Original Research Paper

Volume - 13 | Issue - 08 | August - 2023 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Obstetrics & Gynaecology

INTRAVENOUS FERRIC CARBOXYMALTOSE FOR ANAEMIA IN PREGNANCY:A PROSPECTIVE STUDY

Dr. Nivedita Prashar

Medical Officer, Department of obstetrics and gynaecology, GMC Rajouri, Jammu.

ABSTRACT The World Health Organisation global estimates of anaemia prevalence averaged 56%,with a range of 35%-75%depending on geographical location. In India, the prevalence of anaemia is 52%. **Material and method :** This was a prospective study conducted among 60 pregnant women visiting the Department of Obstetrics and Gynaecology at GMC Rajouri,Jammu. **Results:**28 pregnant women having iron deficiency anaemia belonged to 21-25 age group. In our study, the number of 44 females having anaemia were multigravida as compared to primigravida which were 16.Majority of females belonged to rural areas 40(66.6%).In our study ,mean rise in Hb level in patients was 2.2gm/dl and mean rise in serum ferritin was 54.16ng/ml both of which were statistically significant. Mild adverse effects like nausea, vomiting, diarrhea, constipation etc were observed in 12 patients. **Conclusion:** Ferric carboxymaltose appears to be a safe and effective treatment modality for the correction of IDA in pregnancy, without significant adverse effects.

KEYWORDS :

INTRODUCTION

Anemia is a blood disorder in which hemoglobin (Hb) concentration is less than the normal hemoglobin level. It is affected by age, sex, physiological condition(s) and altitude above the sea level of that person[1].The most common type of anemia in our country is iron deficiency anemia (IDA), which is defined as anemia because of insufficient iron stores in the blood and body[2]. The prevalence of anemia in pregnant women is high, affecting 41.8% of all pregnant women. The prevalence of anemia in pregnancy is much more in developing counties as compared to developed as it is a form of nutritional anaemia[3].The prevalence of Iron deficiency anemia (IDA) in pregnancy in India ranges from 23.6%- 61.4%[4].(4)

According to **WHO,** anemia in pregnancy has been defined as hemoglobin(Hb) <11gm% and haemotocrit levels <33%. Anemia in pregnancy as per **CDC (centre of disease control and prevention**) is defined as Hb levels of < 10 gm% in 1st and third trimester and Hb < 11gm% in second trimester[5]. **ICMR (Indian medical council and research**) has categorized anemia during pregnancy as - **mild**- Hb -10-10.9 gm%,

moderate- Hb-7- 9.9 gm%,
severe- Hb-4-6.9 gm%,
very severe -Hb < 4gm%[6].

During pregnancy, the physiological need for absorbed iron increases from 0.8□ mg/day in the first trimester to 7.5□ mg/day in the third trimester[7]. Dietary iron intake does not compensate for this strongly increased iron demand. Consequently, the risk of iron deficiency and, ultimately, iron deficient anemia increases during pregnancy.

Iron deficiency anaemia (IDA) in pregnancy can cause various kind of gestational complications in form of increased maternal and infant morbidity and mortality[8,9]. Maternal consequences include cardiovascular symptoms, reduced physical, mental and immune functions and peripartum iron reserves[10]. For many decades, the mainstay treatment of IDA has been oral iron and red blood cell (RBC) transfusions. However, oral iron supplementation can lead to significant side effects resulting in non-compliance in many patients and the risks for RBC transfusion are well described and should be avoided whenever[11,12].

The indications for parenteral iron treatment are intolerance to oral iron, non compliance to oral iron and patients who need rapid restoration of iron stores. Intramuscular iron is less commonly used as fear of anaphylaxis with iron dextran formulations, and long infusion time with iron polymaltose, have led to reluctance amongst clinicians[13]. The development of dextran free parenteral iron formulations with an improved safety profile, and a more rapid delivery time suggests that intravenous iron should be considered as a mainstay treatment for moderate to severe IDA[14].A novel intravenous iron agent **ferric carboxymaltose** is a non-dextrose containing drug with a near neutral pH (5-7), physiological osmolarity and increased bioavailability[15].FCM is administered rapidly 500mg in 100ml NS over 6 mins and 1000-1500 mg in 250 ml NS over 15 minutes as intravenous infusion[16].

As it doesn't contain dextran, chance of anaphylaxis is very low. That makes ferric carboxymaltose a potentially ideal alternative for treating anaemia associated with pregnancy. The primary aim of this study was to assess the use of intravenous FCM in the correction of IDA in pregnant women and complications if any.

MATERIALAND METHOD :

This was a prospective study conducted among 60 pregnant women attending out patient department of obstetrics and gynecology at GMC Rajouri. These patients were evaluated for CBC, PBF and S.ferritin levels. The dose of intravenous iron was calculated by the following formulas;

Total iron Requirement: 2.4 x body weight (in kg) x hb deficit+500mg (iron stores). Hemoglobin deficit was calculated by subtracting from 11gm%.

Inclusion Criteria:

In the study, inclusion criteria for the selection of the pregnant female was Singleton pregnancy between gestational age 28-36 weeks.

Exclusion Criteria:

- Hypersensitivity reaction to any iron preparation
- History of blood transfusion
- History of bleeding tendencies
- History of iron overload disorders
- Thalassaemia's or haemochromatosis
- Medical disorders like chronic renal failure, cardiovascular disorder, tuberculosis, hepatitis B or C ,HIV infection were excluded from study .

Patients were given IV ferric carboxy maltose 1000mg single dose (carboxymaltose 1000mg diluted in 250ml of 0.9%NS given in 20 to 30mins). Hb% and serum ferritin were done on day 0 and 30 of last dose of parentral iron. Side effects like headache, nausea, myalgia, arthalgia, nausea, vomiting, epigastric discomfort and anaphylactic reactions were looked for during the procedure. The patients were observed for three hour after infusion, they were called after one month for follow up and then clinical examination was done and investigations were repeated. Result was assessed by measuring the rise in Hb (g/dl) and serum ferritin (mcg/L) and adverse effects were tabulated.

RESULTS:

60 pregnant women diagnosed with Iron deficiency anemia in the Department of Obstetrics and Gynecology, were enrolled in the present study on the basis of selection criteria. The prevalence of IDA among the various age group is depicted in Table 1 where it is depicted that it was maximum in age group of 21-25 years; constituting 28 pregnant women.

Table 1 : Distribution of pregnant females according to age.

Age in years	Number of women(%)
15-20	7(11.66)

21-25	28(46.66)
26-30	17(28.33)
31-35	5(8.33)
35-40	2(3,33)
>40	1(1.66)

Multigravida females were more vulnerable to develop anaemia during pregnancy compared to primigravida females, In our study, the number of multigravida females having anaemia were 44(73.33%) as compared to primigravida which were 16(26.66%).

Majority of females belonged to rural areas (40 females, 66.67%) depicting lack of self-care, proper nutrition and non-compliance to drugs.

In our study ,mean rise in Hb level in patients was 2.2gm/dl which was statistically significant.

Similarly mean rise in serum ferritin was 54.16ng/ml which was statistically significant.

Table 2: Laboratory parameters.

	Pre value	Post value	P value
MeanHb(gm/dl)	8.06	10.26	<0.05
Mean Serum ferritin(ng/ml)	25.86	80.02	<0.05

No serious side effects were reported in our study. Mild adverse effects like nausea, vomiting, diarrhea, constipation etc were observed in 12 patients(20%).

Table 3: Adverse effect

Adverse effects	Number(%)
Injection site reactions	2(3.33%)
Skin discolouration	4(6.67%)
Nausea	1(1.67%)
Vomiting	1(1.67%)
Diarrhea	1(1.67%)
Constipation	2(3.3%)
Headache	1(1.67%)
Abdominal pain	0(0%)
Hypertension/hypotension	0(o%)
Hot flushes	0(0%)

DISCUSSION :

Iron deficiency is the most prevalent nutritional deficiency amongst women in the reproductive age group[17].

Iron deficiency anaemia is one of the most important causes of maternal and neonatal morbidity in both developed and developing countries. So, diagnosis for IDA is important and all pregnant women should be corrected of anaemia before delivery. IDA is also an important indirect cause of maternal death. The mainstay of treatment for iron deficiency anaemia is iron supplementation either oral or parenteral. In majority of cases, anaemia can be treated effectively with oral iron preparations. Many patients can tolerate oral iron supplements well; however, up to 40% have side effects. Another important factor is irrational use of anti-ulcerant drugs, which reduces iron absorption[18]. In cases where oral iron is ineffective, associated with adverse events or cannot be used, IV iron compounds are treatment options.

In this study, maximum anaemic pregnant women were found to be in age group of 21-25years. Multigravida females were more vulnerable to develop anaemia during pregnancy as compared to primigravida in our study. The reason for this could be less inter pregnancy intervals, low socio economic background, nutritional deficiencies in these females.

In our study, rise in Hb level in patients was 2.2gm/dl and that of serum ferritin was 54.16ng/ml ,both of which were statistically significant**. Agarwal D et al**[19] showed Hb rise of 2.92 gm/dl and ferritin rise of 64.97 ng/ml which is similar to our study.

Similarly **Froessler et al**[20]**,** carried out prospective observational study in Australia with 65 anemic pregnant women who received FCM showing significant raise in baseline hemoglobin level.

No serious side effects were reported in our study. Mild adverse effects like nausea, vomiting, diarrhea, constipation etc were observed in 12 patients (20%) which were similar to studies conducted by **Joshi SD et al**[21].

CONCLUSION:

Ferric carboxymaltose appears to be a safe and effective treatment modality for the correction of IDA in pregnancy, without significant adverse effects. Future studies are needed to investigate the effect of IV iron FCM on functional maternal outcomes.

Funding: No funding sources

Conflict of interest:None declared

Ethical approval:approved by IEC

REFERENCES:

1. Idris M, Anis-ur-Rehman (2005) Iron deficiency anaemia in moderate to severely anaemic patients. J Ayub Med Coll Abbottabad 17: 45-47.
2. Bakhtiar UB, Khan Y, Nasar R (2007) Relationship between maternal hemoglobin and perinatal outcome. Age (years) 25: 24
3. Milman N. Anemia- still a major health problem in many parts of the world. Annals of hematology 2011; 90:369-377
4. FOGSI General Clinical Practice Recommendations Management of Iron deficiency anemia in pregnancy 2016
5. Centre for disease control (CDC), criteria for anaemia in children and child bearing age women MMWR. 1989;38:400-4.
6. Indian council of medical research evaluation of nutritional anaemia prophylaxis program task force study New Delhi; 1989. Available at; https://www.icmr.nic.in/sites/default/files/icmr_bull e tins/bufeb00.pdf. Accessed on 12 December 2018.
7. N. Milman, T. Bergholt, K.-E. Byg, L. Eriksen, and N. Graudal, "Iron status and iron balance during pregnancy. A critical reappraisal of iron supplementation," Acta Obstetricia et Gynecologica Scandinavica, vol. 78, no. 9, pp. 749–757, 1999.
8. Milnam N:Prepartum anemia: prevention and treatment. Annals of hematology 2008, 87:949-959.
9. Scholl TO, Hediger ML:Anemia and iron deficiency anemia:compilation of data on pregnancy outcome. The American journal of clinical nutrition 1994,59(2 suppl):492S-500Sdiscussion 500S-501S 6.
10. Ekiz C, A gaoglu LKarkasZ, Gurel N, Yalcin I; The effect of iron deficiency anemia on the function of immune system. The hematology journal: the official journal of the European Hematology Association 2005; 5:579-583.
11. Khalafallah A, Dennis A, Bates J, Bates G, Robertson IK, Smith L, et al. A prospective randomized, controlled trial of intravenous versus oral iron for moderate iron deficiency anaemia of pregnancy. J Intern Med. 2010;268(3):286-95.
12. Shander A, Javidroozi M, Perelman S, Puzio T, Lobel G. From bloodless surgery to patient blood management. Mt Sinai J Med. 2012;79(1):56-65.
13. Chertow GM, Hsu CY, Johansen KL: The enlarging body of evidence: obesity and chronic kidney disease. J Am Soc Nephrol. 2006, 17 (6): 1501-1502. 10.1681/ASN.2006040327.
14. Khalafallah AA, Dennis AE: Iron deficiency anaemia in pregnancy and postpartum: Pathophysiology and effect of oral versus intravenous iron therapy. J Pregnancy. 2012, 2012: 10
15. Bhandal N,Russel R. Intravenous versus oral iron therapy for postpartum anaemia. Bjog 2006, 113(11):1248-52.
16. Joshi SD, Chikkagowdra S, Kumar VCM. Comparative study of efficacy and safety of intravenous ferric carboxy maltose versus iron sucrose in treatment of postpartum iron deficiency anaemia. Int J Reprod Contracept Obstet Gynecol. 2016;5.
17. Jain G, Palaria U, Jha SK. Intravenous iron in postpartum anemia. J Obstet Gynecol India. 2013;63(1):45-8
18. Bayoumeu F, Subiran-Buisset C, Baka NE, Legagneur H, Monnier-Barbarino P, Laxenaire Mc. Iron therapy in iron deficiency anaemia in pregnancy: intravenous route versus oral route. Am J obstet gynaecol.2002; 186:518-22.
19. Patel AR, Patel VS, Patel PR. A comparative study of ferric carboxymaltose and iron sucrose as a parenteral iron treatment in iron deficiency anaemia during pregnancy.
20. Froessler B, Collingwood J, Hodyl NA, Dekker G. Intravenous ferric carboxymaltose for anaemia in pregnancy. BMC pregnancy and Childbirth. 2014;14:115.
21. Joshi SD, Chikkagowdra S, Kumar VCM. Comparative study of efficacy and safety of intravenous ferric carboxy maltose versus iron sucrose in treatment of postpartum iron deficiency anaemia. Int J Reprod Contracept Obstet Gynecol. 2016;5