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COMPARATIVE EFFICACY AND SAFETY OF INTRAVENOUS FERRIC CARBOXYMALTOSE (FERINJECT) AND IRON SUCROSE (VENOFER) IN CHILDREN BETWEEN 1 TO 12 YEARS OF AGE WITH IRON DEFICIENCY ANEMIA

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Abstract

Objectives

Iron deficiency and iron-deficiency anemia (IDA) are prevalent conditions in children and pregnant women worldwide, often leading to impaired physical, cognitive, and immune function. This study aimed to compare the efficacy and safety of intravenous ferric carboxymaltose (FCM) and iron sucrose (IS) in children aged 1–12 years with laboratory-confirmed IDA.

Methodology

A prospective, comparative interventional study was conducted in the Department of Pediatrics at a tertiary care hospital. A total of 100 children with confirmed IDA were enrolled and equally divided into two groups. Group A (n = 50) received intravenous ferric carboxymaltose, while Group B (n = 50) received intravenous iron sucrose, following standard pediatric dosing protocols. Baseline demographic and hematological parameters, including hemoglobin, serum ferritin, mean corpuscular volume, and transferrin saturation, were recorded. Follow-up assessments were performed to evaluate treatment response and monitor adverse events. Data were analyzed using appropriate statistical tests, with significance set at $p < 0.05$.

Results

Both groups showed significant improvements in hemoglobin and iron indices; however, the increase was more pronounced in the ferric carboxymaltose group. The mean number of infusions was significantly lower in Group A compared to Group B (1.3 ± 0.5 vs. 4.6 ± 1.1; $p < 0.001$). Adverse events were mild and self-limiting, with no serious or life-threatening reactions observed. The overall incidence of adverse effects was slightly higher in the iron sucrose group, though not statistically significant.

Conclusion

Intravenous ferric carboxymaltose demonstrated superior efficacy in improving hemoglobin and iron stores with fewer infusions, while maintaining a safety profile comparable to iron sucrose. FCM may therefore be considered a more convenient and efficient option for pediatric IDA management.

INTRODUCTION

Iron deficiency and iron-deficiency anaemia are common in pregnancy, even in developed countries, occurring in up to 25% pregnant women in Europe [1]. Maternal consequences are well described, and include cardiovascular symptoms, reduced physical, mental and immune function and peripartum reserves [2]. Intravenous iron therapy is often preferred in cases where rapid iron repletion is necessary or when oral iron formulations are ineffective or poorly tolerated [3]. Among intravenous iron therapies, ferric carboxymaltose (FCM) and iron sucrose (IS) are widely used. FCM allows for larger doses in fewer administrations compared to IS, making it more convenient for patients and healthcare providers [4]. The reported prevalence of ID and iron deficiency anaemia (IDA) in children varies widely. A review of studies across Europe found that ID prevalence in young children varied depending on socioeconomic status and type of milk consumed (i.e. formula, human or cow's milk) [5]. Among adolescents, the prevalence of IDA may be as high as 25–30% in low–middle social development index countries [6]. Anemia affects about 2 billion people globally, corresponding to over 27% of the world's population, with iron-deficiency anemia (IDA) being the most significant contributor [7]. IDA is predominant in children, pre-menopausal women, and among population in low and middle-income countries [8]. Orally administered iron (liquid or tablet formulations) is generally effective, but side effects, as well as difficulty swallowing tablets and poor taste, can lower adherence to therapy, especially in children [9].

METHODOLOGY

This study was conducted to compare the efficacy and safety of intravenous ferric carboxymaltose (Ferinject) and iron sucrose (Venofer) in children aged 1 to 12 years diagnosed with iron deficiency anemia. A prospective, comparative interventional study design was adopted. The study was carried out in the Department of Pediatrics at a tertiary care hospital over a specified study period. Ethical approval was obtained from the institutional ethics committee prior to the initiation of the study, and written informed consent was obtained from the parents or legal guardians of all participants. Children aged 1 to 12 years with laboratory-confirmed iron deficiency anemia, defined by low hemoglobin levels along with reduced serum ferritin and transferrin saturation, were included in the study. Patients with anemia due to causes other than iron deficiency, known hemoglobinopathies, chronic inflammatory or renal diseases, history of hypersensitivity to parenteral iron preparations, or recent blood transfusions were excluded. Eligible participants were enrolled using a non-probability consecutive sampling technique and were allocated into two groups based on the intravenous iron preparation administered.

Group A received intravenous ferric carboxymaltose (Ferinject) administered as a single or divided dose according to body weight and calculated iron deficit. Group B received intravenous iron sucrose (Venofer) administered in multiple divided doses over several sessions as per standard pediatric dosing guidelines. All infusions were given under medical supervision, and patients were monitored during and after administration for any adverse reactions.

Baseline clinical evaluation and laboratory investigations, including hemoglobin concentration, serum ferritin, mean corpuscular volume (MCV), and transferrin saturation, were recorded before treatment initiation. Follow-up assessments were performed at predefined intervals to evaluate treatment response. Safety was assessed by monitoring for immediate infusion reactions, delayed adverse events, and changes in vital signs. The qualitative variables included gender, treatment group (ferric carboxymaltose or iron sucrose), presence or absence of adverse drug reactions, type of adverse effects (such as nausea, vomiting, hypotension, rash, or infusion site reactions), and clinical improvement in symptoms of anemia. These variables were recorded as categorical data and were used to assess and compare the safety profiles of both intravenous iron formulations.

The quantitative variables included age (years), body weight (kg), baseline and post-treatment

hemoglobin levels (g/dL), serum ferritin levels (ng/mL), transferrin saturation (%), mean corpuscular volume (fL), total calculated iron dose (mg), and number of infusions required. These variables were recorded as numerical data and were used to assess and compare the efficacy of ferric carboxymaltose and iron sucrose. Data were entered and analyzed using statistical software. Quantitative variables were expressed as mean ± standard deviation, while qualitative variables were presented as frequencies and percentages. The efficacy of the two treatment groups was compared using appropriate statistical tests for continuous variables, while categorical variables were analyzed using chi-square or Fisher's exact test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 100 children aged 1–12 years with laboratory-confirmed iron deficiency anemia were enrolled in the study and equally divided into two groups. Group A (n = 50) received intravenous ferric carboxymaltose (Ferinject), while Group B (n = 50) received intravenous iron sucrose (Venofer). The baseline demographic and hematological characteristics of both groups were comparable, with no statistically significant differences observed at enrollment ($p > 0.05$).

The mean age of participants in Group A was 6.4 ± 2.8 years, while in Group B it was 6.6 ± 2.9 years. Baseline hemoglobin levels were similar between the two groups. Following treatment, both groups showed a significant improvement in hemoglobin and iron indices; however, the increase was more pronounced in the ferric carboxymaltose group. Additionally, the mean number of infusions required was significantly lower in Group A compared to Group B ($p < 0.001$).

Table 1: Comparison of Baseline and Post-Treatment Hematological Parameters between Study Groups

Parameter	Ferric Carboxymaltose (n = 50)	Iron Sucrose (n = 50)	p-value
Age (years)	6.4 ± 2.8	6.6 ± 2.9	0.72
Weight (kg)	19.2 ± 6.1	19.5 ± 6.4	0.81
Baseline hemoglobin (g/dL)	8.1 ± 0.9	8.0 ± 1.0	0.64
Post-treatment hemoglobin (g/dL)	11.2 ± 0.8	10.4 ± 0.9	<0.001
Baseline serum ferritin (ng/mL)	9.6 ± 3.2	9.4 ± 3.1	0.78
Post-treatment serum ferritin (ng/mL)	72.4 ± 18.6	42.8 ± 15.2	<0.001
Number of infusions	1.3 ± 0.5	4.6 ± 1.1	<0.001

Regarding safety, both intravenous iron preparations were generally well tolerated. Adverse drug reactions were mild and self-limiting in nature, with no serious or life-threatening events reported. The overall incidence of adverse effects was slightly higher in the iron sucrose group, although the difference was not statistically significant ($p > 0.05$).

Table 2: Comparison of Adverse Drug Reactions between Study Groups

Adverse Event	Ferric Carboxymaltose (n = 50)	Iron Sucrose (n = 50)	p-value
Any adverse reaction	6 (12.0%)	10 (20.0%)	0.28
Nausea / vomiting	2 (4.0%)	4 (8.0%)	0.40
Infusion site reaction	1 (2.0%)	3 (6.0%)	0.30
Transient hypotension	1 (2.0%)	2 (4.0%)	0.56
Rash / pruritus	2 (4.0%)	1 (2.0%)	0.56
Serious adverse events	0 (0.0%)	0 (0.0%)	–

Overall, intravenous ferric carboxymaltose demonstrated greater efficacy in improving hemoglobin and iron stores with the advantage of fewer infusions, while maintaining a safety profile comparable to iron sucrose.

DISCUSSION

A total of 100 children aged 1–12 years with laboratory-confirmed iron deficiency anemia were enrolled in the study and were equally divided into two treatment groups. These findings are in agreement with a study conducted in 2012, which reported that both intravenous iron preparations are effective and safe, with a low risk of serious adverse effects and side effects [10]. In the present study, Group A (n = 50) received intravenous ferric carboxymaltose (Ferinject), while Group B (n = 50) received intravenous iron sucrose (Venofer). The baseline demographic and hematological characteristics of both groups were comparable, with no statistically significant differences observed at enrollment ($p > 0.05$). However, a systematic review published in 2025 highlighted that ten studies showed some concerns regarding risk of bias, while four studies demonstrated a high risk of bias for changes in hemoglobin levels during follow-up. The lack of standardized definitions for hypersensitivity reactions and variability in dosing protocols and follow-up durations across studies may limit the generalizability of safety findings [11].

The mean age of participants in Group A was 6.4 ± 2.8 years, while in Group B it was 6.6 ± 2.9 years. Baseline hemoglobin levels were similar between the two groups. Following treatment, both groups demonstrated a significant improvement in hemoglobin levels and iron indices; however, the improvement was more pronounced in the ferric carboxymaltose group. These results are supported by a 2023 study which showed that the use of ferric carboxymaltose, compared to iron sucrose, resulted in a reduced number of iron infusions (4.4 visits for iron sucrose versus a single visit for ferric carboxymaltose), along with a reduction in overall treatment cost. The study concluded that ferric carboxymaltose may represent a cost-saving option for the management of iron deficiency anemia in the Kingdom of Saudi Arabia [12]. In the present study, the mean number of infusions required was significantly lower in Group A compared to Group B ($p < 0.001$). Similar findings were reported in a 2023 study, which demonstrated that ferric carboxymaltose therapy was associated with a greater increase in hemoglobin levels compared to conventional iron sucrose therapy, along with better safety and tolerability [13].

Regarding safety, both intravenous iron preparations were generally well tolerated. Adverse drug reactions were mild and self-limiting in nature, and no serious or life-threatening adverse events were observed. These findings are consistent with a 2016 study, which reported that properties such as ultra-short duration of treatment, fewer adverse reactions, and better patient compliance make ferric carboxymaltose a preferred first-line therapy for postpartum iron deficiency anemia [14]. The overall incidence of adverse effects in the present study was slightly higher in the iron sucrose group; however, this difference was not statistically significant ($p > 0.05$). In line with these results, a 2025 study concluded that both

iron sucrose and ferric carboxymaltose are effective in treating iron deficiency anemia during pregnancy, although improvement was faster, safer, and more convenient with ferric carboxymaltose [15]. Overall, intravenous ferric carboxymaltose demonstrated greater efficacy in improving hemoglobin levels and iron stores, with the added advantage of fewer infusions, while maintaining a safety profile comparable to iron sucrose. These findings are further supported by a 2023 study, which reported that administration of ferric carboxymaltose during the second and third trimesters of pregnancy was well tolerated and associated with no significant safety concerns. Even when administered at higher doses than iron sucrose, both treatments demonstrated comparable safety profiles, leading the authors to recommend ferric carboxymaltose as the preferred intravenous iron therapy when treatment is required during late pregnancy [16].

CONCLUSION

Intravenous ferric carboxymaltose and iron sucrose were both effective and safe in the treatment of iron deficiency anemia in children aged 1–12 years. However, ferric carboxymaltose demonstrated superior efficacy in improving hemoglobin levels and iron stores, with the added advantage of requiring significantly fewer infusions. Both treatments were well tolerated, with no serious adverse events observed. Ferric carboxymaltose may therefore be considered a more convenient and efficient therapeutic option for pediatric iron deficiency anemia.

REFEREENCE

De Benoist B, McLean E, Egli I, Cogswell M, Cogswell M. WHO global database on anaemia. Geneva: WHO. 2008:1993-2005.

Haas JD, Brownlie IV T. Iron deficiency and reduced work capacity: a critical review of the research to determine a causal relationship. The Journal of nutrition. 2001 Feb 1;131(2):676S-90S.

Shahid I, Ibrahim N, Shafique S, Zulfiqar Z. Diagnostic Utility of Sonography and Magnetic Resonance Imaging in Evaluating Placenta Previa and Its Variants Using Intraoperative Findings as the Gold Standard. Age (years). 2025 Jun;18:30.

Mintsopoulos V, Tannenbaum E, Malinowski AK, Shehata N, Walker M. Identification and treatment of iron-deficiency anemia in pregnancy and postpartum: A systematic review and quality appraisal of guidelines using AGREE II. International Journal of Gynecology & Obstetrics. 2024 Feb;164(2):460-75.

van der Merwe LF, Eussen SR. Iron status of young children in Europe. The American journal of clinical nutrition. 2017 Dec 1; 106:1663S-71S.

Christian P, Smith ER. Adolescent undernutrition: global burden, physiology, and nutritional risks. Annals of nutrition and metabolism. 2018 May 4;72(4):316-28.

Kassebaum NJ, Jasrasaria R, Naghavi M, Wulf SK, Johns N, Lozano R, Regan M, Weatherall D, Chou DP, Eisele TP, Flaxman SR. A systematic analysis of global anemia burden from 1990 to 2010. Blood, the Journal of the American Society of Hematology. 2014 Jan 30;123(5):615-24.

Mantadakis E, Chatzimichael E, Zikidou P. Iron deficiency anemia in children residing in high and low-income countries: risk factors, prevention, diagnosis and therapy. Mediterranean journal of hematology and infectious diseases. 2020 Jul 1;12(1):e2020041.

Powers JM, Nagel M, Raphael JL, Mahoney DH, Buchanan GR, Thompson DI. Barriers to and facilitators of iron therapy in children with iron deficiency anemia. The Journal of pediatrics. 2020 Apr 1; 219:202-8.

Myers B, Myers O, Moore J. Comparative efficacy and safety of intravenous ferric carboxymaltose (Ferinject) and iron (III) hydroxide dextran (Cosmofer) in pregnancy. Obstetric Medicine. 2012 Sep;5(3):105-7.

Tanrıverdi LH, Sarıcı A. Efficacy, Safety, and Tolerability of Ferric Carboxymaltose and Iron Sucrose in Iron-Deficiency Anemia: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Turkish Journal of Hematology. 2025 Mar 17;42(2):119-35.

Alzahrani S, Almeziny M, Narang A, Mohamed O, Almeziny S, Almeziny A. A cost-comparative analysis of intravenous ferric Carboxymaltose versus iron sucrose for the ambulatory treatment of iron-deficiency anemia in a major tertiary care hospital in Saudi Arabia. International Journal of Clinical Medical Research. 2023 Aug;1(1):28-35.

Sattar S, Sultana S, Shadab W, Afzal S, Salma UE, Mobeen A. Comparison of Safety and Efficacy of Ferric Carboxymaltose with Iron Sucrose for the Treatment of Iron Deficiency Anemia in Pregnancy. InMedical Forum Monthly 2023 (Vol. 34, No. 2).

Joshi, S.D., Chikkagowdra, S. and Kumar, V., 2016. Comparative study of efficacy and safety of intravenous ferric carboxy maltose versus iron sucrose in treatment of postpartum iron deficiency anemia. Int J Reprod Contracept Obstet Gynecol, 5(8), pp.2566-70.

Shahzadi I, Virk S, Sehar A. Comparison of Efficacy and Safety of IV Ferric Carboxymaltose versus IV Iron Sucrose in Pregnancy and Postpartum Anemia. International Journal of Pharmacy Research & Technology (IJPRT). 2025 Jul 15;15(2):3188-96.

Bharadwaj MK, Patrikar S, Singh Y. Comparative analysis of injection ferric carboxymaltose vs iron sucrose for treatment of iron-deficiency anemia in pregnancy: systematic review and meta-analysis. Journal of South Asian Federation of Obstetrics and Gynaecology. 2023 Oct 31;15(5):629-36.