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Efficacy and Side Effects of Ferric Carboxymaltose on Antenatal Anaemic Patients

DR. BANSI POPAT[1], DR. A. U. MEHTA[2]

[1](*Resident doctor in Department of obstetrics & gynaecology, B.J. Medical college, Ahmedabad, Gujarat, India)*
[2(]*Professor and head in Department of obstetrics & gynaecology, B.J. Medical college, Ahmedabad, Gujarat, India)*

Abstract
BACKGROUND : *Anaemia during pregnancy is most common cause of adverse maternal and perinatal outcomes. Anaemia during pregnancy treated by various routes. This study will evaluate the effects of ferric carboxymaltose in antenatal patients and its Feto-Matenal Outcomes.*
MATERIALS & METHODS : *This is a prospective study. Study was carried out at tertiary care centre, on 100 Antenatal patients having iron deficiency anaemia. After investigations and dose calculation, inj. FCM (Ferric carboxymaltose) was administered with proper aseptic precautions and monitoring. Patients were evaluated at the end of 3 weeks.*
RESULT : *Out of 100 patients 63% patients were belonging to age group 20-29years, 55% patients were multigravida (gravida 3 or more), 46% presented with anaemia in third trimester of pregnancy, 13% patients presented with side effects of FCM (Ferric carboxymaltose). Rise in the Hemoglobin was significant, around 2-3gm% in 52% patients, 3-4gm% in 31% patients.*
CONCLUSION: *Intravenous Ferric carboxymaltose transfusion is an effective treatment strategy for pregnant patients with severe anaemia during late pregnancy and in patients non-compliant to oral therapy.*
Key Word: *FCM (Ferric carboxymaltose), Hemoglobin (Hb), Multigravida, Anaemia, Anaphylactic reaction.*

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I. Introduction

In world anaemia is major health problem. About 1/3 of population is anaemic throughout the world. According to World Health Organization (WHO) prevalence of anaemia in women is 2-45% in developed countries and relatively high 35-75 % (average 56%) in developing countries.[1] In India, prevalence of anaemia has been reported to be in the range of 33-89%. Prevalence is 47.4% in preschool-age children, 50% in women of reproductive age, 55% in adolescent girls.[2,3] India alone contributes to 50% of global maternal deaths. India contributes to about 80% maternal deaths in South Asia.[4] 40-60% of all maternal deaths by directly and indirectly attributed to anaemia.

Anaemia is a silent killer throughout the women's life. Women with even milder anaemia may experience fatigue and reduced work capacity. Anaemia in pregnancy is not only associated with adverse maternal outcomes like Puerperal Sepsis, Ante partum haemorrhage, postpartum haemorrhage, increased risk of maternal morbidity and mortality but also adverse foetal outcomes like increased incidents of premature births, low birth weight babies and high perinatal mortality.

The high prevalence of anaemia among women in India is a burden for them, for their families, and for the economic development and productivity of the country.In India anaemia is very prevalent because most of women are from low socioeconomic class, illiterate , having false dietary habit (most of are strict vegetarian),low intake and high demand, blood loss due to heavy menstrual cycle and during labour, younger age at marriage, early pregnancy, less spacing between previous and index pregnancy, more number of children, or due to less resources in joint families, lesser and infrequent intake of Iron-folic acid tab in pregnancy, social negligence , health problems neglected by females.[5]

Anaemia is highly prevalent among women who is the heart of family. Anaemia is the one of the most common causes of maternal morbidity and mortality which is preventable and treatable by which risk can be minimize.

Parenteral iron seems to be a better alternative to the oral iron in women who are noncompliant or cannot tolerate oral therapy because of the gastrointestinal side effects. It is superior to the oral therapy, as there is no need for constant motivation and the critical time is saved in non-responders in the late pregnancy, decreasing the need for blood transfusion which carries its own risk including transfusion of wrong blood, any of which would be devastating for the mother.[6]

Intravenous Ferric carboxymaltose appears to be a treatment of choice with no serious side effects, indicated in the rapid correction of anaemia in pregnancy or restoring maternal iron stores, especially because the total stores can be administered over a short period as compare to oral iron therapy. The side effects were mild and very few major complications were reported.[7,8]

II. Materials And Method

The present study was conducted in Maternity wards of civil hospital, Obstetrics and Gynaecology department, B. J. Medical College, Ahmedabad for 1 years during June 2019 to May 2020.

INCLUSION CRITERIA :
Antepartum single tone pregnancy with severe anaemia.
Haemoglobin concentration less than 7 gm%.
MCV<100 fl and a ferritin level <50microgm/l.
Gestation >20 weeks

EXCLUSION CRITERIA :
Medical disorder like tuberculosis, diabetes, renal and hepatic disorder.
Patients with haemoglobin more than 7 gm%.
Patients with multiple pregnancy, acute and chronic infections.
Women with comorbidities other than anaemia (like Thromboembolism, DVT, Renal or Hepatic Cardiovascular dysfunction, COPD, Asthma, Any infective foci).
Women with anaemia other than iron deficiency.
Women with history of hypersensitivity reaction to injectable Ferric carboxymaltose.
SAMPLE SIZE : 100 cases
STUDY DESIGN : Prospective study
DURATION OF STUDY : 1 years (June 2019 to May 2020)
STUDY PLACE : Department of Obstetrics and Gynaecology, B.J.Medical college, Ahmedabad, Gujarat, India.

III. Methodology

100 antenatal women with Hb% less than 7 gm% from the maternity wards were selected for the study after taking consent. Investigations involving complete hemogram with blood indices obtained by automated haematology analyser with using fresh blood sample, blood smear examination will be done by using Leishman's stain to study morphology of RBC'S and serum ferritin at the time of inclusion.Baseline tests for renal function, liver function, urine for routine microscopic examination and culture sensitivity and stool examination for ova and cyst were done.
Deficit of iron was calculated by the following formula:

Total iron dose (mg) = weight (kg) x (Target Hb – Present Hb in gm/dl) x 2.4 + 500 mg for replenishment of iron stores.

Calculated dose of Ferric carboxymaltose is given i.v. slowly and Patients will be closely monitored for adverse drug reactions. Emergency drugs like steroids, anti-histaminics and antipyretics are kept ready. The maximum weekly dose of FCM is 1000mg (upto20mg/kg bodyweight) in a single infusion given over at least 15minutes.

Patients in whom adverse reactions were noted were reported for ADR. Reaction developed after how much time of starting the infusion is noted. The transfused doses after which the reactions occurred were noted.
Hb% levels is repeated 3 weeks after treatment.
Effect of Ferric carboxymaltose was evaluated by improvement in clinical features of patients and monitored by Hb level, reticulocyte count and blood indices. Patients in whom adverse drug reactions were noted were reported for adverse drug reaction.

IV. Results

Table no. 1 : According to age

Age (in years)	No. of the patients
=<19	20
20-29	63
30-39	15
=>40	2
Total	100

Table no. 2 : According to gravidity of the patients

Gravida	No. of patients
Primi	20
2nd	25
3rd and more	55
Total	100

Table no. 3: According to weeks of gestation

Antenatal patients with gestational age	No. of patients
20-28 weeks	54
28-36 weeks	46

Table no. 4 : Diet and anaemias

Diet	Patients (%)
Vagetarian	74
Mixed diet	26

Table no. 5 : Type of anaemia

Type of anaemia	Patients (%)
Microcytic hypochromic	72
Dimorphic anaemia	28

Table no. 6 : Hb before treatment

Hb(gm%)	No. of patients
4-4.9	10
5-5.9	30
6-7	60

Table no. 7 : Type of reaction

Type of reaction	Total
Injection site pain	3
Phlebitis	1
Headache	2
Fever with chills	3
Pruritus/Urticaria	2
Arthralgia	1
Anaphylactic reaction	1
Severe adverse reaction/ICU admission	0
Death	0
Total	13

Table no. 8 : Raise in Hb(gm%) (after 3 weeks)

Hb(gm%)	Patients (%)
1-1.9	13
2-2.9	52
3-3.9	31
=>4	3

V. Discussion

Among the total 100 patients,20% patients were of ≤19 years, 63% patients were between 20 to 29 years,15 % patients were between 30 to 39 years,2% patients were ≥40 years. In Pushpa O Lokare study, 87.2% subjects were between 20 to 30 years having anaemia.[9] This finding are comparative to our study.

In 100 patients,20 patients were primigravida,25 patients were 2nd gravida, 55 patients were 3rd gravid or more. In H.K. Cheema et al study[10],90.8% anaemic women had parity >3 and 87.5 % women with spacing between current pregnancy and outcome of last delivery <1 year suffered more from maternal anaemia as

compared to women with birth interval more than 3 years and parity <2. In our study, high prevalence of anaemia were noted in 3rd gravid or more, it may be due to repeated pregnancies and less spacing between pregnancies which causes loss of iron stores. These findings are in correlates with study conducted by Bios S et al (2011)[6] in a study among pregnant women in West Bengal in which anaemia was significantly ($p<0.05$) higher among participants having a gap of less than two years between two pregnancies. Singh R et al (2015)[11] in a study among 352 antenatal mothers observed significant association between anaemia and parity.

Most of the patients (46) with anaemia were diagnosed after 28 weeks, this was because maximum number of pregnant women booked themselves for antenatal check- up in last trimester. This findings collaborates with study by Singh R et al (2015)[11]. Vandana S et al, Among the 25 pregnant women manifested with severe IDA, 21 (84%) of them were in 30-36 weeks of gestation and 4 (16%) of them were below 30 weeks of gestation at the time of diagnosis[12]. Dietary pattern significantly influences the anemia status. Here 74% patients were vegetarian while 26% were having mixed diet. According to H. K. Cheema et al study[10] 83.3% anaemic women belongs to vegetarian diet group. Rammohan A et al (2011)[13] and Singh R et al (2015)[11] studies have also supported the role of diet in anaemia, vegetarians are more anaemic as compared to non vegetarian.72% had microcytic hypochromic anaemia and 28% having dimorphic anaemia. 10 patients having 4-4.9gm% Hb, 30 patients having Hb 5-5.9gm%, while 60 patients having Hb 6-7.

In Agrawal et study[14] 76% of patients had moderate (7-10.9 g/dL), 14% had severe (4-6.9 g/dL) and 10% had very severe (<4 g/dL) anaemia. Out of 13 patients, 4 patients developed intravenous route related side effects-3 3of them developed pain at injection site, 1 patient developed Phlebitis. 9 patients developed generalized type of side effects-2 patients developed headache, 3 patients developed fever with chills, 2 patient developed pruritus, 1 patient developed arthralgia. 1 patient developed Anaphylactic reaction.There is no any severe adverse event like ICU admission, preterm labour pains or death due to intravenous FCM, indicating that intravenous FCM is safe even if given in last trimester of pregnancy in women with severe anaemia. Bernd Froessler study[15] also conducted study on efficacy and safety of intravenous ferric carboxymaltose in pregnancy and found that there were no serious adverse drug reactions and intravenous ferric carboxymaltose is better than ferric carboxymaltose.Our study is comparable to Bernd froessler study. Increase in Hb after treatment of ferric carboxymaltose therapy was measured after 3 weeks . Increase in heamoglobin was significantly high around 2-3gm% increased. Vandana S et al study[12],the total rise in the mean Hb status over three weeks following ferric carboxymaltose transfusion therapy was found to be 2.5 gm%.

VI. Conclusion

Anaemia is serious health problem where the pregnant women and her child are endangered. Anaemia directly proportional to parity, less spacing between pregnancies and related to lower education status.Intravenous ferric carboxymaltose transfusion is an effective treatment strategy for pregnant patients with severe anaemia during late pregnancy and in patients non-compliant to oral therapy.[8]

The data from this prospective case series is consistent with existing retrospective data that ferric carboxymaltose administration in the second and third trimester of pregnancy is likely to be safe and effective. In our study ferric carboxymaltose successfully corrected IDA prior to delivery. The intervention prevented significant postpartum anaemia in all women resulting in post-partum haemoglobin values higher than their pre-treatment antenatal values. Despite moderate to severe anaemia at presentation, labour associated blood loss was tolerated well resulting in low peri-partum RBC transfusion rates. No serious adverse events were recorded. Reactions occurred due to ferric carboxymaltose are minimal, and not required active management. Intravenous iron causes rapid rise in haemoglobin level and replacement of stores was faster. Other advantages of ferric carboxymaltose: It can be used in peripheral level where blood bank facilities are not available also reduce the burden over blood bank. Calculation, preparation and starting of ferric carboxymaltose is very easy that staff nurse also can give the injections to the patients. Ferric carboxymaltose can be given at outdoor basis so hospital stay and burden can be reduced.

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