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STUDY TO EVALUATE THE EFFICACY AND SAFETY OF INJECTABLE FERRIC CARBOXY MALTOSE AND IRON SUCROSE IN POSTPARTUM ANAEMIA

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ABSTRACT

Introduction: Iron deficiency anaemia is the most common cause of post-partum anaemia in India. It is primarily due to inadequate iron intake and due to post-partum blood loss. As per WHO, post-partum anaemia is defined as haemoglobin level < 10 gm%. This study aims to compare safety and efficacy of intravenous ferric carboxy maltose with intravenous Iron sucrose in iron deficiency anaemia in post-partum period.

Material and Method: In this prospective study, 50 post-partum women with iron deficiency anaemia (Hb < 10 g%) were divided into two groups. Group 1: 25 women were treated with intravenous ferric carboxy maltose and Group 2: 25 women were treated with iron sucrose. The efficacy of intravenous ferric carboxy maltose in comparison to intravenous iron sucrose was assessed. The evaluation of safety and tolerance with the parenteral iron therapy was also performed.

Results: Maximum number of patients in our study were belonged to low socioeconomic class and from age group 25-29years. The mean rise in the haemoglobin level with ferric carboxymaltose was 1.44 gm/dl and with that of iron sucrose was 1.31gm/dl. Ferric carboxymaltose was observed to be safer with no adverse events in comparison to the iron sucrose.

Conclusion: In our study, intravenous FCM was very effective in improving Haemoglobin concentration as well as in early replenishment of iron stores in patients with post-partum anaemia. Intravenous ferric carboxy maltose was more efficacious and safer in comparison to the intravenous Iron sucrose. Hence, from this study we can recommend its use in post-partum women with iron deficiency anaemia.

KEYWORDS : Postpartum anaemia, Ferric carboxy maltose, Iron sucrose.

INTRODUCTION

Anaemia is the most common nutritional deficiency in the world. Globally, anaemia affects 1.62 billion people which constitute to 24.8% of the total population and the group with the greatest number of individuals affected being pregnant women[1]. In reproductive age women main causes of anaemia are Menstrual blood loss, pregnancy and delivery. It is estimated that 20-40% of maternal deaths in India is due to anaemia [1].

World Health Organization (WHO) has defined postpartum anaemia (PPA) as haemoglobin of <10 gm% during the postpartum period[2]. The prevalence of PPA varies from 4% to 27%[3]. Iron deficit being the most common as 50-60% in Post-partum females in India. Postpartum Iron Deficiency Anaemia is mostly due to inadequte intake before pregnancy and due to peripartum blood loss.

Different preparations of iron supplements have been in use for treatment of iron-deficiency anaemia, whereas blood transfusion is an option for more severe cases of anaemia. Oral iron supplementation gives satisfactory results in raising haemoglobin level but side effects like nausea, constipation, gastritis tend to affect the compliance. Intravenous iron preparation have been used for treating iron deficiency anaemia with a promising result and making it possible to avoid blood transfusion and side effects of oral iron preparation. Iron sucrose has been widely used with promising results but multiple dosing is required which decreases the compliance of its use.

Ferric carboxy maltose (FCM) is non-dextran containing intravenous iron agent, having a very low immunogenic potential and therefore not predisposed to high risk of anaphylactic reactions, designed to be administered in large doses in a short period of time, with very less side effects overcoming the limitations of the existing intravenous iron agents[4]. FCM is cost effective and require less frequent hospital visits which improve patient compliance. It provides quick replenishment of iron stores and can be given up to a maximum single dose of 1000 mg in a duration of less than 15 minutes.

OBJECTIVES

To evaluate the efficacy and safety of FCM injection in improving haemoglobin level in postpartum anaemia and compare it with iron sucrose in treating postpartum anaemia.

MATERIALAND METHODS

It was a prospective study done over a period of one year in the department of Obstetrics and Gynaecology,Smt S.C.L General Hospital, saraspur, Ahmedabad, a tertiary care hospital. Postpartum patients with haemoglobin of less than 10gm/dl were included in the study. Complete haemogram and peripheral blood smear for cell morphology were done before administering iron injection. The patients with Hb <10 g/dl, suffering from postpartum anaemia were randomly categorised to receive IV FCM and IV Iron Sucrose. The doses for IV FCM and IV iron sucrose were calculated as under:

Dose calculation /total drug infusion for ferric carboxy maltose

The cumulative dose required for Hb restoration and repletion of iron stores is calculated by the following **Ganzoni** formula:

Cumulative iron deficit (mg)=body weight in kg ×(Target Hb – Actual Hb g/dl) ×2.4 + iron storage depot(mg).

For patients <=66kg: The calculated cumulative dose is to be rounded down to the nearest 100 mg. For patients >66kg: The calculated cumulative dose is to be rounded up to the nearest 100mg.

In this study, FCM was administered only by IV drip infusion. IV drip infusion – maximum single dose of 1000mg (20ml) diluted in 250ml sterile 0.9% sodium chloride solution over 15 min not more than once a week and not exceeding 0.3ml of FCM injection (15mg of iron) / kg body weight or the calculated cumulative dose.

Dose calculation/total dose infusion for intravenous iron sucrose

In PPA = 2.4*W*D+500 where W=weight in kg, D=Target-Actual Hb/Hb deficit, Target Hb in postpartum women =12g/dl, 500mg for body stores in lactation. The factor 2.4 is derived from blood volume, which is 7% of body weight and iron content of Hb, which is 0.34%.0.07*0.0034*100=2.4(conversion from g/dl to mg).

Iron sucrose is given by IV injection according to the iron deficit calculated and rounded up to the nearest multiple of 100 for each individual. 300mg elemental iron diluted in 300ml normal saline 0.9% was the maximum dose given as slow IV infusion over 30min in this study and was repeated on alternate days when necessary.

SAMPLE SIZE

The study comprised of 50 cases which are randomly distributed into 2 groups:

Group A: 25 cases in this group receive intravenous iron sucrose therapy
Group B: 25 cases in this group receive intravenous ferric carboxy maltose therapy.

ELIGIBILITY CRITERIA
INCLUSION CRITERIA:
- Age 18-45 years
- Postpartum patients
- No infection
- Haemoglobin 7-10 gm/dl

EXCLUSION CRITERIA:
- Anaemia other than Iron deficiency anaemia
- History of blood transfusion
- Known history of allergy to parentral iron
- Postpartum haemorrhage

OBSERVATION AND DISCUSSION
Table 1: Distribution According To Age

AGE	GROUP A (IRONSUCROSE)	GROUP B(FERRIC CARBOXYMALTOSE)	P VALUE
20-24YEARS	08	09	
25-29YEARS	12	14	
30-35YEARS	03	04	NS

In present study, Maximum number of patients belongs to age group 25-29 years 12(48%) in Group A and 14 (54%) in Group B. In Verma U et al maximum patients found in age group 20-25 years[6].

Table 2: Distribution According To Parity

PARITY	GROUP A(IRON SUCROSE)	GROUP B(FERRIC CARBOXYMALTOSE)	P VALUE
1	10	11	
2	06	06	
3	06	05	
>3	03	03	NS

In present study, Majority of the patients are multiparous in group A 15(60%) and group B 14(56%). In Verma U et al , 80% cases were multiparous[6].

Table 3: Distribution According To Socio Economis Class And Residence

EPIDEMIOLOGICAL DATA	GROUP A(IRON SUCROSE)	GROUP B(FERRIC CARBOXYMALTOSE)	*P VALUE*
ECONOMIC CLASS			
Class 4	8	11	
Class 5	17	14	NS
RESIDENCE			
Rural	12	15	
Urban	10	13	NS

In present study,Total 31 patients were from lower socio-economic class according to Modified B.J.Prasad Classification.Most of the patients were residing at rural areas 27(54%). In Lunagariya et al, most of patients belongs to lower socio-economic class and majority of patients were from rural areas[7].

Table 4: Hemoglobin Level Before And After 2 Weeks Of Treatment

HB level gm/dl	Group A (iron sucrose)	Group B (FCM)	*P* value
Hb level before starting treatment			
7-8	11	09	
8.1-9	11	12	
9.1-10	03	04	
Hb level before therapy (mean +or-SD)	8.284 SD +or -0.61	8.356 SD +or- 0.81	
Hb level after therapy (mean +or-SD)	9.595 SD +or-0.74	9.800 SD +or-0.70	
Mean rise of Hb in gm	1.31 P value <0.0001	1.44 P value <0.0001	>0.05 significant

Mean Hb before starting of therapy in group A was 8.284 +or- 0.61 and in group B was 8.356 +or- 0.81. While comparing mean rise of Hb level between Group A (1.31gm/dl) and B (1.44gm/dl), Group B had significant rise of Hb level after 2 weeks. In Lunagariya et al study shows that rise in Hb in group B after 2 weeks of treatment is 1.9 gm/dl in comparison to group A 1.66 gm/dl[7].

Table 5: Mean Heamatological parameters Before and After 2 weeks of therapy

	Group A (Iron Sucrose)		Group B(Ferric carboxymaltose)	
Parameters	**Before Therapy**	**After Therapy**	**Before Therapy**	**After Therapy**
MCV	60.46	61.97	59.81	61.51
MCH	27.22	28.72	27.33	29.03
MCHC	23.49	24.99	23.17	24.87

In present study, mean increase in Heamatological parameters is more in Group B ferric carboxymaltose (1.7) as compared to Group A Iron sucrose (1.5).

Table 6:Comparison Of Adverse Effects

Adverse Effect	Group A (Iron sucrose)	Group B(ferric carboxymaltose)
Pain at injection site	5	3
Itching and rash	1	0
Abdominal pain	0	0
Arthralgia	2	0
Nausea, vomiting	1	0
Anaphylactic reaction with hypotension	0	0
Total	09	03
Hospital stay in days (mean +or- SD)	07.16 +or-1.08	3.12 +or-0.29

In present study, 36% patients in group A had adverse effects as compared to group B where only 12% had adverse effects. Rathod et al study reported that incidence of adverse effects with ferric carboxymaltose therapy is between 6.3% and 10.6%[8].

Mean duration of hospital stay in group A was 7.16 days and compare to group A, it was very less in group B 3.12. In Lunagariya et al , mean duration of hospital is more in group A as compared to group B[7].

CONCLUSION
Nutritional anaemia in pregnancy and post-partum period is a major public health problem especially in India and most common in Iron deficiency anaemia.

Our study indicates that post-partum anaemia can be treated effectively by ferric carboxymaltose as compared to iron sucrose with additional advantage of single infusion, less side-effects and better patient compliance. FCM was very effective in improving Hb concentration as well as in early replenishment of iron stores. As the hospital stay is less in patients receiving ferric carboxymaltose, it increases patient compliance and decreases bed occupancy and burden on health facility in developing country like India.

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