

Study of safety and efficacy of intravenous Ferric Carboxy Maltose in Iron deficiency anaemia during 2nd and 3rd trimester of pregnancy

Dr. Payal H. Panchal¹, Dr. Kush a. Shah², Dr. Sushma R. Shah³,
Dr. Ami V. Mehta⁴

¹(Assistant professor), ²(3rd year resident), ³(professor), ⁴(associate professor)

Department of Obstetrics and Gynecology, Sheth V.S. General Hospital,

Smt. N.H.L Municipal Medical college, Ahmedabad

Corresponding Autor: Dr. Payal H. Panchal

Abstract

- **Objectives:** Study of safety and efficacy of intravenous Ferric Carboxy Maltose in Iron deficiency anaemia during 2nd and 3rd trimester of pregnancy^{4,5}.
- **Background and objectives:** Iron deficiency is common among women of childbearing age in both the developed and developing countries. Intravenous Ferric carboxy maltose (FCM) is a novel molecule which can be safely administered upto 1000mg in single dose with no significant adverse effects.
- **Method :** A hospital based prospective study included 53 antenatal women of ≥ 24 to ≤ 34 weeks gestation with documented iron deficiency anaemia, ferric carboxy maltose was administered and improvement in hemoglobin was assessed after 3 weeks. Safety was also assessed during study.
- **Result :** There was a significant improvement in hemoglobin over a period of 3 weeks from mean Hb 7.7 to Hb 9.6. No serious adverse effects were noted in this study.^{6,7}
- **Conclusion :** Intravenous FCM is effective in treatment of iron deficiency anaemia without significant adverse effects in pregnancy in 2nd and 3rd trimester.

Date of Submission: 05-10-2018

Date of acceptance: 20-10-2018

I. Introduction:

- WHO has defined anemia in pregnancy as hemoglobin less than 11 gm% . Lack of iron intake, increased iron demand, faulty dietary habits, parasitic infestation & malaria are some common causes of iron deficiency during antenatal period.^{1,2,3}
- There are various iron preparations available for the treatment of iron deficiency anemia. Oral iron is the preferred route of administration for mild anemia. Treatment with oral iron preparations is used routinely in pregnant women, if iron deficiency anemia develops. However, oral iron supplementation often leads to adverse effects, such as constipation, diarrhea & abdominal pain. If these unwanted gastrointestinal effects arise, adherence to iron treatment decreases. Packed cell transfusion is reserved for cases with severe anemia but carries significant risk of transmissible diseases as well as risk of anaphylactic and allergic reactions. Parenteral iron preparations like iron dextran, iron – sucrose and ferric carboxy maltose (FCM) have been considered as an alternative to oral iron. Iron dextran may cause allergic reaction and iron sucrose requires repeated doses infusion. Ferric carboxy maltose is a novel molecule composed of a polynuclear iron (III) hydroxide complexes to carboxy maltose. A single or two dose, upto 1000mg in single seating infused slowly over 30 minutes and very less adverse reaction render this novel agent a potentially ideal candidate for the treatment of iron deficiency anemia. FCM is cost effective with other positive benefits of fewer hospital visits and improved patient compliance.
- To date, there are few clinical studies using ferric carboxy maltose in pregnant women. The primary aim of this study was to assess the use of intravenous ferric carboxy maltose in the correction of iron deficiency anemia in pregnant women in mild and moderate anaemia in 2nd and 3rd trimester . The secondary aims were to determine the extent and severity of adverse effects of ferric carboxy maltose.

II. Materials and methods

- This is a prospective study conducted over a period of 6 months from 1st september 2017 to 28th february 2018 including 53 patients attending the Obstetric and gynecology department of Smt V.S. Hospital, Ahmedabad. We included pregnant women of more than 18 years old with gestation age ≥ 24 weeks ≤ 34

Study of safety and efficacy of intravenous Ferric Carboxy Maltose in Iron deficiency anaemia during

weeks. All patients had definitive diagnosis of iron deficiency anemia and hemoglobin between 7 to 11 gm. %. Iron deficiencies was diagnosed on parameters like complete blood count, peripheral smear(microcytic hypochromic), packed cell volume, serum ferritin, serum total iron binding capacity, serum iron.Parasiticinfestation was ruled out.In each case NST was reactive and daily fetal movement count was adequate.History of thalassemia and previous allergic reaction to iron was elicited. Patients were explained about drug, its effect and possible side effects. Informed and written consent was obtained. Patient with anemia of other causes and hemodynamic instability were excluded. Injection vitcofol(Cyanocobalamin 500 MCG+Folic acid 15 MG+Niacinamide 200 MG.)

- Total dose of ferric carboxy maltose was calculated on the basis of hemoglobin deficit and body weight using:

Ganzoni formula: Total iron deficit (milligram)= body weight(kg) x [target Hb - actual Hb (gm %)] x 0.24 + depot iron (500mg)

- 1000 mg ferric carboxy maltose stored in cool place at <8 degree C was infused in 100 ml NS over 30 minutes.
- In our study all subjects were classified according to WHO guidelines of degree of anemia

Degree of anaemia	No. of patients
Mild	5
Moderate	48
Severe	0

III. Results

Improvement in hematological parameters after FCM therapy		
Parameters	Booking mean values	Post mean values
Hemoglobin (gm/dl)	7.7	9.6
PCV	29.7	37.2
S.Ferritin(ng/ml)	25.8	93.7
MCV(fl/red cell)	66.2	78.3
MCHC(g/dl)	25.4	33.6
MCH(pg/red cell)	22.3	27.9

Side effects	No of patients
Headache	2
Shivering	3
Urticaria	1
Anaphylaxis	0
Intra uterine death	0
Decreased daily fetal movement count	0

Hb(gm/dl) before treatment	No of patients	Average Hb(gm/dl) after treatment
7-7.9	32	9.2
8-8.9	16	10.5
9-9.9	5	10.7
10-10.9	0	-

Improvement in Hb in different gestational age			
Gestational age(wks)	No of anaemic patients	Average Hb(gm/dl)	Average Hb (gm/dl)after treatment
24.1-28	4	8.1	9.7
28.1-32	36	7.6	9.5
32.1-33.6	13	7.9	9.7

Comparison of studies

	Mean Hb (gm/dl) before fcm	Mean Hb (gm/dl) after fcm
Our study	7.7	9.6
DZeba et al	8.9	10.5
Anouk Pels and Wessel Ganzevoort 2015	8.4	10.7

IV. Discussion

- In this study, mean total iron deficit was around 1000 mg against which mean actual elemental iron administered through FCM injection/infusion was also 1000mg representing 100% replenishment of deficit. Treatment with FCM increased mean Hb by 1.9 gm/d in all patients after 3 weeks which is clinically significant.
- Ferric carboxy maltose infusion is found to be relatively safe as there were only 3 cases of headache, 2 cases of shivering, 1 case of urticaria.^{8,9}
- Ferric carboxy maltose is also as cost effective as iron sucrose and blood transfusion.
- It takes at least 2-3 weeks to improve hemoglobin level.^{10,11,12}

V. Conclusion

- Intravenous Ferric carboxymaltose offers rapid correction of hemoglobin and replenishment of iron storage in body without significant adverse effects in pregnancy after first trimester. FCM should be offered to all women with IDA to minimize maternal morbidity & mortality.

References

- [1]. Christoph P, Schuller C, Studer H, Irion O, De Tejada BM, Surbek D. Intravenous iron treatment in pregnancy: comparison of highdose ferric carboxymaltose vs. iron sucrose. *Journal of Perinatal Medicine* 2012;40(5):469-474.
- [2]. Froessler B, Collingwood J, Hodyl NA, Dekker G. Intravenous ferric carboxymaltose for anaemia in pregnancy. *BMC pregnancy and childbirth* 2014; 14:115.
- [3]. Institute of Medicine, Committee on Nutritional Status During Pregnancy and Lactation. Washington DC: National Academy press.1990; 272:98.
- [4]. Al-Momen AK, Al-Meshari A, Al-NuaimL, Saddiqe A, Abotalib Z, Khashogji T, et al. Intravenous iron sucrose complex in the treatment of iron deficiency anaemia during pregnancy. *Eur J ObstetGynecolReprod Biol.*1996; 69:121-4.
- [5]. LoneFW, Qureshi RN, Emanuel F. Maternal anaemia and its impact on perinatal outcome in a tertiary care hospital in Pakistan. *Eastern Mediterr Health J.* 2004; 10:801-7.
- [6]. VanWyck DB, Martens MG, Seid MH, Baker JB, Mangione A. Intravenous ferric carboxymaltose compared with oral iron in the treatment of postpartum anaemia: a randomized controlled trial. *Obstet Gynecol.*2007; 110:267-78.
- [7]. Breyman C, Gliga F, Bejenariu C, Strizhova N. Comparative efficacy and safety of intravenous ferric carboxymaltose in the treatment of postpartum iron deficiency anemia. *Int. J Gynacol Obstet.*2008; 101:67-73.
- [8]. Thomsen JK, Prien-Larsen JC, Devantier A. Low dose iron supplementation does not cover the need for iron during pregnancy. *ActaObstetGynecol Scand.*1993; 72:93-98.
- [9]. Ehrenthal DB, Chichestet ML, Cole OS, Jiang X. Maternal risk factors for peripartum transfusion. *J Womens Health.*2012; 21(7):792-97.
- [10]. Khalafallah A, Dennis A, Bates J, Bates G, RobertsonIK,Smith L, et al. A prospective randomized controlled trial on intravenous versus oral iron for moderate iron deficiency anaemia of pregnancy. *J intern Med.*2010; 268:286-95.
- [11]. 10.Pavord S, Myers B, Robinson S, Allard S, Strong J. UK guidelines on the management of iron deficiency in pregnancy. *Br J Haematol.*2012; 156:588-600.
- [12]. Crosby WH. The rationale for treating iron deficiency anaemia. *Arch Int Med.* 1984; 144:471-2.
- [13]. BhandalN,Russel R. Intravenous versus oral iron therapy for postpartum anaemia. *Bjog* 2006, 113(11):1248-52.

Dr.Payal H. Panchal1 “Study of safety and efficacy of intravenous Ferric Carboxy Maltose in Iron deficiency anaemia during 2nd and 3rd trimester of pregnancy” *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, vol. 17, no. 10, 2018, pp 01-03.