

A comparative study of efficacy of single dose of intravenous ferric carboxymaltose over oral iron therapy in severe iron deficiency Anemia

Makarand Balwant Mane^{1*}, Priyanka Makarand Mane², Akshay Shirshat³, Tejas Uttamrao Bhosale⁴

¹Associate Professor, ^{3,4}Senior Resident, Department of Medicine} ²Assistant Professor, Department of Microbiology} Krishna Hospital, P B Road, Malkapur Karad, Satara, Malkapur, INDIA.

Email: makarand.mane@gmail.com

Abstract

Background: Iron deficiency anemia (IDA) is a very common hematological complication with a global prevalence of 2% among adult men and 9–20% among adult women both pregnant and non-pregnant, depending on race and ethnicity. **Objectives:** to compare the efficacy of intravenous ferric carboxymaltose over oral iron therapy in adult males and non-pregnant females with severe iron deficiency anemia. **Methodology:** observational comparative study, carried out in a tertiary care hospital in western Maharashtra for a period of 6 months with a sample size of 100 patients. 50 cases each of anaemic patients treated with iv. Ferric Carboxymaltose and oral iron therapy. The iv. Ferric Carboxymaltose was given in two doses of 15 mg/kg (750mg) seven days apart, and oral iron tablets with 200 mg of elemental iron daily. The data was entered in Microsoft excel and was analysed using EpiInfo software. **Results:** There were 38 males and 62 females in the study, in which 20 males received oral therapy while 18 received IV. Ferric Carboxymaltose, amongst females, 30 received oral therapy while rest 32 received IV. Ferric Carboxymaltose therapy. The mean levels of Hb in males at the start of the treatment was 7.2 ± 0.8 g/dL, while in females it was 6.7 ± 1.3 g/dL. **Interpretation:** Salve M.P. at el which showed that target Hb levels were achieved significantly in even a single dose of IV. Ferric Carboxymaltose compared to oral iron. **Conclusion:** Intravenous Ferric Carboxymaltose is a very effective mode of treatment. **Keywords:** Anemia, Iron deficiency, Ferric Carboxymaltose, oral iron.

*Address for Correspondence:

Dr. Makarand Balwant Mane, Associate Professor, Department of Medicine, Krishna Hospital, P B Road, Malkapur Karad, Satara, Malkapur. INDIA.

Email: makarand.mane@gmail.com

Received Date: 24/01/2019 Revised Date: 02/03/2019 Accepted Date: 12/04/2019

DOI: <https://doi.org/10.26611/102110227>

Access this article online

Quick Response Code:



Website:

www.medpulse.in

Accessed Date:

24 May 2019

INTRODUCTION

Iron deficiency anemia (IDA) is a very common hematological complication with a global prevalence of 2% among adult men and 9–20% among adult women both pregnant and non-pregnant, depending on race and ethnicity¹. 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 cases of acute blood loss resulting from gastrointestinal (GI) bleeding, trauma, infections, surgery, and obstetrics / gynecology and other surgical conditions². In developing countries like India the situation is even worse, according to National Iron Plus Initiative, Ministry of Health and Family Welfare India, the prevalence of anemia in India is as high as 43% making it a major public health problem of the country³. Oral iron (in addition to a thorough evaluation of the cause) is usually the initial treatment for anemia due to absolute iron deficiency, but a significant number of patients will not respond adequately, many have reported various side effects and low absorption due to various causes⁴. Iron deficiency anemia (IDA) is a common hematological complication with potentially serious clinical consequences that may require blood transfusions in severe cases. Intravenous iron therapy is a successful alternative to blood transfusion

How to cite this article: Makarand Balwant Mane, Priyanka Makarand Mane, Akshay Shirshat, Tejas Uttamrao Bhosale. A comparative study of efficacy of single dose of intravenous ferric carboxymaltose over oral iron therapy in severe iron deficiency Anemia. *MedPulse International Journal of Medicine*. May 2019; 10(2): 162-164. <https://www.medpulse.in/Medicine/>

which also helpful in preventing the complications from blood transfusion and also in cases when blood is not easily available. Ferric carboxymaltose (FCM) is a stable, nondextran iron formulation administered intravenously in large single dose to treat IDA. This study has been carried out to compare the efficacy of intravenous ferric carboxymaltose over oral iron therapy in adult males and non-pregnant females with severe iron deficiency anemia.

METHODOLOGY

Study Design: Observational comparative study

Study Site: A tertiary care hospital and teaching institute in western Maharashtra.

Study Period: The study was done for a period of 6 months which was done between January 2018 and June 2018.

Sample size: According to Ministry of Health, India data, the prevalence of anaemia is estimated as 43% in developing countries like India [3]. So, $p = 43\%$

Using formula for sample size (n) calculation,

$$n = \frac{4 \times p \times q}{e^2}$$

where, $p = 43\% = 0.43$ $q = 1 - p = 0.57$

Taking e, absolute error of 10%, $e = 0.1$

$$\text{So, } n = \frac{4 \times 0.43 \times 0.57}{0.1 \times 0.1}$$

$$n = 98.04 \approx 100$$

A total of 100 patients were included in the study.

RESULTS

Amongst 100 patients of severe anemia, 50 patients received IV. Ferric Carboxymaltose and the rest 50 oral iron therapy.

Table 1: Gender and Treatment received.

	Male	Female	Total
IV. Ferric Carboxymaltose	18	32	50
Oral Iron	20	30	50
Total	38	62	100

$$\chi^2 = 0.17, p = 0.68$$

There were 38 males and 62 females in the study, in which 20 males received oral therapy while 18 received IV. Ferric Carboxymaltose, amongst females, 30 received oral therapy while rest 32 received IV. Ferric Carboxymaltose therapy. There was no any significant association between gender and the treatment received ($p = 0.68$).

Table 2: Gender Wise Change in Hb with treatment

	Male (38) Mean \pm SD	Female (62) Mean \pm SD	p value
Day 0	7.2 \pm 0.8	6.7 \pm 1.3	0.035*
Day 14	9.3 \pm 1.4	9.4 \pm 1.9	0.770**
Day 30	10.5 \pm 3.2	10.2 \pm 2.8	0.624**

*Significant **Not Significant

The mean levels of Hb in males at the start of the treatment was 7.2 ± 0.8 g/dL, while in females it was 6.7 ± 1.3 g/dL. there was significant difference ($p = 0.035$) between the mean Hb levels in males and females at the start of the treatment, which was not significant after 14 days ($p = 0.770$) and 30 days ($p = 0.624$) of treatment. The mean levels of Hb after complete 30 days of treatment in males was 10.5 ± 3.2 g/dL and in females it was 10.2 ± 2.8 g/dL.

Inclusion criteria:

1. Patients aged more than 18 years, both genders.
2. Patients diagnosed as iron deficiency anemia, with $Hb < 8$ g/L.
3. Patient willing to participate in the study by giving written informed consent.

Exclusion criterion:

1. Pregnant females
2. Patients with other causes of anemia.
3. Patients with Hb levels ≥ 8 g/L.

Source of Data and Data Collection:

The study took anaemic cases from medical wards and medicine OPD from the tertiary care hospital. The nature and purpose of the study was described to the subjects and informed consent was obtained from those willing to participate in the study. The study used a pre-tested semi structured proforma which was contained detailed information of the subjects which included personal history and examination details, lab investigations and treatment provided. 50 cases each of anaemic patients treated with iv. Ferric Carboxymaltose and oral iron therapy were selected for the study and the results were compared using Hb levels at the start of the treatment, at 14 days and at 30 days. The iv. Ferric Carboxymaltose was given in two doses of 15 mg/kg (750mg) seven days apart, and oral iron tablets with 200 mg of elemental iron daily. The data was entered in Microsoft excel and was analysed using EpiInfo.

Table 3: Treatment received and change in Hb levels.

	Iv. Ferric Carboxymaltose (50) Mean ± SD	Oral Iron (50) Mean ± SD	p value
Day 0	7.1 ± 0.8	7.4 ± 0.9	0.081**
Day 14	9.5 ± 0.7	7.9 ± 1.1	< 0.0001*
Day 30	12.3 ± 1.9	8.2 ± 1.5	< 0.0001*

*Significant **Not Significant

The mean levels of Hb in the comparison groups at the start of treatment were 7.1 ± 0.8 g/dL in IV. Ferric Carboxymaltose group and 7.4 ± 0.9 in oral iron therapy group. There was no any significant difference between the two groups (p= 0.081). The Hb levels increased significantly after 14 days (p < 0.0001) and 30 days of treatment in IV. Ferric Carboxymaltose group compared to oral iron group, with means of 9.5 ± 0.7 g/dL and 12.3 ± 1.9 g/dL in IV. Ferric Carboxymaltose group and 7.9 ± 1.1 g/dL and 8.2 ± 1.5 g/dL in oral iron group at 14th and 30th days respectively.

DISCUSSION

In our study, significant difference was found between the mean Hb levels after the treatment with IV. Ferric Carboxymaltose compared to oral iron therapy, similar results were seen in a study conducted by Salve M.P. at el⁵ which showed that target Hb levels were achieved significantly in even a single dose of IV. Ferric Carboxymaltose compared to oral iron. Their study also showed that the IV. Ferric Carboxymaltose therapy had more compliance in patients compared to oral iron therapy. Another study done by Naqash A. *et al*⁶ compared effectiveness and safety of ferric carboxymaltose compared to iron sucrose in women showed that the A significant increase in the mean Hb was observed from 7.76 ± 0.709 to 13.25 ± 0.606 in patients treated with FCM and 7.64 ± 0.710 to 11.59 ± 0.733 g/dL (P < 0.001) in patients treated with IS after four weeks of therapy. No any severe adverse effects were observed in their study.

CONCLUSION

Intravenous Ferric Carboxymaltose is a very effective mode of treatment in Iron deficiency anemia. It is having

more compliance and is more effective treatment method for treating anemia than oral iron therapy.

REFERENCES

1. S. Killip, J. M. Bennett, and M. D. Chambers, "Iron deficiency anemia," American Family Physician, vol. 75, no. 5, pp. 671– 678, 2007
2. J. Umbreit, "Iron deficiency: a concise review," American Journal of Hematology, vol. 78, no. 3, pp. 225–231, 2005.
3. Ministry of Health and Family Welfare, Government of India. Guidelines for control of Iron deficiency anaemia. New Delhi: Ministry of Health and Family Welfare, Government of India; 2013. Available at: http://www.unicef.org/india/10._National_Iron_Plus_Initiative_Guidelines_for_Control_of_IDA.pdf. Accessed 18 January 2018.
4. Killip, S., Bennett, J. and Chambers, M. (2007) Iron deficiency anemia. Am Fam Physician 75: 671–678.
5. Salve MP, Inamdar SA, Bhaumik DK, Patil AR. Single dose intravenous carboxymaltose versus oral iron therapy in the treatment of anaemia in postpartum patients in a rural area. Journal of Evidence Based Medicine and Healthcare. 2017 Jan 1;4(14):842-7.
6. Naqash A, Ara R, Bader GN. Effectiveness and safety of ferric carboxymaltose compared to iron sucrose in women with iron deficiency anemia: phase IV clinical trials. BMC women's health. 2018 Dec;18(1):6.

Source of Support: None Declared
Conflict of Interest: None Declared