral iron as the first-line treatment in primary care.

Ethics Committee Approval: The Hacettepe University Ethics Committee granted approval for this study (date: 15.12.2023, number: SBA-23/415).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Conflict of Interest: The authors have no conflict of interest to declare.

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