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# *Navigating the Side Effects: Our Insights on IV Ferric Carboxymaltose Study*

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**Abstract**

**Background:**
**Intravenous ferric carboxymaltose (brand name Ferinject) is commonly used to treat iron deficiency anemia. For many clinicians, it is the treatment of choice for severe iron deficiency requiring rapid correction. Intravenous ferric carboxymaltose (FCM) can be the treatment of choice in various medical conditions. It is also given when oral iron supplements are proven to be ineffective. Ferric carboxymaltose delivers iron directly into the bloodstream. This study aims to identify the incidence of adverse reactions in individuals who experienced side effects following ferric carboxymaltose (FCM) administration. We analysed patient demographics, types of reactions, and treatments administered.The study was conducted over a one-year period at the Abu Dhabi Stem Cells Centre (ADSCC) and Yas Clinic Hospital in Khalifa City (YCKC), the only licensed stem cell facility in the region. To the best of our knowledge, no published data on this topic exists for the Gulf region.**
**Objective:**
**The primary objective of our study is to determine the incidence, type of reactions, and confounding factors that influence adverse reactions to the use of Ferric carboxymaltose.**
**Methods:**
**A retrospective observational study was conducted over a one-year period at YCKC (managed by ADSCC), UAE from January 17 until December 28, 2023. 136 patients were included in this observational study who underwent ferric carboxymaltose infusion. All individuals included in this study had valid indications for infusion, as determined by the treating clinician. The data collected comprised patient demographics, severity of post-infusion reactions, and administered treatments. This information was analysed using the TRAKCARE medical records system of the hospital.**
**Results:136 patients were enlisted in the study, of whom 5 had sudden allergic reactions after the infusion. Based on the standard guidelines, the infusion rate depends on the weight of the patient and the target hemoglobin. As per the standard guidelines, the ferric carboxymaltose infusion duration is usually 10-15 minutes. In our study, the infusion was given in various doses and varying durations. All of the infusions given totalled 16.1-30.3 mg/min. All five patients in the study exhibited mild to moderate reactions, characterised by redness and itchiness on their bodies. Appropriate treatment was given to all patients.**
**Conclusion:**
**The primary objective of this study was to assess the occurrence of adverse reactions to FCM and analyse any correlating factors. By analysing the incidence and nature of these adverse reactions, we aim to gain a deeper insight into the safety profile of Ferinject carboxymaltose and to identify any potential risk factors associated with its administration. This information is crucial for enhancing patient management and ensuring the safe and effective use of this treatment in clinical practice.**

**Keywords: Ferric carboxymaltose, , adverse reactions, iron deficiency anemia (IDA), intravenous, infusion, vitamin D deficiency, female, allergic**

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**Introduction**

Anaemia is diagnosed when haemoglobin is two standard deviations below the mean, specific for the age and gender of the patient. Iron is an essential component of the Hb molecule. Iron deficiency anaemia is multifactorial. It appears as microcytic hypochromic anaemia on peripheral blood smear. The patients may present with a myriad of symptoms ranging from fatigue, shortness of breath, hair fall, and pica, to name a few. Management often involves multidisciplinary teams to treat underlying pathology along with iron supplementation. Iron supplementation is often given orally, but certain case scenarios require intravenous iron infusion. Patients with iron-deficiency anaemia often experience frequent hospital visits and extended hospital stays for any clinical interventions.[1,2,3].

Although iron deficiency anaemia (IDA) is usually not fatal, it is significant to note its detrimental effects on the overall well-being of an individual. For the most part, women with heavier periods, pregnant women, and their children constitute the most at-risk population for this [4]. This is why it is significant to measure the iron and improve it accordingly.

Iron supplementation taken orally is generally the first-line management. However, issues with patient compliance and the risk of iron depletion from iron stores can compromise the effects of treatment with oral iron [5]. In cases of moderate to severe anaemia, conventional oral treatment is often inadequate, requiring immediate elevations of haemoglobin for fast replenishment of iron. This highlights the role of intravenous FCM for rapid repletion of iron stores, demonstrating the importance of parenteral treatments [6].

Ferric carboxymaltose, an iron complex composed of ferric hydroxide stabilised by a carbohydrate shell, controls the amount of iron delivered to the target tissues when given intravenously. It successfully treats anaemia due to iron deficiency by giving a dose of 1000 mg within a short duration, **approximately fifteen minutes**, as per standard guidelines in the UK. Various trials have illustrated that IV FCM quickly increases Hb levels and restores iron in individuals with IDA. FCM is a suitable alternative when oral supplements are infective in conditions like uterine bleeding, iron deficiency seen in postpartum women, or any long-standing renal illnesses. The occurrence of drug-related adverse events in individuals getting IV FCM is comparable to those getting oral ferrous sulfate. Drug-related adverse reactions like rashes and allergic responses seen at the infusion site are quite commonly observed with ferric carboxymaltose [7].

Despite several studies that have appeared promising and shown positive impacts of ferric carboxymaltose (FCM) in iron-deficient individuals, additional information is required to create strong evidence for patients, practitioners, and policymakers to evaluate enhanced integration of intravenous FCM for the treatment of moderate to severe iron deficiency. Additionally, it is vital to decide the optimal dose of the drug for this group of patients if the information permits [8].

FCM showed significant adverse reactions such as nausea, vomiting, and arthralgia during the clinical trials conducted prior to FDA approval. Greater than one percent of participants experienced vomiting; some of the other side effects were breathlessness and myalgia, though these reactions were rare, occurring in less than one percent of participants. The likely cause of nausea and breathlessness is a hypersensitivity reaction, especially an anaphylactic type known as type 1 hypersensitivity. Post-marketing surveillance has shown that these adverse events occur in more than 1 in 1000 individuals using the drug [9].

**Aim of study:**

This study aimed to primarily investigate the incidence of adverse reactions in individuals who received intravenous ferric carboxymaltose. Secondly, we looked at correlations between adverse reactions and factors such as vitamin D deficiency, generalised bodily infections, and gender. Our co-author, who has worked in the UK, observed fewer adverse reactions to IV ferric carboxymaltose in the UK compared to her experience in the UAE. This finding prompted us to examine possible reasons for the increased incidence of adverse reactions in the UAE, leading to the initiation of this study. To our knowledge, there is no published information on this topic in the Gulf region.

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**Methods**

Type of Study:

This study is a retrospective observational study . It reviewed medical records of 136 patients who received intravenous ferric carboxymaltose over a one-year period, collecting information on demographics, infusion details, adverse reactions, and treatments, without any intervention.

Type of Participants:

The study focused on individuals of all age groups with confirmed IDA. We collected data on patient demographics, inclusive of their age and gender, the nature of their reactions, and the treatment administered. The study was conducted at Yas Clinic managed by Abu Dhabi Stem Cells Center, Abu Dhabi and involved 136 individuals that received intravenous ferric carboxymaltose.

Type of Comparisons:

Out of the 136 individuals, we analysed them based on their reactions and the treatment administered. Additionally, we analysed their medical histories to find any correlations.

Method to analyze the review:

We utilised the TrakCare software system to analyse the information of 136 individuals that participated in this study.

**Results:**

**Table: Description of patients with adverse reactions to Ferinject Carboxymaltose**

| *Patient Age/Gender* | *Dosage/ Duration* | *Adverse Reactions* | *Treatment given* |
|---|---|---|---|
| 37/ Female | 1000 mg/55 minutes | Red itchy blotches and pimples on hands + chin | Chlorphenamine 10mg IVI + Hydrocortisone 100mg IVI |
| 36/ Female | 1000 mg/62 minutes | Red itchy blotches and pimples on hands + legs and buttocks | Chlorphenamine 10mg IMI + Hydrocortisone 100mg IVI |
| 39/ Female | 1000 mg/60 minutes | Red itchy blotches on inner forearm (elbow area) + left knee | Hydrocortisone 50mg IVI + Diphenhydramine 25mg IVI |
| 22/ Female | 500 mg/31 minutes | Red itchy blotches and pimples on hands + shoulders, back + left side of the face | Chlorphenamine 10mg IVI + Hydrocortisone 100mg IVI |
| 32/ Female | 1000 mg /33 minutes | Red itchy blotches and pimples on hands + shoulders, neck + left side of mouth | Chlorphenamine 10mg IMI |

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All participants in the study received varying doses, ranging from 500 to 1000 milligrammes, administered at a rate of 16.1 to 30.3 milligrammes per minute. Among them, 5 individuals experienced a sudden hypersensitivity reaction. Upon reviewing the information of the individuals with adverse reactions, we identified some commonalities. Notably, many of these individuals had recurrent infections and gastric conditions for which they took long-term antibiotics; this may have contributed to their adverse reactions. This finding is further supported by an article published on this topic.

Based on our study, we discovered an article where the author similarly perceived that excessive use of antibiotics could contribute to adverse reactions in individuals. The author highlights that in cases of atopic dermatitis, a skin barrier defect can elevate the risk of infectious diseases in affected individuals. However, concerning the observed negative association between allergic rhinitis and antibiotic susceptibility, it is hypothesised that this phenomenon may be attributed to the overprescription of antibiotics. In earlier research involving two birth cohorts derived from the National Health Insurance Research Database, which encompasses the entire population of Taiwan. Their findings demonstrated that exposure to antibiotics within the first year of life has a temporal effect on the subsequent development of common allergic diseases. This evidence suggests the potential long-term impact of antibiotic exposure on the immune system and its role in the pathogenesis of allergic conditions [10].

We also observed that although both genders participated in our study, only female patients experienced adverse reactions.

This finding is validated by evidence presented in a related article where the author mentions that regardless of the identical immunological mechanisms that trigger the release of mediators and subsequent manifestations in immediate-type allergies, there is an observable medical distinction between both genders with allergies; although males have a higher chance of developing allergies in early years, females from adolescence onwards appear to be at a major disadvantage concerning atopic conditions, allergies, and anaphylaxis. Clinical observations have recognised the link between hormonal status and allergic reactivity for several decades; however, only in recent years has the mechanistic role of sex hormones in immune reactions been recognised. In the context of allergies, sex hormone receptors on lymphocytes and leukocytes may influence the type of immune response and regulate inflammation. Oestrogens have been found to have a receptor-mediated effect on mast cell releasability, affecting threshold levels during the effector phase of an allergy. These findings have significant gender-specific implications for the avoidance and treatment of allergies [11].

Additionally, we noted that most of the individuals exhibited a deficiency in vitamin D, a condition prevalent in the Middle East.This may explain why our co-author observed fewer adverse reactions while practicing in the UK. Our study identified three articles that shared similar perspectives.

One of the articles published states that throughout the recent few decades, they observed a significant elevation in the occurrence of nearly all types of hypersensitivity conditions, which includes asthma, allergic rhinitis, allergies to food, eczema, and anaphylaxis. Although the hygiene hypothesis explains a partial explanation for this spike, other experts also suggest that it might be connected to vitamin D deficiency. This can be supported by a theory in which scientific data indicates that food allergies and anaphylaxis occur at a greater rate in regions with less sun exposure, especially at higher latitudes [12, 13].

An additional study indicated that many unidentified variables in existing research lead to inconclusive or inconsistent results. Despite strong experimental evidence showing that vitamin D affects immune cell functions, it is difficult to translate these findings into definitive dietary recommendations due to the inticacy of the immune system in the general population [14].

The role that vitamin D plays in controlling immunity has garnered increased attention and understanding in recent years. The hormonal form of vitamin D interacts with the nuclear vitamin D receptor (VDR), a ligand-regulated transcription factor, at the molecular level. The accommodating and inborn branches of the immune system contain enzymes involved in the metabolism of vitamin D and VDR. Many genes controlling innate and adaptive immunity have been found to be controlled by VDR, according to genome-wide gene expression profiling. Molecular data suggests that vitamin D signalling suppresses inflammatory immune responses linked to autoimmunity and regulates allergy responses while bolstering innate immunity against bacterial and viral infections. Clinical research linking vitamin D deficiency to a higher incidence of allergies and infections has validated these findings [15].

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**Discussion**

This study evaluated the occurrence of adverse reactions to intravenous ferric carboxymaltose (FCM) in 136 patients at Yas Clinic Hospital, Abu Dhabi. Five patients (3.7%) developed mild to moderate hypersensitivity, mainly presenting as red, itchy skin eruptions. Although FCM is generally safe, these cases highlight potential factors that may predispose certain individuals to reactions, particularly in the Gulf region.All affected patients were female, reflecting evidence that post-pubertal women are more prone to immediate allergic responses. Estrogen may enhance mast cell activation and inflammatory mediator release, lowering the threshold for hypersensitivity reactions.A notable commonality was a history of recurrent infections and prolonged antibiotic use. Such exposures may disrupt immune tolerance and alter the microbiome, increasing susceptibility to allergic reactions. Vitamin D deficiency, widespread in this region, was also present in affected patients. Vitamin D is critical for regulating innate and adaptive immunity, and deficiency may impair immune balance, predisposing individuals to hypersensitivity. Adverse reactions occurred primarily at higher FCM doses (500–1000 mg, 16.1–30.3 mg/min) but were mild and effectively treated with antihistamines and corticosteroids. In summary, intravenous FCM remains safe, with low incidence of mild reactions. Female gender, recurrent infections, and vitamin D deficiency may increase risk. Awareness of these factors can guide patient assessment, dosing, and monitoring, supporting safer clinical use and informing future research on intravenous iron therapy in the Middle East.

**Conclusion:**

After conducting a thorough analysis, in our experience, some factors may have contributed to the adverse reactions seen in some individuals. Firstly, gender appeared to play a substantial role, as only female participants experienced adverse reactions. This may be due to hormonal differences.

Additionally, a common characteristic among the patients who experienced adverse reactions was the occurrence of recurrent infections in the body. This could potentially trigger allergic reactions, leading to the adverse effects that were recorded.

Moreover, vitamin D deficiency was prevalent in individuals from the Middle East, and this deficiency may contribute to hypersensitivity reactions, given that vitamin D plays a crucial role in immune function. The disparity in adverse reactions observed by our co-author, who practices in the UK where Vitamin D deficiency is less frequent, further promotes this potential link.

It is important to note that these observations are based on clinical findings, and further studies are necessary to establish statistically significant correlations for the factors mentioned above. A more extensive trial would help to confirm these preliminary findings and offer a clearer understanding of the underlying mechanisms driving these adverse reactions.

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The author and the co-author have no conflict of interest to declare.

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