Therapeutic Comparison of Ferric Carboxymaltose and Fractionated Iron Sucrose in Iron Deficiency Anemia: Toward Optimizing Patient Outcomes

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ABSTRACT

Background: Iron deficiency anemia (IDA) is a widespread hematologic condition characterized by low hemoglobin levels. Intravenous (IV) iron is used for replenishing iron stores. Iron sucrose is administered in multiple low-dose infusions and recognized for its favourable safety and efficacy profile. Ferric carboxymaltose (FCM), a newer IV formulation, permits higher iron doses in a single infusion and may improve patient adherence. However, FCM is linked to a high incidence of adverse effects.

Aims: To compare the efficacy of IV FCM and iron sucrose in improving hemoglobin levels in patients with IDA and the number of hospital visits, and to assess the safety of ferric carboxymaltose

Method: In this study, 30 patients diagnosed with IDA at Aldiwaniay Teaching Hospital. 15 patients received iron sucrose, and 15 received FCM. Hematologic response was evaluated via complete blood count performed before treatment and two weeks following the final infusion.

Result: Iron sucrose produced a modest yet statistically significant improvement in hemoglobin levels compared to FCM. Nevertheless, FCM was associated with fewer hospital visits, offering a benefit in terms of treatment convenience. Notably, the FCM group experienced a high adverse event.

Conclusion: While iron sucrose demonstrated slightly superior hematologic efficacy, FCM remains an alternative, particularly in settings where resource optimization and patient accessibility are central considerations.

Keywords: Ferric carboxymaltose, haemoglobin, Iron deficiency anaemia, Iron sucrose.

مقارنة علاجية بين كاربوكسي مالتوز الحديديك وسكروز الحديد المجزأ في فقر الدم الناجم عن نقص الحديد: نحو تحسين نتائج المرضى

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الخلاصة

الخلفية: فقر الدم الناجم عن نقص الحديد هو حالة دموية واسعة الانتشار تتميز بانخفاض مستويات الهيموغلوبين. يُستخدم الحديد الوريدي لتجديد مخزون الحديد. يُعطى سكروز الحديد في دفعات متعددة منخفضة الجرعات، وهو معروف بسلامته وفعاليته. يسمح كربوكسي مالتوز الحديديك (FCM)، وهو تركيبة وريدية أحدث، بجرعات أعلى من الحديد في دفعة واحدة، وقد يُحسّن التزام المريض بالعلاج. ومع ذلك، يرتبط كربوكسي مالتوز الحديديك بارتفاع معدل الآثار الجانبية.

الأهداف: مقارنة فعالية كربوكسي مالتوز الحديديك الوريدي وسكروز الحديد في تحسين مستويات الهيموغلوبين لدى مرضى فقر الدم الناجم عن نقص الحديد وعدد زيارات المستشفى، وتقييم سلامة كربوكسي مالتوز الحديديك.

الطريقة: أجريت هذه الدراسة على ٣٠ مريضًا مُشخصين بفقر الدم الناجم عن نقص الحديد في مستشفى الديوانية التعليمي. تلقى ١٥ مريضًا سكروز الحديد، وتلقى ١٥ مريضًا كربوكسي مالتوز الحديديك. تم تقييم الاستجابة الدموية من خلال تعداد الدم الكامل الذي أُجري قبل العلاج وبعد أسبوعين من التسريب النهائي.

النتيجة: أدى استخدام سكروز الحديد إلى تحسن طفيف، وإن كان ذا دلالة إحصائية، في مستويات الهيموغلوبين مقارنةً بـ FCM. ومع ذلك، ارتبط استخدام FCM بزيارات أقل للمستشفى، مما وفّر فائدة من حيث سهولة العلاج. والجدير بالذكر أن مجموعة FCM شهدت آثارًا جانبية عالية.

الاستنتاج: على الرغم من أن سكروز الحديد أظهر فعالية دموية أعلى بقليل، إلا أن FCM يبقى بديلاً، لا سيما في الحالات التي يكون فيها تحسين الموارد وإمكانية وصول المرضى أمرًا بالغ الأهمية.

الكلمات المفتاحية: كاربوكسي مالتوز الحديدي، الهيموجلوبين، فقر الدم الناجم عن نقص الحديد، سكروز الحديد.

INTRODUCTION

Iron deficiency anemia (IDA) represents a more advanced stage of iron deficiency (ID), where reduced iron levels are associated with anemia and the appearance of microcytic, hypochromic red blood cells. ID can be classified into two main types: absolute and functional.[1] In developing countries, IDA is commonly linked to poverty, malnutrition, and famine, particularly among children and pregnant women. Conversely, in developed countries, IDA is often associated with strict vegan or vegetarian dietary patterns, impaired absorption, and chronic blood loss due to conditions like heavy menstrual bleeding. [2] Hematological and biochemical parameters are integral to diagnosing IDA. IDA, marked by reduced hemoglobin (Hb) concentration. Based on the World Health Organization criteria (WHO), anemia is defined as an Hb concentration below 130 g/L in males, under 120 g/L in nonpregnant females. Assessment of ferritin levels, serum iron concentration, and transferrin saturation represents a standard approach for diagnosing ID across a range of clinical scenarios.[3]

Effective management of ID involves identifying its root cause and restoring the body's iron levels. Oral iron supplementation remains the initial treatment of choice for individuals with ID, owing to its affordability, widespread availability, and proven efficacy in restoring iron levels. [4]

In the early 20th century, the initial parenteral iron formulations introduced into clinical use were colloidal ferric hydroxide-based. However, their application was constrained by toxicity concerns arising from the excessive release of labile (free) iron. This challenge led to the innovation of iron preparations featuring a stabilized iron core encased within a carbohydrate shell, designed to regulate iron release and minimize toxicity. During the 1990s, iron gluconate and iron sucrose emerged as novel intravenous (IV) formulations, featuring non-dextran carbohydrates bound to the iron core. These agents demonstrated significantly reduced rates of severe adverse events, and studies confirmed that individuals previously reactive to high molecular weight dextran were generally tolerant to these newer options. [5] Iron sucrose was among the earliest IV iron formulations to be introduced, reaching clinical use over seven decades ago.

Iron sucrose remains one of the longest-standing therapeutic agents still widely employed today. Its active component consists of an iron (III) hydroxide complex stabilized by sucrose. [6] Advances in pharmaceutical technology subsequently facilitated the creation of third-generation IV iron therapies aimed at overcoming both the toxicity concerns of earlier formulations and the dosing limitations associated with iron sucrose. Third generation IV iron formulation, including ferric carboxymaltose (FCM), iron isomaltoside, and ferumoxytol.[5] Iron sucrose requires multiple administrations to achieve therapeutic goals, which can negatively affect patient adherence. In contrast, FCM is a non-dextran-based intravenous iron formulation characterized by low immunogenicity, thereby reducing the likelihood of anaphylactic responses. Its design allows for the administration of large single doses over a short duration, minimizing side effects while addressing the limitations associated with earlier IV iron therapies. Clinical studies have demonstrated that FCM is both safe and effective in treating IDA, showing marked improvements in Hb levels. [7] Compared to other intravenous iron formulations, FCM demonstrates a similar profile for common adverse events, but tends to show lower rates of hypotension and dysgeusia. Notably, FCM is more frequently associated with hypophosphatemia and flushing. Injection site reactions, especially pain, extravasation, and discoloration, can persist for months. However, flushing the catheter with saline before needle withdrawal significantly reduces the risk of residual drug leakage and post-infusion discoloration. [8] FCM carries a higher acquisition cost, but it has demonstrated superior clinical outcomes compared to iron sucrose and oral iron preparations. Multiple studies have underscored its cost-effectiveness, largely attributed to reduced need for repeated dosing and fewer hospital visits, which together contribute to improved patient adherence. [7]

MATERIALS AND METHODS

Study Setting

This prospective, interventional study was conducted between October 2024 and May 2025 at Al-Diwaniyah Teaching Hospital in Diwaniyah, Iraq. A total of 30 patients diagnosed with iron deficiency anemia were eligible, following evaluation and recruitment by a haematologist.

Patient Inclusion Criteria

Eligible patients had a confirmed diagnosis of iron deficiency anaemia, haemoglobin levels ≤11 g/dL, age between 18 and 65 years, and the patient was indicated for intravenous iron therapy.

Drug Used in the Study

Fifteen patients were included in this study received Ferric carboxymaltose, and fifteen patients received Iron sucrose

A. Ferric Carboxymaltose :

A 500 mg vial of ferric carboxymaltose was administered as a single intravenous infusion in 200 mL of 0.9% normal saline over 15 minutes [9]

B. Iron Sucrose:

A total of 200 mg of iron sucrose (two ampoules, each containing 100 mg/5 mL) was administered as an intravenous infusion in 200 mL of 0.9% normal saline over 30 minutes on alternate days, until a total dose of 600 mg was delivered within one week. [10]

Laboratory Analysis and other Measurements

A- Hematologic parameters were assessed pre-treatment and two weeks following the final injection.

The blood samples with 1 ml were collected from the patients placed in an Ethylene Diamine Tetra acetic Acid (EDTA) tube. Tubes were gently inverted 8–10 times to mix, avoiding hemolysis. Before analysis, samples were kept upright at room temperature (~25°C) and gently remixed either manually or on a slow-speed roller mixer for 5 minutes.

Samples were then loaded into the Mindray BA-88A (China) automated analyzer for aspiration, analysis, and result output, following the manufacturer's instructions.

B- The number of patient visits to the hospital and the adverse effects caused by FCM was recorded

Statistical Analysis

Statistical analysis of haematological parameters was performed using SPSS software (version 26). A p-value less than or equal to 0.05 was considered statistically significant. Data were presented as mean ± standard error of the mean (SEM) and standard deviation

RESULT

1-Demographic Data

This study involved 30 Iraqi patients diagnosed with IDA, of whom the majority were female (93.3%, n = 28) and only two were male (6.7%). The mean gender distribution, coded numerically, was identical in both treatment groups, iron sucrose and ferric carboxymaltose with a mean ± standard error (SE) of 1.07 ± 0.067, yielding a P-value of 1.000.

The average age of participants in the iron sucrose group was 31.6 ± 2.72 years, while the FCM group showed a mean age of 31.8 ± 2.75 years (P = 0.959).

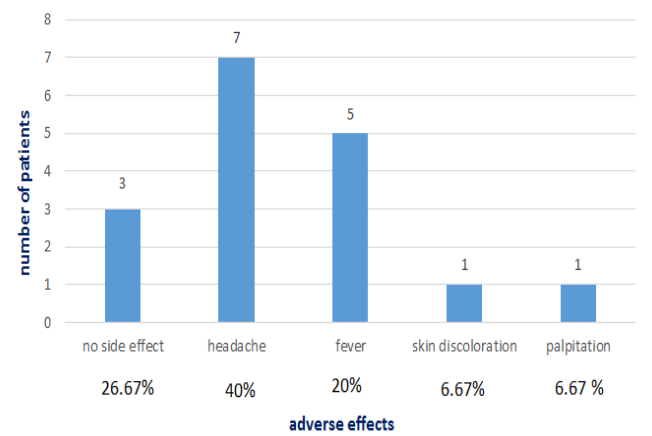

Figure (1): The side effects of FCM (Note: some patients experience more than one side effect)

2-Hospital Visit Frequency

A. Number of infusions

Table (1): Number of infusions for each FCM and iron sucrose

	Groups	Mean	Standard deviation	SE mean	P value
Number of infusions	Iron sucrose	2.33	1.447	0.374	0.001
	Ferric carboxymaltose	1.00	0.000	0.000	

B. Time of infusion

All 15 patients in the iron sucrose group received the drug in a 30-minute infusion, whereas all 15 patients in the ferric carboxymaltose group received the drug in a 15-minute infusion.

3-Hematological Outcomes

For FCM before and after 2weeks

Table (2): Value of hemoglobin before and after 2 weeks of treatment with Ferric carboxymaltose

	Mean (g/dl)	95% Confidence Interval	St. Deviation	SE mean	P value
Haemoglobin level before treatment	7.880	7.42 – 8.34	0.8300	0.2143	0.044
Haemoglobin level after 2 weeks	8.227	7.69 – 8.77	0.9747	0.2517	

For IS before and after 2weeks

Table (3): Value of haemoglobin before and after 2 weeks of treatment with Iron sucrose

	Mean (g/dl)	95% Confidence Interval	St. Deviation	SE mean	P value
Haemoglobin level before treatment	7.851	7.17 – 8.54	1.2354	0.3190	0.001
Haemoglobin level after 2 weeks	9.056	8.39 – 9.73	1.2110	0.3127	

For FCM and IS before and after treatment

Table (4): Value of hemoglobin before and after treatment with Ferric carboxymaltose and Iron sucrose

	Groups	Mean	SE mean	P value
Haemoglobin level before treatment	Iron sucrose	7.851	0.3190	0.940
	Ferric carboxymaltose	7.880	0.2143	
Haemoglobin level after 2 weeks	Iron sucrose	9.056	0.3127	0.048
	Ferric carboxymaltose	8.227	0.2517	

DISCUSSION

A randomized controlled trial was conducted in patients with IDA of varying etiologies, comparing a single 500 mg dose of FCM with three separate 200 mg doses of intravenous Iron sucrose. The selected FCM dosage was guided by its availability, the comparable elemental iron content between the treatment regimens, and to minimize the risk of hypophosphatemia (a life-threatening side effect), which is more commonly associated with higher doses. [11]

Clinical assessment of treatment outcomes revealed a statistically significant reduction in hospital visits among patients receiving FCM compared to those treated with IS ($p = 0.001$).

This difference is attributed to FCM being administered as a single dose per patient, whereas IS requires multiple visits. These findings align with a randomized controlled trial by Jose et al (2019), which also reported fewer hospital visits with FCM treatment. [12]

Although FCM reduces hospital visits due to its efficient dosing, the Hb response was lower than that seen with IS within the 2-week follow-up. Further studies using higher FCM doses or extended monitoring are recommended to assess whether comparable Hb outcomes can be achieved in such visits.

Baseline hematological parameters showed no significant differences between treatment groups ($p > 0.05$), confirming their comparability before intervention, a key factor in maintaining internal validity for post-treatment analyses. A modest but statistically significant rise in hemoglobin levels was observed in the FCM group, indicating a therapeutic response within two weeks. This contrasts with earlier studies that reported more pronounced increases in Hb following FCM administration [13,14]

The modest Hb response observed in this analysis may be linked to the relatively low 500 mg dose of FCM or the early evaluation timeframe.

Notably, multiple studies have reported more pronounced Hb increases when assessments are conducted three weeks or later following infusion. [15,16] A retrospective analysis by Wani, Noushad, and Ashiq (2019) at Corniche Hospital in Abu Dhabi demonstrated that administering higher doses of FCM resulted in more Hb improvements without a corresponding rise in adverse effects.[17]

A statistically significant rise in Hb levels was observed after two weeks of IS therapy, underscoring its effectiveness in correcting anemia within a short treatment period. These results are consistent with findings reported by Hong et al (2021), which highlighted the rapid hematologic response associated with IS administration.[18]

These findings are further supported by Desai et al (2017) [19] investigated the therapeutic efficacy of IS injections and reported a statistically significant elevation in Hb concentrations following treatment.

Although FCM is recognized for its rapid iron repletion, findings from this study indicated that IS yielded higher Hb levels after two weeks.

Supporting this observation, a retrospective study conducted in Doha, Qatar (2020) reported that IS was associated with slightly greater increases in Hb compared to FCM. [20]

The safety profile of FCM revealed that 73.33% of patients experienced at least one adverse event following administration, while 26.67% remained symptom-free. Headache was the most commonly reported adverse effect, occurring in 40% of patients, followed by fever (20%), with skin discoloration and palpitations each noted in 6.67% of cases.

According to a systematic review by Magagnoli et al (2025), headache was among the most prevalent non-serious adverse events, especially in female patients and those receiving higher FCM doses.[21] Fever may reflect a mild acute phase response triggered by cytokine release following FCM infusion. This is consistent with findings from Qunibi et al (2019), who noted that mild fever may reflect an acute-phase response driven by cytokines after IV iron therapy. [22]

Skin discoloration is generally attributed to localized iron extravasation or superficial vascular responses. [23]

Palpitations and tachycardia have been identified as post-marketing adverse events associated with FCM. [24]

The high incidence of adverse events following FCM administration underscores the importance of thorough pre-infusion screening, dose management, and post-infusion monitoring. Although most reactions were mild and self-limiting, their frequency highlights the need for patient education and vigilance, particularly in individuals with cardiovascular risk or prior hypersensitivity.

CONCLUSION

In this study, both agents effectively increased hemoglobin levels, with iron sucrose showing a slightly greater improvement within the initial two-week period. However, FCM was linked to a higher incidence of adverse effects. To gain a clearer understanding of the long-term efficacy and safety of these therapies, future research should involve extended follow-up periods, larger and more diverse patient populations, and an evaluation of how factors such as renal function and anemia severity influence treatment outcomes.

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Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this manuscript

Ethical Consideration

Approval for conducting this research was obtained from the ethics committee of the college of medicine, University of al-Qadisiyah, Iraq. (letter 30/1193) on May 25th, 2025. Prior to participation, all patients were provided with a verbal explanation of the study's objectives and procedures, and verbal informed consent was obtained from each patient before the initiation of any study-related interventions or data collection.

Authors Contribution

All authors contributed substantially to the study. BIM led the study conception, design, and protocol development. NKW performed data analysis, interpretation, and was responsible for drafting and critically revising the manuscript for intellectual content. DHA contributed to patient recruitment, data acquisition, and reviewed the manuscript for accuracy.

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