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AN OBSERVATIONAL STUDY ON SAFETY PROFILE OF FERRIC CARBOXYMALTOSE INTRAVENOUS INFUSION IN IRON DEFICIENCY ANAEMIA PATIENTS IN A TERTIARY CARE HOSPITAL, BANGALORE

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ABSTRACT

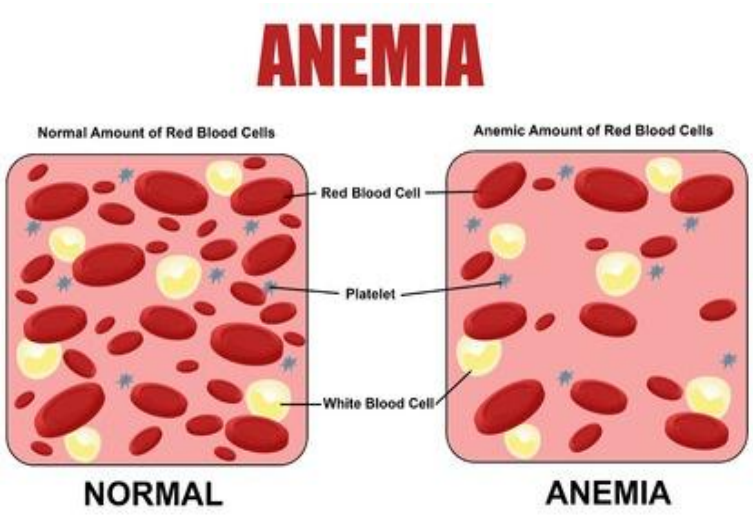
Background: Iron deficiency anaemia accounts for the majority of anaemia. Although iron replacement therapy is effective conventional iron formulations has some disadvantages like Gastro-intestinal side effects for oral formulations and issues like frequent administration for intravenous formulations. Ferric carboxymaltose, which overcomes these limitations and it can be used widely as an intravenous iron sucrose. Ferric carboxymaltose combines with the positive characteristics of iron dextran and iron sucrose but not associated with dextran induced adverse reactions and can be given in higher doses than iron gluconate/sucrose. **Objective**: The objective of the study is to "Study the safety profile of "FERRIC CARBOXY MALTOSE INTRAVENOUS infusion" in iron deficiency anaemia patients. **Materials and Methods**: A prospective observational study was carried out in the general medicine department in a Tertiary care hospital, Bengaluru, Karnataka. Data obtained through patient case sheets, medication charts and laboratory data reports. **Results**: In our present study, the total number of subjects enrolled were 100 and out of 100 patients, 49 were males and 51 were females which resembles the 49% of male patients and 51% of female patients out of counter sample (100%). During the course of study, it has been observed that patients aged 40-80 years with iron deficiency anaemia (60% counter sample) were more in number compared to other group patients. **Conclusion**: To conclude, although

this study had a small size it give us an overall idea about observational study on safety profile of ferric carboxymaltose intravenous infusion in Iron deficiency anaemia patients.

KEYWORDS: Iron deficiency anaemia, Ferric carboxy maltose, Intravenous Infusion, safety profile.

INTRODUCTION

Iron deficiency anaemia (IDA) is anaemia caused due to insufficient iron. Anaemia is defined as a decrease in the number of the red blood cells or amount of haemoglobin in blood. IDA is common haematological complication with a prevalence of 2% among adult men and 9-20% among adult women depending on race and ethnicity. IDA occurs in several medical conditions including inflammatory bowel disease (IBD) and chronic kidney disease (CKD), in association with cancer and its treatment, and in the cause of acute blood loss resulting from gastrointestinal (GI) bleeding, trauma, surgery and obstetrics/gynaecology conditions. IDA contributes significantly to morbidity, disease burden and decreased quality of life.[1] IDA is also very common in women post-partum.[2]



Causes

Blood loss: Haemorrhage decreases the host's red cell mass, decreases the supply of iron and increases the iron demand for erythropoiesis.

The Maternal-Foetal Bridge of Iron Deficiency: Iron demand is high in menstruating as well as pregnant females. During pregnancy, it is estimated that iron 1200mg iron are required from conception through delivery. Iron intake and stores in the mother must satisfy foetal development, and blood loss at delivery.

Diet and Malabsorption of iron: The diet infrequently causes iron deficiency anaemia in the absence of severe malnourishment or co morbidity.

Recently a new parenteral iron carboxy maltose, was developed to facilitate effective treatment of IDA as well as rapid replacement of iron stores than oral iron treatment with ferrous sulphate was standard care in IDA mainly in post-partum cases but which is not tolerated due to GI adverse effect, in patient compliance or in patient with more severe anaemia.[3]

Single dose Ferric carboxy maltose is evaluated in fatigued, iron-deficient. Since iron is not only a component of haemoglobin (Hb) but also a key element of various essential enzymes in all metabolic pathways. ID can have an Hb -independent effect on physical performance and fatigue.[4]

Iron supplementation is used to correct anaemia and replenish iron stores in patients with iron-deficiency anaemia. Ferric carboxy maltose is an intravenous iron preparation approved in numerous countries for the treatment of iron deficiency. Ferric carboxy maltose is formulated as a colloidal solution of poly nuclear iron (III) ox hydroxide stabilized by the carbohydrate polymer carboxymaltose solution has isotonic osmolarity and a pH of 4.5-7.0 and the complex has a molecular mass of ≈150 kDa. Ferric carboxy maltose is designed to provide controlled delivery of iron to the macrophages of the reticulo endothelial system in the liver, spleen and bone marrow, with subsequent delivery to the transport protein transferrin, without large amounts of ionic iron being released into the serum.

Iron supplementation may be provided either orally or intravenously. However, oral absorption of iron is poor in many CKD patients due to their chronic micro-inflammatory status with hepcidin levels.[9]

Intravenous Ferric carboxy maltose was generally well tolerated in patients with iron deficiency with or without anaemia, and also ferric carboxy maltose was better tolerated than other oral iron preparation in patients with iron deficiency anaemia associated with no dialysis-dependent chronic kidney disease.[6]

Ferric carboxy maltose is an innovative, intravenous iron preparation surrounded by a non-dextran carbohydrate shell which it allows the iron to release in a controlled manner. And it is does not react with dextran antibodies.8Ferric carboxy maltose can be administered in a short

period of time and at large doses ensuring the amount of iron needed to promptly relieve patients from the severe effects of iron-deficiency.[7]

METHODOLOGY

Study Site: The study was carried out at Aster CMI hospital, hebbal, Bengaluru. It is one of the leading healthcare institution offering multi-speciality tertiary care of international standards.

Study Design: A prospective observational study.

Study Criteria: The patients with iron deficiency anaemia visiting general medicine department were enrolled in the study after taking their consent and by considering following inclusion and exclusion criteria.

Inclusion Criteria

Patients diagnosed with iron deficiency anaemia, patients visiting Gynaecology & Obstetrics department.

Exclusion Criteria

Pediatric patients.

Data Collection

The data was collected from the patients who met the inclusion criteria. To study the safety profile of ferric carboxy maltose intravenous infusion in patients with iron deficiency anaemia, relevant details of every in-patient was collected from the patient case sheet, medication chart, laboratory data reports.

Statistical Analysis

Collected information was analysed using Microsoft office (Ms Word and Excel) 2013. Descriptive analysis has been performed in the form of demographic variables and drug therapy were shown as various tables, pie-charts and graphs for better understanding of data. For the analysis of results, simple percentage calculations were used to arrive at a conclusion of our study.

RESULTS

During the course of the study, the total number of subjects were 100 and out of these patients, 49 were males and 51 were Females which resembles the 49% of the Male and 41% of Female Patients out of the counter Sample (100%).

Table No 1: Gender wise categorization.

S.No	Gender	No. of Patients	Percentage (%)
01.	Male	49	49%
02.	Female	51	51%
	Total	100	100%

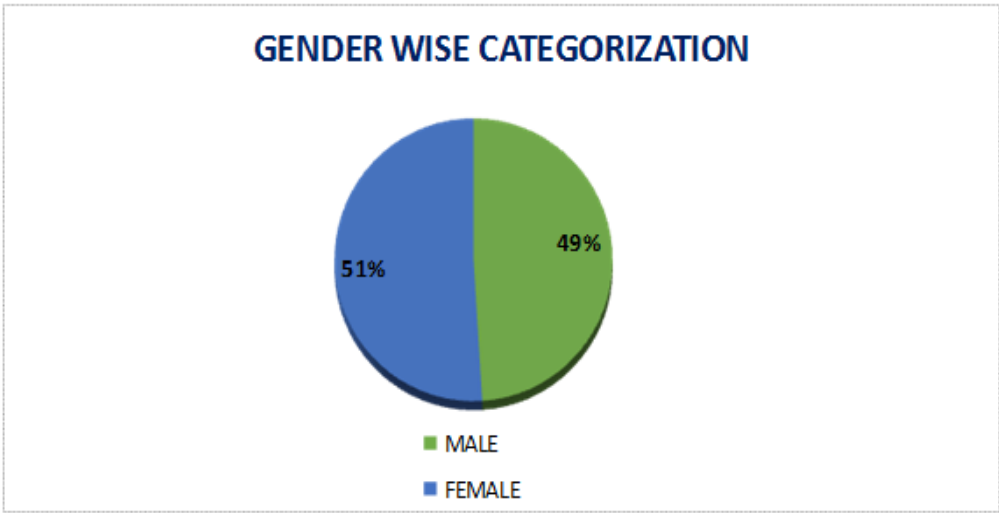


Figure 1: Gender categorization.

During the course of the study in among the 100 subjects, it has been observed that patient aged 40-80 years with **IRON DEFECIANCY ANEMIA** (60% out of the counter sample) were more in number compared to the other group patients.

Table No 2; – Age wise distribution.

S.no	Age Group (Years)	No. of patients	% of patients
1.	**0-20**	**06**	**06%**
2.	**21-40**	**29**	**29%**
3.	**41-60**	**30**	**30%**
4.	**61-80**	**30**	**30%**
5.	**>81**	**05**	**05%**
	Total	**100**	**100%**

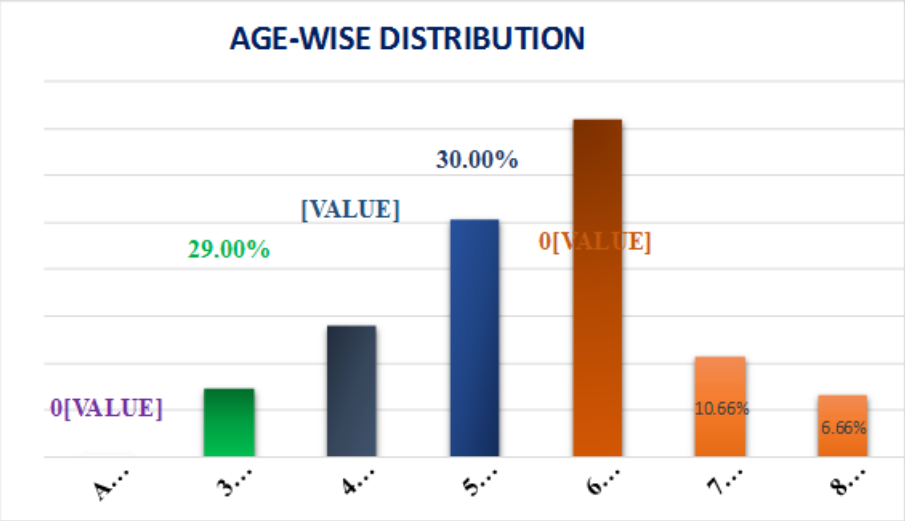


Fig 2: Age wise distribution

DISCUSSION

Figure 1: Gender Categorization

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Figure 2: Age wise distribution

During the course of the study in among the 100 subjects, it has been observed that patient aged 40-80 years with IRON DEFECIANCY ANEMIA (60% out of the counter sample) were more in number compared to the other group patients.

CONCLUSION

To conclude, although this study had a small size it give us an overall idea about the observational study on safety profile of FERRIC CARBOXYMALTOSE Intravenous Infusion in Anaemia in a Tertiary Care Hospital. Despite of the fact that the patients with iron deficiency anaemic condition are safe to use FERRIC CARBOXYMALTOSE. The current study revealed that the FERRIC CARBOXYMALTOSE was prescribed more frequently than other Iron preparation and safety profile of FERRIC CARBOXYMALTOSE was more than that observed to other Iron preparation. Most of the patient who reported with iron deficiency anaemia to the hospital were prescribed with FERRIC CARBOXYMALTOSE.

The present study revealed that poly pharmacy and prescription by brand names were common. Use of generic name in the prescriptions need to be promoted and encouraged.

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