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Original Research Article

AIM HD-CKD study: assessment of the efficacy and safety of ferric carboxymaltose in iron deficiency anemia management in haemodialysis patients with chronic kidney disease

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ABSTRACT

Background: Iron deficiency anemia (IDA) is a common complication in patients with chronic kidney disease (CKD) undergoing hemodialysis (HD). Intravenous (IV) iron supplementation is essential for managing IDA in these patients, and ferric carboxymaltose (FCM) has emerged as a promising treatment option.
Methods: This multicentric, retrospective observational study was conducted from April to August 2023, involving 52 adult HD-CKD patients with IDA in India. During dialysis sessions, 48 patients received 4 weekly doses of 100 mg FCM IV push, while 4 patients received 3 doses. Hematological parameters, including haemoglobin (Hb), serum ferritin, transferrin saturation (TSAT), C-reactive protein (CRP), and estimated glomerular filtration rate (eGFR), were measured at baseline and after the final FCM dose. The primary outcome was the change in Hb levels, with secondary outcomes focusing on changes in ferritin, TSAT, CRP, eGFR, and the safety profile of FCM.
Results: Following FCM administration, a significant increase was observed in Hb levels (+0.69 g/dl, $p<0.001$), serum ferritin (+8.61 ng/ml, $p=0.003$), and TSAT (+3.69%, $p<0.001$). CRP levels showed a slight, non-significant decrease, while eGFR slightly increased, and neither reached statistical significance. No serious adverse events were reported, indicating a favorable safety profile for FCM.
Conclusion: The study demonstrated that 100 mg IV FCM is an effective and safe treatment for managing iron deficiency anemia in Indian HD-CKD patients. The significant improvement in Hb, ferritin, and TSAT levels post-FCM administration supports its use as a reliable therapeutic option in this patient population.

Keywords: Ferric carboxymaltose, Intravenous iron supplement, Iron deficiency anaemia, Chronic kidney disease, Dialysis dependent, Haemoglobin

INTRODUCTION

Managing anemia is crucial for reducing morbidity and enhancing the quality of life in chronic kidney disease (CKD) patients.[1] In hemodialysis-dependent chronic kidney disease (HD-CKD) patients, functional iron deficiency is common, characterized by poor iron mobilization from stores, normal or high ferritin levels, and low transferrin saturation (TSAT), which limits iron transport for erythropoiesis. The inflammatory state increases serum hepcidin, blocking iron absorption from the duodenum and release from the liver and macrophages, thereby disrupting iron recycling.[1] There are reports of around 2.5 litre of blood loss annually in HD-CKD patients, due to blood loss during dialysis, regular blood sampling as well as occult intestinal blood loss.[2,3]

Anemia in HD-CKD is managed with erythropoiesis-stimulating agents (ESAs) or iron supplementation, using either oral or intravenous (IV) iron. According to KDIGO guidelines, both methods are recommended for treating iron deficiency in CKD patients. However, over 35% of patients experience gastrointestinal side effects with oral iron, leading to poor compliance and suboptimal absorption. IV iron preparations are often preferred, particularly when rapid and effective iron replacement is necessary.[4]

The earliest intravenous irons used dextran, which reduced non-transferrin-bound iron reactions but were linked to potentially fatal allergic reactions. Later iron preparations, like iron sucrose and ferric gluconate, used non dextran carbohydrates to reduce hypersensitivity reactions.[4]

Ferric carboxymaltose (FCM) is a non-dextran iron injection approved in over 50 countries since its European approval in 2007. After administration, FCM partially breaks down in the blood, leading to a gradual release of iron and preventing an early spike in TSAT.[1]

FCM can be administered in single doses of up to 750 mg in the USA and 1000 mg elsewhere. It was FDA-approved in 2013 for treating iron deficiency anemia in adults who are intolerant to or unresponsive to oral iron, as well as those with no dialysis-dependent CKD. Despite initial safety concerns delaying its approval in the US, over a million patients have been treated with FCM globally.[5] FCM is ideal for outpatient use, as it can be administered in a single 15-minute dose, reducing the need for multiple clinic visits and venipunctures.[6]

Anemia is a common early complication of CKD, contributing to symptoms like fatigue, reduced exercise tolerance, dyspnea, cognitive impairment, and insomnia, as well as to disease progression and cardiovascular issues like left ventricular hypertrophy and diastolic dysfunction.[7]

The safety and efficacy of FCM in HD-CKD patients with iron deficiency anaemia (IDA) have been evaluated in international studies including randomized controlled trials. However, its data on safety and efficacy in Indian settings is limited. The present study aimed to assess the efficacy and safety of ferric carboxymaltose in the correction of IDA in HD-CKD patients in the Indian population in real world setting.

METHODS

Study design, patient population and treatment characteristics

This study is a multicentric, retrospective observational analysis involving adult outpatients with advanced chronic kidney disease (CKD) who attended nephrology clinics and were undergoing haemodialysis from April to August 2023.

The medical records of these patients were reviewed for inclusion criteria, and sociodemographic as well as clinical data were collected via paper case report forms (CRF). All patients signed informed consent, and the study protocol was approved by the Independent Ethics Committee of Dhanashree Hospital, Pune, India.

The study focused on haemodialysis dependent CKD (HD-CKD) patients with iron deficiency anaemia (IDA), who were at least 18 years old and had an estimated glomerular filtration rate (eGFR) ≤30 ml/min/1.73m². These patients received weekly ferric carboxymaltose (Encicarb, 100 mg IV injection Emcure pharmaceuticals Ltd.) as an undiluted IV push of 100 mg directly into the venous line of the dialyzer about 30–60 minutes into the dialysis session and had their iron parameters (haemoglobin, serum ferritin, transferrin saturation), C-reactive protein (CRP), and eGFR measured at baseline and after the final dose of FCM. The diagnosis of IDA was based on the 2012 KDIGO guidelines, requiring haemoglobin (Hb) concentration below 13.0 g/dl (130 g/l) in males and below 12.0 g/dl (120 g/l) in females, ferritin ≤ 500 ng/ml, and TSAT ≤ 30%, along with stable ESA therapy.[8]

Exclusion criteria

Exclusion criteria included recent significant gastrointestinal bleeding or acute blood loss, incomplete medical or follow-up records, early iron therapy shift, the initiation of dialysis, or death during follow-up. The study assessed the efficacy and safety of FCM, with data collected at a single point in time, capturing haematological parameters at baseline and after the final dose of FCM. The study design is illustrated in Figure 1.

Treatment

Eligible patients received intravenous FCM with dosing determined by the physician based on the patient's baseline haematological parameters and FCM prescribing

guidelines. The iron supplementation aimed to achieve and maintain ferritin levels ≥500 ng/ml and TSAT ≥30%.[8]

Serious adverse events, including those resulting in death, life-threatening conditions, or hospitalization, were recorded, along with blood pressure during FCM infusion.

Study outcomes

Primary outcome

The primary outcome was the effectiveness of FCM in correcting IDA in HD-CKD patients as assessed by comparing Hb (g/dl) after the last prescribed dose of FCM with the baseline values.

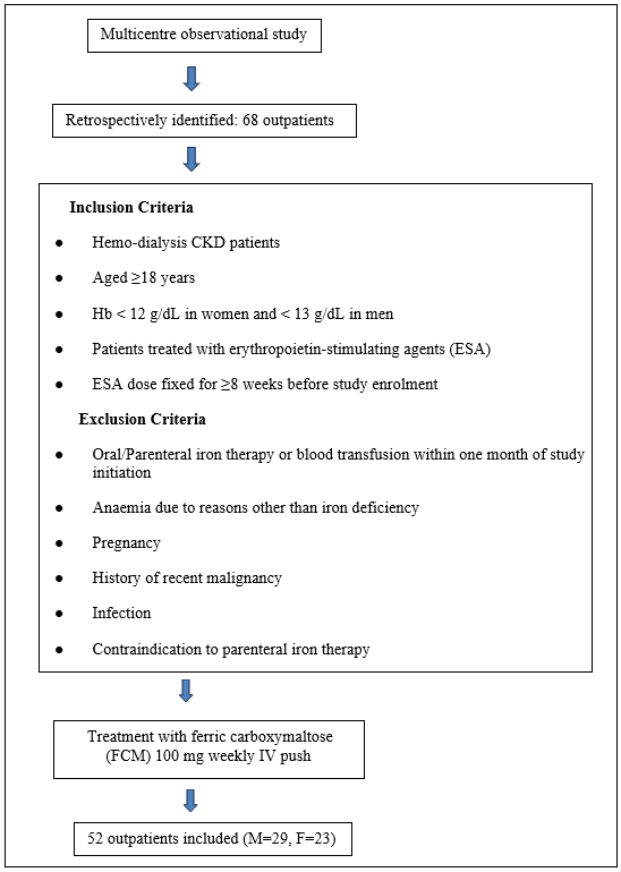

Figure 1: Study design.

Secondary outcome

The secondary outcomes of the study focused on the change in transferrin saturation (TSAT, %) and serum ferritin levels (ng/ml) observed at least four weeks after the final administration of FCM, compared to baseline values. Additionally, the safety profile of FCM was evaluated by documenting the incidence and severity of adverse events (AEs) following each dose.

The assessment also extended to other key health indicators, including C-reactive protein (CRP) levels (mg/L), which serve as a marker of inflammation, and estimated glomerular filtration rate (eGFR, mL/min/1.73m²), a crucial measure of kidney function. These parameters were compared to their baseline levels to provide a comprehensive understanding of the treatment's impact.

Statistical analysis

Data analysis was conducted using SPSS (Statistical Package for the Social Sciences). Descriptive statistics were used to summarize demographic and clinical characteristics. Continuous variables were presented as mean±standard deviation (SD), median (interquartile range (IQR)), and range. Categorical variables were expressed as frequencies and percentages.

To assess the efficacy of ferric carboxymaltose (FCM), paired t-tests were used to compare hematological parameters (hemoglobin, serum ferritin, transferrin saturation) before and after treatment. A p value<0.05 was considered statistically significant. The study also assessed the safety profile of FCM by recording and analyzing adverse events. Statistical significance in changes between baseline and post-treatment values was determined using appropriate parametric or non-parametric tests, depending on the data distribution.

RESULTS

Baseline clinical characteristics-CKD –dialysis patients

This multicentre retrospective observational study included a total of 52 patients, with an almost equal number of male and female patients (age group 25-80 years, F=23, M=29).

Comorbid diseases such as hypertension were found to be the most common condition in 49 patients (94%), followed by diabetes in 41 patients (79%), a cardiac disorder in 5 patients, 43 patients received previous oral iron therapy while 19 received previous intravenous (IV) iron therapy (at least more than a month before baseline data collection) and 49 patients (94%), were currently on erythropoietin stimulating agent (ESA).

Haematological parameters

When compared to baseline, a statistically significant increase of +0.69 gm/dl in mean haemoglobin level was observed post-FCM (p<0.001) (Table 1 and Figure 2).

Similarly, a statistically significant difference was also recorded in the serum ferritin levels and transferrin saturation (TSAT) in post-FCM haematological evaluations with increase in 8.61 ng/ml (p=0.003) and 3.69% respectively (p<0.001) (Figure 3 and 4).

Table 1: Observation table for haematological parameters of CKD dialysis patients.

	N	Mean±SD	Median (IQR)	Range	P value
Haemoglobin (Hb) (g/dl)					
Baseline	52	8.45±0.91	8.60 (7.90-9.13)	6.50-10.30	<0.001
Post FCM	52	9.14±0.90	9.40 (8.58-9.80)	7.20-11.40	
Serum ferritin (ng/ml)					
Baseline	48	108.58±40.26	95 (93.43-123.75)	29-201	0.003
Post FCM	48	117.19±52.62	98 (94-128.88)	9.5-249.7	
TSAT (%)					
Baseline	49	13.66±4.73	12 (10-18)	7.3-23	<0.001
Post FCM	49	17.35±6.44	18 (11-22)	8-29	

Table 2: Observation table for other parameters of CKD dialysis patients.

	N	Mean±SD	Median (IQR)	Range	P value
CRP (mg/l)					
Baseline	43	9.36±4.77	8 (7-11)	2-24	0.315
Post FCM	43	9.19±3.57	9 (7-11)	3-20	
eGFR (ml/min/1.73)					
Baseline	44	12.28±3.87	12 (11-13)	5-30	0.432
Post FCM	44	12.36±3.96	11.5(10.0-14)	8-32	

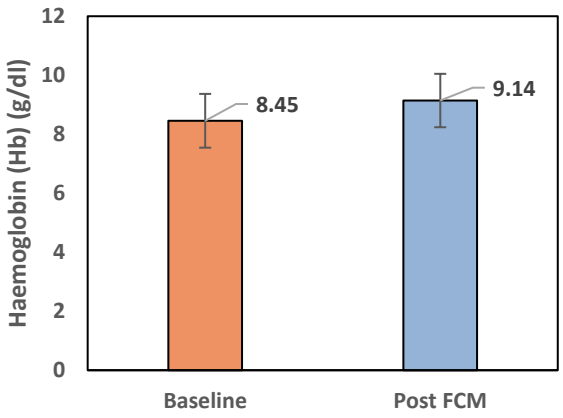

Figure 2: Mean haemoglobin (g/dl) levels from baseline to post 3rd & 4th dosage of FCM (p<0.001).

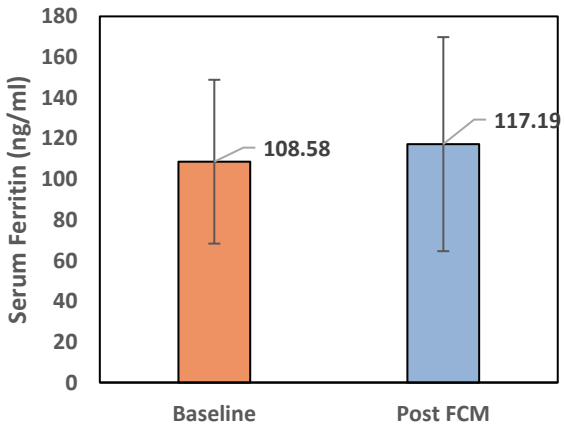

Figure 3: Mean change in serum ferritin (ng/ml) levels from baseline to post 3rd & 4th dosage of FCM.

Other parameters

C-reactive protein (CRP) and eGFR data were available for 43 and 44 patient records respectively at baseline and post-FCM. There was a decrease in C-reactive protein (CRP) (mg/l) by a mean of 0.17 (p=0.315) and an increase in eGFR by a mean of 0.08 (ml/min/1.73m^2) (p=0.432) post-FCM (Table 2).

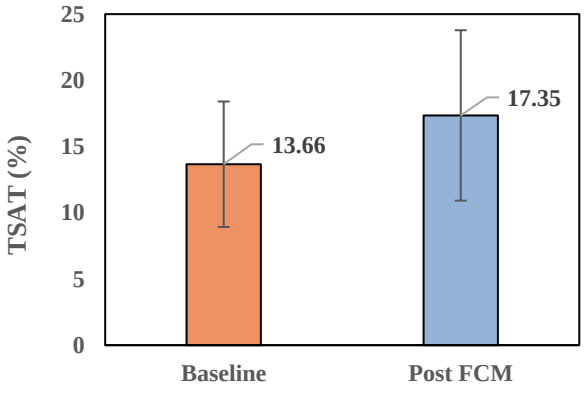

Figure 4: Mean change in TSAT (%) from baseline to post 3rd & 4th dosage of FCM (p<0.001)

Safety

No serious adverse events (SAEs) were reported in any of the subjects

DISCUSSION

Anemia in CKD patients can be managed with erythropoiesis-stimulating agents (ESAs) and/or iron

supplementation, administered either orally or intravenously. However, oral iron preparations often pose challenges, including a high tablet burden for patients who are already managing multiple medications and the risk of gastrointestinal side effects.[9] In dialysis patients, FCM is approved for administration of up to 200 mg per dialysis session. Common maintenance dosing schedules involve administering 100 or 200 mg every 2–4 weeks.[3]

The novel intravenous ferric carboxymaltose (FCM) formulation represents a significant advancement in the management of HD-CKD patients. It can be administered as a single-dose regimen. In a study by Covic et al, 2010, patients received 100–200 mg of iron as ferric carboxymaltose (FCM) through an intravenous bolus-push injection into the haemodialysis (HD) venous line, administered two to three times weekly for up to six weeks.[2] This approach simplifies treatment and reduces the need for repeated clinic visits.

Despite these advancements, there is no universal consensus on the optimal IV iron replacement regimen for adults with chronic kidney disease, resulting in varied local, state, and international guidelines and practices. The KDOQI guidelines recommend IV iron to maintain haemoglobin levels between 11–12 g/dl, ferritin levels <500 ng/ml, and transferrin saturation (TSAT) > 30%.[10]

Clinical trials involving hundreds of individuals with iron deficiency anemia (IDA) associated with various medical conditions have shown that FCM treatment leads to significant improvements in haemoglobin levels and effectively replenishes depleted iron stores.[11] FCM has proven to be more efficacious and better tolerated than oral iron, particularly in treating iron deficiency in individuals with HD-CKD. Several comparative studies have favoured ferric carboxymaltose (FCM) over other intravenous iron formulations, highlighting its superior efficacy, safety, and cost-effectiveness as discussed below.

A study by Hofman 2018, retrospectively compared the effects of iron sucrose (IS) and ferric carboxymaltose (FCM) on anemia in 221 haemodialysis patients who were switched from IS to FCM. Haemoglobin levels increased in all groups after the switch, while the weekly iron dose was significantly lower with FCM. Serum ferritin, transferrin saturation, and haemoglobin levels improved, and the dose of darbepoetin α (ESA) was significantly reduced. These findings suggest that FCM is more effective than IS in improving iron status and reducing ESA needs in haemodialysis patients.[12]

Another study by Lacquaniti et al, 2020, retrospectively examined the long-term effects of switching from ferric gluconate (FX) to ferric carboxymaltose (FCM) in 25 haemodialysis patients over a 4-year period. The results showed that FCM significantly increased transferrin saturation (TSAT) levels by 11.9% and reduced the frequency of TSAT falling below 20%. Patients required lower doses of erythropoietin (EPO) and had a reduced erythropoietin resistance index during FCM treatment. Ferritin levels were higher, while transferrin levels decreased compared to FX treatment. Overall, FCM allowed for better anemia control with reduced EPO dosing.[1]

In the present study of 52 patients, a significant increase ($p<0.001$) was recorded in the haemoglobin, and TSAT levels after the treatment with ferric carboxymaltose (FCM). A non-significant difference ($p<0.001$) was also recorded in the serum ferritin levels after the treatment with FCM where mean baseline levels were found to be 108.58±40.26 ng/ml which increased to 117.19±52.62 ng/ml after the treatment with FCM. Also, a significant difference ($p<0.001$) was recorded in the transferrin saturation (TSAT) where the mean baseline TSAT was found to be 13.66±4.73% while the post-FCM mean TSAT was 17.35±6.44 %.

Over a 12-month period, a cohort of 38 haemodialysis (HD) patients who switched to FCM showed improved haemoglobin (Hb) levels, with the percentage of patients achieving target Hb values increasing from 63% to 82%. Additionally, key iron metabolism markers, such as ferritin, transferrin saturation, and the erythropoietin resistance index, also improved. The switch to FCM resulted in cost savings of €14–46 per patient per month, primarily due to reduced erythropoiesis-stimulating agent (ESA) usage. Overall, FCM demonstrated a more favourable efficacy profile and lower costs compared to FG in managing iron deficiency anemia in HD patients.[7]

Similarly, switching 77 haemodialysis patients from intravenous ferric gluconate (FG) to ferric carboxymaltose (FCM) led to improved iron status, haemoglobin levels increased from 61% to 75.3% of patients, and transferrin saturation increased by 37.7%. The erythropoietin resistance index decreased, indicating reduced ESA use. Safety remained stable with minimal adverse events, and FCM treatment saved 11.11 EUR per patient per month. FCM proved effective, safe, and cost-effective for managing iron deficiency anemia in these patients.[13]

None of the patients reported any adverse effects as reported in similar studies discussed further. Charytan et al, 2013 compared the safety of FCM to standard medical care (SMC) in patients with chronic kidney disease (CKD), both on dialysis (HD) and non-dialysis-dependent (NDD). FCM was administered, with HD-CKD patients receiving 200 mg and NDD-CKD patients up to 1000 mg. Serious adverse events were more common in the SMC group, particularly in those receiving iron sucrose or sodium ferric gluconate. There were no significant differences in haemoglobin improvement between the FCM and SMC groups, indicating that FCM is a safe and effective option for iron repletion in CKD patients, with comparable efficacy to other IV iron formulations.

Another retrospective study investigated the impact of intravenous ferric carboxymaltose (FCM) on cardiovascular events in iron-deficient haemodialysis patients over a year. Among 53 patients who received FCM, there was a significant reduction in both erythropoiesis-stimulating agent (ESA) doses and cardiovascular events, compared to 19 control patients who did not receive FCM. However, no significant differences were observed in echocardiographic parameters.

The FCM group achieved better iron status with improved transferrin saturation and ferritin levels, along with fewer coronary and cardiovascular events.[14] Effects of intravenous ferric carboxymaltose (FCM) on ferritin and transferrin saturation (TSAT) in haemodialysis patients was examined in a study by Diebold et al, 2019. After administering 100 mg or 200 mg doses, ferritin levels significantly increased and remained elevated for up to three weeks, while TSAT levels spiked but returned to baseline within four days. The results suggest that blood sampling for iron status should be timed carefully with IV iron dosing to avoid misleading ferritin readings.[3]

Although FCM dosing is dependent on baseline haemoglobin and weight of the patient, this being a real-world observational study dosing of FCM was at the physician's discretion. Our study showed that on average total dose of 400 mg in 4 divided doses of 100 mg during each infusion is the preferred dose for iron replacement in HD-CKD. In this study, the median patient weight was 58 kg. The CRP for 43 patients decreased with the mean baseline reading of 9.36±4.77 mg/l to 9.19±3.57 mg/l post-FCM administration(p=0.315). While the eGFR increased from 12.28±3.87 ml/min/1.73 to 12.36±3.96 ml/min/1.73 (p=0.432). C-reactive protein (CRP) is an acute-phase protein associated with acute kidney injury (AKI) and chronic kidney disease (CKD), and a decrease in CRP levels may indicate that iron therapy helps reduce inflammation.[15]

The findings are consistent with previous international studies, further supporting ferric carboxymaltose (FCM) as a superior option to other intravenous iron formulations due to its efficacy, tolerability, and potential to reduce doses of erythropoiesis-stimulating agents (ESAs). Although changes in C-reactive protein (CRP) and estimated glomerular filtration rate (eGFR) were not significant, the overall results suggest that FCM is a valuable option for managing iron deficiency anemia (IDA) in patients with haemodialysis-dependent chronic kidney disease (HD-CKD), especially in resource-limited settings.

CONCLUSION

This multicentric, retrospective observational study highlights the efficacy and safety of ferric carboxymaltose (FCM) in correcting iron deficiency anemia (IDA) in haemodialysis-dependent chronic kidney disease (HD-CKD) patients within an Indian clinical setting. The study demonstrated a significant improvement in haemoglobin levels, serum ferritin, and transferrin saturation (TSAT) after FCM administration (100 mg) over the short one-month observation period, without any reported serious adverse events. We discovered that a weekly dose of 100 mg was administered, and over the short one-month observation period, the Hb increase was +0.69 g/dl (p<0.001).

The findings align with previous international studies, reinforcing FCM as a superior alternative to other intravenous iron formulations due to its effectiveness, tolerability, and potential to reduce erythropoiesis-stimulating agent (ESA) doses. Despite the non-significant changes in C-reactive protein (CRP) and estimated glomerular filtration rate (eGFR), the overall results suggest that FCM is a valuable option for managing IDA in HD-CKD patients, particularly in resource-limited settings. Further studies could explore optimal dosing strategies and long-term outcomes to refine treatment protocols.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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