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

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ABSTRACT

Background: Iron deficiency anemia is associated with fatigue, reduced functional capacity, and impaired quality of life. This study assessed the impact of intravenous ferric carboxymaltose on quality of life and hematological outcomes in patients with iron deficiency anemia.

Methods: This prospective observational study was conducted over one year at SLN Medical College and Hospital, Koraput. A total of 110 patients with iron deficiency anemia receiving intravenous ferric carboxymaltose were included. Quality-of-life scores and hematological parameters were assessed at baseline and follow-up.

Results: The cohort was predominantly female, 74 patients (67.3%), and rural residence was reported in 70 patients (63.6%). Most patients had moderate anemia, 78 patients (70.9%), and 90 patients (81.8%) received a single infusion. Total quality-of-life score improved from 50.9 ± 6.9 to 73.9 ± 8.9, with a mean increase of 23.0 points. Quality-of-life response was achieved in 102 patients (92.7%). Hemoglobin increased from 8.43 ± 1.11 g/dL to 10.92 ± 0.93 g/dL, with a mean rise of 2.49 g/dL, and hematological response was achieved in 83 patients (75.5%). Ferritin, transferrin saturation, serum iron, and mean corpuscular volume improved significantly, while total iron-binding capacity decreased. Mild adverse events were recorded in 19 patients (17.3%).

Conclusion: Intravenous ferric carboxymaltose significantly improved quality of life, hemoglobin, and iron stores in patients with iron deficiency anemia, with good tolerability.

Keywords*: Iron deficiency anemia; ferric carboxymaltose; quality of life; hemoglobin; intravenous iron.*

INTRODUCTION

Iron deficiency anemia (IDA) is one of the most prevalent nutritional and haematological conditions globally and is linked to fatigue, decreased exercise capacity, impaired cognition, decreased work productivity and decreased health-related quality of life. Oral iron is the first-line treatment, but it may be ineffective due to gastrointestinal intolerance, poor adherence, slow hematological response, malabsorption, persistent blood loss, and the need for rapid iron repletion in moderate to severe anemia [1].

Intravenous iron therapy is a practical alternative in patients who need more rapid correction of iron deficiency or who are intolerant or unresponsive to oral iron. Ferric carboxymaltose is a non-dextran intravenous iron preparation that can be given in relatively large doses over a short infusion time, which can rapidly replenish iron stores and improve hemoglobin levels [2]. This feature is especially valuable in standard clinical practice where frequent hospital visits might be challenging, particularly in areas with limited resources or geographical access.

Ferric carboxymaltose has been shown to be effective and well tolerated in IDA in several clinical studies in various patient populations. Van Wyck et al. found that large dose intravenous ferric carboxymaltose was superior to oral iron in women with iron deficiency anemia from heavy uterine bleeding, with more rapid hematological response [3]. Similarly, studies in postpartum anemia have shown that ferric carboxymaltose leads to significant hemoglobin correction with acceptable safety and tolerability [4]. Ferric carboxymaltose has also been demonstrated to be effective for iron repletion and anemia correction in inflammatory bowel disease-related IDA, which is consistent with its use in a variety of etiological contexts [5].

In addition to laboratory correction, the clinical relevance of IDA treatment is the improvement of patient-centered outcomes including fatigue, physical functioning, vitality, emotional well-being, and overall quality of life. Clinical practice and prospective studies have shown that ferric carboxymaltose is linked to significant improvements in fatigue and health-related quality-of-life scores following treatment [6]. Huguet et al. found that health-related quality of life was significantly improved after ferric carboxymaltose therapy in iron deficient patients, and Kwong et al. found that patients treated with ferric carboxymaltose in routine clinical care had improved fatigue, physical function and global health [7,8].

Although there is growing evidence in favor of ferric carboxymaltose, there is still limited data on its effect on quality of life in IDA patients, especially from peripheral tertiary-care centers in tribal and rural areas. Nutritional deficiency, chronic blood loss, delayed presentation and repeated follow-up visits are common problems among patients attending SLN Medical College and Hospital, Koraput. Thus, it is clinically relevant to assess the effect of intravenous ferric carboxymaltose on quality of life in this context.

The present prospective observational study was carried out in SLN medical college and hospital, Koraput for a period of one year in 110 patients with iron deficiency anemia to evaluate the effect of intravenous ferric carboxymaltose therapy on quality of life and hematological response following therapy.

OBJECTIVES

1. To assess baseline quality of life among patients with iron deficiency anemia before administration of intravenous ferric carboxymaltose.
2. To evaluate the change in quality-of-life scores after intravenous ferric carboxymaltose therapy.
3. To assess the hematological response to intravenous ferric carboxymaltose by comparing pre-treatment and post-treatment hemoglobin and iron parameters.

METHODS

Study design and setting

This prospective observational study was conducted at Saheed Laxman Nayak Medical College and Hospital, Koraput, over a period of one year. The study included patients with iron deficiency anemia who received intravenous ferric carboxymaltose and completed post-treatment follow-up assessment.

Study population

A total of 110 patients with iron deficiency anemia were enrolled. Patients were included if they had confirmed iron deficiency anemia based on clinical assessment and hematological/iron profile parameters and were planned for intravenous ferric carboxymaltose therapy. Patients with incomplete baseline or follow-up data, anemia due to causes other than iron deficiency, known hypersensitivity to intravenous iron preparations, or severe uncontrolled systemic illness were excluded.

Data collection

Baseline demographic and clinical details were recorded, including age, sex, residence, body mass index, etiology of iron deficiency anemia, and anemia severity. The etiological categories included nutritional deficiency, gastrointestinal blood loss, heavy menstrual bleeding, pregnancy/postpartum state, malabsorption or other causes, and chronic disease/chronic kidney disease.

Treatment-related details included total ferric carboxymaltose dose, number of infusions, follow-up duration, and any recorded adverse events. The usual administered dose was 1000 mg, with dose adjustment according to clinical requirement and severity of iron deficiency.

Quality-of-life assessment

Quality of life was assessed at baseline before ferric carboxymaltose administration and again at follow-up. The assessment included physical, energy/fatigue, emotional, and social domains. Each domain was scored on a 0–100 scale, with higher scores indicating better quality of life. A total quality-of-life score was calculated from the domain scores.

Quality-of-life response was defined as an increase of at least 10 points in the total quality-of-life score from baseline to follow-up.

Hematological and iron profile assessment

Hemoglobin, mean corpuscular volume, serum ferritin, transferrin saturation, serum iron, and total iron-binding capacity were measured at baseline and follow-up. Hematological response was defined as a hemoglobin rise of at least 2 g/dL after ferric carboxymaltose therapy.

Outcomes

The primary outcome was change in total quality-of-life score after intravenous ferric carboxymaltose therapy. Secondary outcomes included changes in individual quality-of-life domains, hemoglobin, mean corpuscular volume, ferritin, transferrin saturation, serum iron, total iron-binding capacity, frequency of hematological response, and recorded adverse events.

Statistical analysis

Continuous variables were presented as mean ± standard deviation or median (interquartile range) as appropriate. Categorical variables were presented as frequency and percentage. Paired t-test was used to compare normally distributed baseline and follow-up continuous variables. For non-normally distributed paired variables (ferritin, transferrin saturation, and serum iron), Wilcoxon signed-rank test was used.

Pearson and Spearman correlation analyses were used to evaluate the correlation between hemoglobin change and total quality-of-life change. Independent t-test was used to compare quality of life improvement between hematological responders and non-responders. Categorical comparisons such as quality-of-life response and hematological response between groups were made using the chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 110 patients with iron deficiency anemia receiving intravenous ferric carboxymaltose were included. Baseline characteristics and treatment exposure are summarized in Table 1. The cohort was predominantly female, with nutritional deficiency and gastrointestinal blood loss forming the commonest etiological categories. Most patients had moderate anemia at presentation, received a 1000 mg total dose, and completed follow-up at a median of 8 weeks.

Table 1. Baseline characteristics and treatment exposure

Characteristic	Value
Age, years, mean ± SD	40.5 ± 12.4
Female sex, n (%)	74 (67.3%)
Rural residence, n (%)	70 (63.6%)
BMI, kg/m², mean ± SD	21.0 ± 3.1
Etiology of iron deficiency anemia, n (%)	
Nutritional deficiency	37 (33.6%)
Gastrointestinal blood loss	26 (23.6%)
Heavy menstrual bleeding	22 (20.0%)
Pregnancy/postpartum	13 (11.8%)
Malabsorption/other	10 (9.1%)
Chronic disease/CKD	2 (1.8%)
Baseline anemia severity, n (%)	
Moderate	78 (70.9%)
Severe	32 (29.1%)
Total FCM dose, mg, median (IQR)	1000 (1000–1000)
500 mg, n (%)	2 (1.8%)
1000 mg, n (%)	88 (80.0%)
1500 mg, n (%)	20 (18.2%)
One infusion, n (%)	90 (81.8%)
Follow-up duration, weeks, median (IQR)	8 (6–10)
Recorded adverse event, n (%)	
None	91 (82.7%)
Headache	6 (5.5%)
Nausea	5 (4.5%)
Transient dizziness	5 (4.5%)
Mild rash	3 (2.7%)

Baseline quality-of-life scores were reduced across all domains, with the lowest baseline score in the energy/fatigue domain. After ferric carboxymaltose therapy, all quality-of-life domains improved significantly (Table 2). The total quality-of-life score increased by 23.0 points, and 102 (92.7%) patients met the predefined threshold for quality-of-life response.

Table 2. Change in quality-of-life scores after ferric carboxymaltose therapy

QoL domain	Baseline, mean ± SD	Follow-up, mean ± SD	Mean change (95% CI)	Test statistic	p-value
Physical	48.8 ± 8.3	72.8 ± 10.7	24.0 (22.4–25.6)	t(109)=29.32	<0.001
Energy/Fatigue	45.3 ± 8.5	70.7 ± 11.7	25.4 (23.7–27.0)	t(109)=30.60	<0.001
Emotional	54.3 ± 8.3	76.1 ± 11.0	21.7 (20.2–23.3)	t(109)=27.72	<0.001
Social	54.9 ± 9.7	75.8 ± 11.4	20.9 (19.3–22.4)	t(109)=26.93	<0.001
Total	50.9 ± 6.9	73.9 ± 8.9	23.0 (21.6–24.4)	t(109)=32.33	<0.001
QoL response	—	—	102 (92.7%)	Descriptive	—

QoL scores are scaled from 0 to 100, with higher scores indicating better quality of life. QoL response was defined as a total score increase of ≥10 points.

Hematological and iron parameters also showed significant improvement after treatment (Table 3). Hemoglobin increased by 2.49 g/dL, and 83 (75.5%) patients achieved hematological response. Ferritin and transferrin saturation increased substantially, while total iron-binding capacity decreased, consistent with repletion of iron stores.

Table 3. Hematological and iron parameter response after ferric carboxymaltose therapy

Parameter	Baseline	Follow-up	Change	Test statistic	p-value
Hemoglobin, g/dL	8.43 ± 1.11	10.92 ± 0.93	2.49 (2.35–2.64)	t(109)=33.28	<0.001
MCV, fL	71.8 ± 3.8	82.4 ± 4.6	10.5 (10.0–11.1)	t(109)=38.83	<0.001
Ferritin, ng/mL	7.3 (5.2–9.8)	116.2 (101.0–139.9)	108.3 (93.6–130.6)	W=0.0	<0.001
TSAT, %	7.9 (6.3–9.1)	28.2 (25.4–30.7)	20.7 (17.9–22.9)	W=0.0	<0.001
Serum iron, µg/dL	35.0 (28.0–42.8)	118.5 (107.0–128.0)	83.5 (70.2–95.0)	W=0.0	<0.001
TIBC, µg/dL	455.1 ± 35.3	416.0 ± 40.2	-39.2 (-44.0–-34.4)	t(109)=-16.16	<0.001
Hematological response	—	—	83 (75.5%)	Descriptive	—

Hemoglobin, MCV, and TIBC are reported as mean ± SD with mean change and 95% CI; ferritin, TSAT, and serum iron are reported as median (IQR) with median change. Hematological response was defined as a hemoglobin rise of ≥2 g/dL. Patient-level paired changes are shown in Figures 1 and 2. The paired plots demonstrate a consistent shift toward higher quality-of-life scores and hemoglobin values following therapy, with the cohort mean increasing in both outcomes.

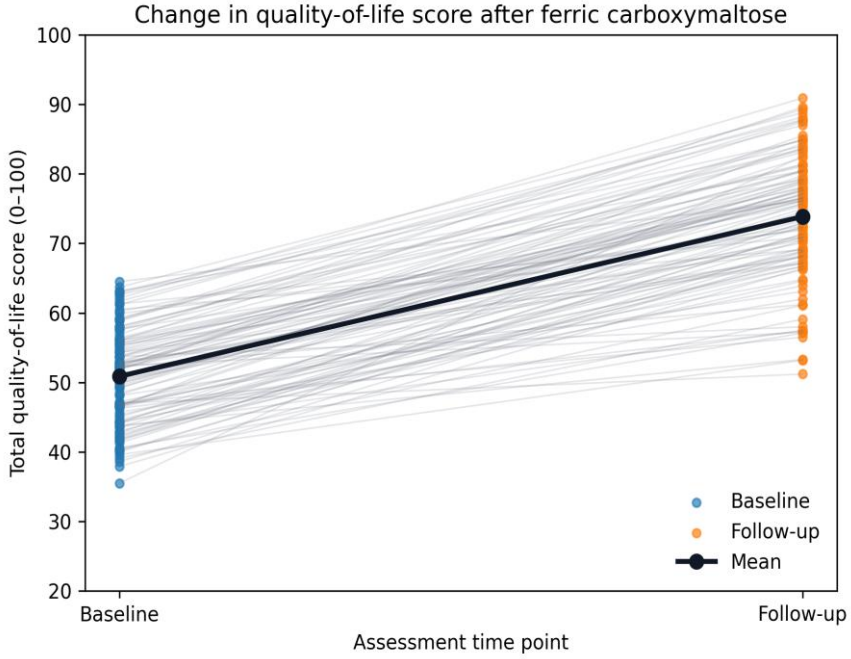

Figure 1. Change in total quality-of-life score after ferric carboxymaltose therapy

Patient-level paired plot showing baseline and follow-up total quality-of-life scores. The heavier line represents the cohort mean.

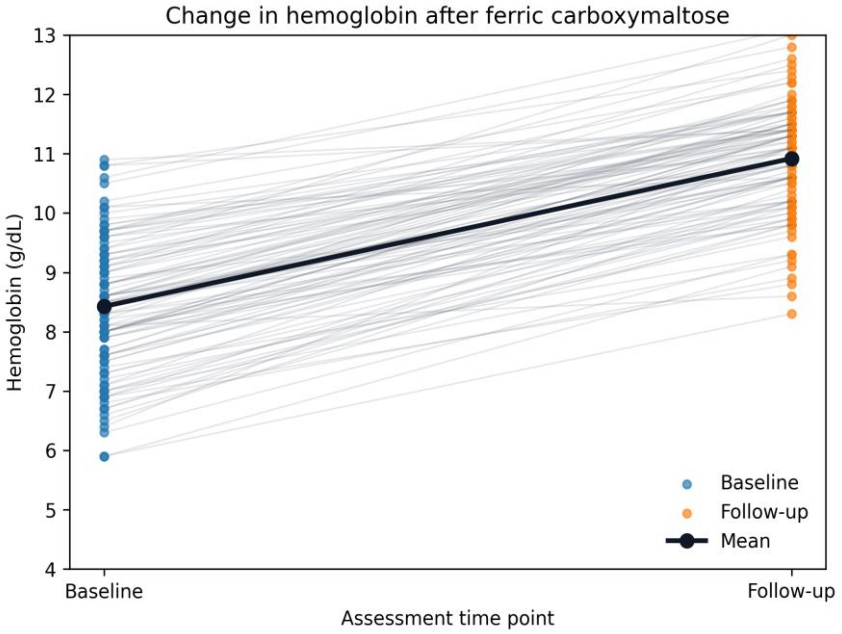

Figure 2. Change in hemoglobin after ferric carboxymaltose therapy

Patient-level paired plot showing baseline and follow-up hemoglobin levels. The heavier line represents the cohort mean.

Relationship Between Hematological Response and Quality-of-Life Improvement

Improvement in quality of life was further examined in relation to hematological recovery and baseline anemia severity. As shown in Table 4, greater hemoglobin rise was associated with greater improvement in total quality-of-life score. Patients who achieved hematological response demonstrated larger gains in quality of life and a higher frequency of clinically meaningful quality-of-life response. Baseline anemia severity was also associated with treatment response, with patients presenting with severe anemia showing lower baseline quality-of-life scores and greater hemoglobin improvement after ferric carboxymaltose therapy.

Table 4. Relationship between hematological response, anemia severity, and quality-of-life improvement

Analysis	Result	Test statistic	p-value
Hemoglobin change vs total QoL change	Pearson r = 0.621	T (108) = 8.23	<0.001
Hemoglobin change vs total QoL change	Spearman ρ = 0.586	Rank correlation	<0.001
Ferritin change vs total QoL change	Spearman ρ = 0.328	Rank correlation	<0.001
QoL change in hematological responders	25.1 ± 6.2 points		
QoL change in hematological non-responders	16.5 ± 7.3 points	t = 5.48	<0.001
QoL response among hematological responders	81/83 (97.6%)		
QoL response among hematological non-responders	21/27 (77.8%)	$\chi^2 = 11.86$	<0.001
Baseline QoL in moderate anemia	52.8 ± 6.0		
Baseline QoL in severe anemia	46.0 ± 6.6	t = 5.05	<0.001
Hemoglobin rise in moderate anemia	2.30 ± 0.76 g/dL		
Hemoglobin rise in severe anemia	2.96 ± 0.64 g/dL	t = 4.67	<0.001
QoL change in moderate anemia	22.2 ± 7.2 points		
QoL change in severe anemia	25.1 ± 7.7 points	t = 1.84	0.071
Hematological response in moderate anemia	53/78 (67.9%)		
Hematological response in severe anemia	30/32 (93.8%)	$\chi^2 = 8.16$	0.004

DISCUSSION

This prospective observational study of 110 patients with iron deficiency anemia (IDA) treated with intravenous ferric carboxymaltose (FCM) showed significant improvement in quality of life and hematological parameters. The cohort was mostly female, mostly rural, and most patients presented with moderate anemia. Most patients received a single dose of 1000 mg FCM, and follow-up was performed at a median of 8 weeks. The total quality-of-life score increased from 50.9 ± 6.9 to 73.9 ± 8.9, with a mean increase of 23.0 points, and 92.7% of patients had a clinically meaningful quality-of-life response. Hemoglobin rose from 8.43 ± 1.11 g/dL to 10.92 ± 0.93 g/dL (mean increase 2.49 g/dL), and ferritin and

transferrin saturation also improved significantly. The positive correlation between hemoglobin rise and total quality-of-life improvement further supports the clinical relevance of hematological recovery in improving patient-centered outcomes.

The hemoglobin response seen in the current study is similar to large randomized trials of FCM in gynecological and obstetric IDA. In a randomized controlled trial of 477 women with IDA from heavy uterine bleeding, Van Wyck et al. found that FCM resulted in a ≥2 g/dL increase in hemoglobin in 82% of women, compared with 62% who received oral ferrous sulfate, and anemia correction in 73% versus 50% [9]. They also experienced higher improvements in vitality, physical function and fatigue symptoms with FCM. Our study showed a ≥2 g/dL hematological response in 75.5% of patients, with the greatest improvement in the energy/fatigue domain, which is consistent with the clinical benefit of FCM across the reproductive-age and mixed-etiology IDA populations.

The same has been observed in postpartum anemia. Seid et al. randomized 291 women within 10 days of delivery to intravenous FCM or oral ferrous sulfate and found that FCM resulted in hemoglobin >12 g/dL more quickly, a greater increase in hemoglobin ≥3 g/dL, and higher ferritin and transferrin saturation levels, with fewer adverse events related to the drug [10]. Although pregnancy/postpartum cases represented only 11.8% of our cohort, the present study similarly showed rapid iron-store repletion, with median ferritin increasing from 7.3 ng/mL to 116.2 ng/mL and TSAT from 7.9% to 28.2%. This helps to explain the biological consistency of FCM in replenishing iron stores in various etiologies of IDA.

Evstatiev et al. conducted the FERGIcor trial, which compared a simplified FCM dosing regimen to iron sucrose in inflammatory bowel disease (IBD) in the setting of chronic gastrointestinal disease-related IDA. In 240 FCM-treated and 235 iron sucrose-treated patients analyzed, hemoglobin response was higher with FCM than iron sucrose at week 12 (65.8% vs 53.6%) and hemoglobin normalization was also higher (72.8% vs 61.8%) [11]. Both groups showed quality-of-life improvement. Gastrointestinal blood loss was the second most common etiology in our cohort (23.6%) and had a higher overall hematological response (75.5%). This could be due to variations in baseline disease profile, timing of follow-up, and the predominance of nutritional and blood-loss etiologies over active inflammatory bowel disease.

The practical advantage of FCM in reducing infusion burden is also supported by randomized trial data. Barish et al. reviewed two RCTs that used 750 mg FCM and reported that hemoglobin and iron indices improved significantly more than with standard medical care, and fewer infusions were required to achieve target iron levels, with up to 2 FCM infusions required in the multidose study versus 3–5 infusions of intravenous comparator therapies [12]. This is applicable to the current context where 63.6% of patients were rural and 81.8% received a single infusion. In these populations, a therapy that offers significant hematological and quality-of-life benefit with reduced visits has significant operational and patient-access benefits.

Data from chronic kidney disease cohorts also suggest that FCM is effective in patients where oral iron may be insufficient. In non-dialysis-dependent CKD, Qunibi et al. found that intravenous FCM was associated with a greater increase in hemoglobin (≥1 g/dL) compared with oral iron (60.4% vs. 34.7%), higher ferritin and TSAT increases with FCM, and fewer adverse events related to the treatment (2.7% vs. 26.2%) [13]. Onken et al. randomized 2584 patients with IDA and impaired renal function to FCM or iron sucrose in the REPAIR-IDA trial, and found that FCM resulted in a greater mean hemoglobin increase (1.13 versus 0.92 g/dL) and more patients had a hemoglobin increase ≥1 g/dL (48.6% versus 41.0%), with no significant difference in the composite cardiovascular safety endpoint [14]. The number of patients in our study with chronic disease/CKD was small, but the pattern of safety was similar, with adverse events reported being mild and the majority of patients not having an adverse event documented.

Real-world studies offer especially relevant comparators to the current observational design. Robalo Nunes et al. evaluated 459 outpatients receiving FCM and found that at 6 weeks, 41% of patients had an increase in hemoglobin ≥2 g/dL, 20% had an increase in hemoglobin ≥3 g/dL, and 63% had a TSAT >20%, with treatment-emergent adverse events occurring in <4% [15]. In our study, the ≥2 g/dL hemoglobin response was 75.5% and the median TSAT improvement was 28.2%, which may be due to the lower baseline hemoglobin and ferritin levels, which resulted in a greater measurable response following iron repletion.

The results are also in line with the Indian real-world data. Charmila et al. reported the results of IDA treatment with FCM in 1800 Indian patients in 269 centres. At 4 ± 1 weeks, hemoglobin rose by 2.76 g/dL, with greater increases in severe anemia (3.31 g/dL) than in moderate anemia (2.63 g/dL) [16]. In the current study, the mean increase in hemoglobin was 2.49 g/dL, with a higher increase in severe anemia compared to moderate anemia (2.96 versus 2.30 g/dL). This similarity indicates the reproducibility of the effectiveness of FCM in Indian clinical settings and that patients with more severe baseline anemia may experience greater hematological gain.

The main result of the current study is the improvement of quality of life. Huguet et al. assessed FCM in 98 patients with inflammatory bowel disease and iron deficiency without anemia, and found that a single dose of 500 mg was effective in improving iron parameters, symptoms, EQ-5D dimensions, EQ-5D visual analogue scale, and SF-12 scores at 1 month [17]. More recently, Bozkuş et al. evaluated 528 patients with IDA who received FCM and found that hemoglobin levels increased from 9.17 ± 1.36 to 13.12 ± 0.82 g/dL, ferritin levels increased from 6.23 ± 4.38 to 178.91 ± 123.99 ng/mL, and physical and psychological quality-of-life domains were significantly improved [18]. We also found improvements in physical, energy/fatigue, emotional and social areas, with the greatest improvement in energy/fatigue. This helps to reinforce the fact that FCM benefit is not just about correcting laboratory parameters, but is about real recovery as perceived by the patient.

It is important to highlight the correlation between hematological response and improvement in quality of life in our study. There was a strong positive correlation between hemoglobin change and total quality-of-life change, and the quality-of-life gain was higher in hemoglobin responders than in non-responders. This helps to improve hemoglobin as a key factor in symptomatic recovery. The strong association between ferritin change and quality-of-life improvement, however, indicates that replenishment of iron stores may also play a role in improving fatigue, physical functioning and overall well-being. This is clinically relevant because iron deficiency alone, prior to full haematological repletion, may affect muscle function, cognition and energy.

The safety profile in this study was acceptable. The majority of patients did not have an adverse event recorded and those that did had mild adverse events such as headache, nausea, transient dizziness and rash. This is consistent with comparator trials and real-world cohorts showing good tolerability of FCM. The present study, however, did not involve systematic monitoring of phosphate, which is a limitation as recent FCM literature has identified hypophosphatemia as a relevant adverse effect after infusion, especially with higher cumulative doses. In the future, serum phosphate should be evaluated in this population, particularly in those who receive multiple or high doses of FCM.

There are limitations to this study. It is an observational single-center study and cannot prove causality as strongly as a randomized trial. No oral iron or iron sucrose comparator arm was used, and follow-up was only for a median of 8 weeks. Concurrent treatment of the underlying cause of IDA, nutritional improvement, or clinical counseling may also affect quality-of-life outcomes. The study has its limitations, but it offers valuable regional data from SLN Medical College and Hospital, Koraput, especially with the good representation of rural patients and mixed etiologies of IDA.

Overall, intravenous ferric carboxymaltose was associated with substantial improvement in quality of life, hemoglobin, MCV, ferritin, TSAT, and serum iron in patients with IDA. The magnitude of the hemoglobin increase and the quality-of-life response is comparable to randomized and real-world comparator studies. The high correlation between hematological response and improvement in quality of life suggests that FCM can be used not only as a hematinic intervention but also as a patient-centred therapeutic approach in moderate-to-severe IDA, where rapid correction and fewer hospital visits are clinically relevant.

CONCLUSION

Intravenous ferric carboxymaltose produced significant improvement in quality of life and hematological parameters in patients with iron deficiency anemia. The greatest quality-of-life gain was observed in the energy/fatigue domain, and improvement was strongly associated with hemoglobin rise. Ferric carboxymaltose also led to substantial replenishment of iron stores with good tolerability. These findings support its use as an effective and patient-centered treatment option for moderate-to-severe iron deficiency anemia, especially where rapid correction and fewer hospital visits are desirable.

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