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Comparison of ferric carboxymaltose versus Iron Sucrose for treatment of iron deficiency anemia in pregnancy.

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ABSTRACT… Objective: To compare the mean increase in hemoglobin level with ferric carboxymaltose injection and iron sucrose injection for the management of the pregnant females presenting with iron deficiency anemia. **Study Design:** Randomized Controlled Trial. **Settings:** Department of Obstetrics and Gynecology Madina Teaching Hospital affiliated with University medical and Dental College Faisalabad. **Period:** July 2019 to December 2019. **Material & Method:** A total number of 100 patients presented in OPD satisfying the selection criteria were enrolled in the study. The patients were randomly divided in two groups. In group A, females were given ferric carboxymaltose and in group B, females were given iron sucrose. After calculating the total iron deficit, patients in group A were given intravenous FCM. Patients in group B were given IS. Follow up of the patient was done after 3 weeks of intravenous iron treatment. The baseline Hb and values after 3 weeks of intravenous iron treatment were compared between the FCM and IS groups and increase in Hb level calculated as mean and SD. Both groups were analyzed for rise in Hb level by using independent sample t test. P value < 0.05 was taken as significant. **Results:** A total 100 pregnant female were found eligible for study, and were randomized into two groups of 50 each. Mean increase in hemoglobin level with ferric carboxymaltose and iron sucrose was evaluated, it shows that baseline Hb was 8.84±0.68 in Group A and 8.78 ±0.76 in Group B, P value was 0.67, after treatment Hb was 12.02±0.89 in Group A and 10.92 ±0.99 in Group B. Mean increase was 3.18 ±0.60 in Group A and 2.14±0.81 in Group B. P value was 0.001. **Conclusion:** Ferric carboxymaltose significantly increase Hb level and restores the iron stores as compare to iron sucreose. FCM is safe and effective intravenous treatment for iron deficiency anemia in pregnancy. FCM has the advantages of single large dose administration and fewer hospital visit. FCM is most suitable drug for the treatment of patients with IDA who required quick replenishment of iron stores.

Key words: Ferric Carboxymaltose, Iron sucrose, Iron Deficiency Anemia.

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INTRODUCTION

Anemia during pregnancy is a major health issue all over the world.[1] Iron deficiency anemia is the most common type of anemia and its prevalence is high in South Asia.[2] The incidence of anemia in pregnancy is 42 %.[3] In Pregnancy the requirement of iron increased with average of 1000mg.[4] The reasons for anemia are low dietary intake of iron, repeated pregnancies, poor bio –availability of iron, chronic blood loss and infections like malaria, hookworm infestation.[5]

The clinical manifestations of anemia are shortness of breath, palpitations, easy fatigue ability, poor concentration.[6] Iron deficiency is significantly associated with poor maternal and fetal outcome. There is increase risk of preterm labor, intrauterine growth restriction, low birth weight infants.[7] Iron deficient mothers are at risk of delivering iron deficient neonates.[8]

Parentral iron treatment is safe, effective, well tolerated and rapidly restore the iron stores in pregnancy.[9] The most commonly used parentral preparations are IS and iron dextran, their side effects include nausea, dizziness and local irritation.[10] A novel iron formulation ferric carboxymaltose is considered to be a better

potential for replenishing iron stores in short time, minimum side effects and better tolerance.[11]

MATERIAL & METHODS

The study was conducted in the department of Obstetrics and Gynecology Madina Teaching Hospital affiliated with University Medical and Dental College Faisalabad between July 2019 to December 2019.

Inclusion Criteria

All patients diagnosed with IDA of age 18-40 years, between 24-36 weeks of gestation.

Exclusion Criteria

Patients with anemia other than iron deficiency like sickle cell anemia and thalasaemia.

A total number of 100 patients presented in OPD satisfying the selection criteria were enrolled in the study after permission from ethical committee. Informed consent was obtained and patient's demographic information (name, age, gestational age and parity) was recorded.

On enrollment, a detailed clinical history which includes previous iron treatment and chronic medical illness was taken. Clinical examination was done. Routine antenatal investigations were performed according to unit protocol. Investigations for anemia include hemoglobin, reticulocyte count, peripheral film and red cell indices, serum ferritin level and Hb electrophoresis if indicated. The patients were randomly divided in two groups. In group A, females were given ferric carboxymaltose and in group B, females were given iron sucrose.

Iron requirement assessed according to Ganzoni's formula.

After calculating the total iron requirement, patients in group A were administered intravenous FCM. Maximum dose per sitting was 1000mg which was diluted in 200 ml 0.9% normal saline and given as an IV infusion over 30 minutes. Successive doses (if required) were infused on day 7 and day 14.

Patients in group B were given IS maximum dose of 200mg diluted in 200 ml normal saline as slow infusion over 30 minutes on alternate day, maximum 600mg /week.

A test dose was given to check for any adverse reaction for both, FCM and IS.

Follow up of the patient was done after 3 weeks of intravenous iron treatment. The baseline Hb and values after 3 weeks of intravenous iron treatment were compared between the FCM and IS groups and increase in Hb level calculated as mean and SD. Both groups were analyzed for rise in Hb level by using independent sample t test. P value < 0.05 was taken as significant.

RESULTS

A total 100 pregnant female were qualified for study, and were randomized into two groups of 50 each. All 100 patients completed the treatment and were included in analysis.

Age distribution shows that 64 % (n=32) in Group A and 66% (n=33) in Group B were between 18-30 years of age whereas 36 % (n=18) in Group A and 34 % (n=17) in Group B were between 31 -40 years of age, mean age was 29.38 ±3.69 years in Group A and 29.14 ±3.77 years in Group B. (Table-I)

Regarding gestational age 66 5%(n= 66) patients in Group A and 62 % (n=31) in Group B were between 25-34 weeks of gestation whereas 34% (n= 17) in Group A and 38% (n= 19) in Group B were between 34-36 weeks of gestation. Mean age was 32.1 ±3.53 weeks in Group A and 32.28±3.57 weeks in Group B. (Table-II)

Mean increase in hemoglobin level with ferric carboxymaltose and iron sucrose was evaluated, it shows that baseline Hb was 8.84±0.68 in Group A and 8.78 ±0.76 in Group B, P value was 0.67, after treatment Hb was 12.02±0.89 in Group A and 10.92 ±0.99 in Group B.

Mean increase was 3.18 ±0.60 in Group A and 2.14±0.81 in Group B. P value was 0.001. (Table-III)

Age (in year)	Group-A (n=50)		Group-A (n=50)	
	No. of Patients	%	No. of Patients	%
18-30	32	64	33	66
31-40	18	36	17	34
Total	50	100	50	100
Mean±SD	29.38±3.69		29.14±3.77	

Table-I. Age distribution (n=100)

G.Age (in weeks)	Group-A (n=50)		Group-B (n=50)	
	No. of Patients	%	No. of Patients	%
25-34	33	66	31	62
>34	17	34	19	38
Total	50	100	50	100
Mean±SD	32.1±3.53		32.28±3.57	

Table-II. Gestational age (n=100)

Hb(g/dl)	Group-A (n=50)		Group-B (n=50)		P-Value
	Mean	SD	Mean	SD	
At baseline	8.84	0.68	8.78	0.76	0.67
After Treatment	12.02	0.89	10.92	0.99	0.0001
Mean Increase	3.18	0.60	2.14	0.81	0.001

Table-III. Mean increase in hemoglobin level with ferric carboxymaltose injection and iron sucrose injection for management of females presenting with iron deficiency anemia (n=100)

DISCUSSION

Anemia in pregnancy is a global health concern.[12] Anemia during pregnancy increase the risk of low birth weight, preterm labor, maternal and perinatal mortality with poor Apgar score.[3] Anemia increase the risk of infection and maternal morbidity.[13]

The aim of the study was to compare the efficacy FCM with IS in female with iron deficiency anemia. This present study have its results consistent with a study conducted by Agarwal D in India.[1]

Cristoph et al conducted a study and found FCM more efficacious and safe than iron sucrose.[5] Breymann C et al. concluded to consider FCM to be first line treatment option for correction of iron deficiency anemia.[14]

Froessler et al. have documented remarkably increased ferritin level after FCM infusion in females with iron deficiency anemia.[15] A Khalafallah et al. demonstrate that FCM is more effective and convenient than other treatments.[16] Qassim et al. concluded that no IV iron preparation appeared to be superior.[17]

A study conducted in UAE also demonstrate that IV FCM effectively increase hemoglobin in pregnant female with iron deficiency anemia.[18] Another study conducted in Turkey also document that intravenous carboxymaltose improve hemoglobin in short time.[19]

Ferric carboxymaltose seems to be superior to other parentral iron formulations due to its high efficacy, safety and compliance revolutionizing the management of iron deficiency anemia during pregnancy.[20]

CONCLUSION

Ferric carboxymaltose significantly increase Hb level and restores the iron stores as compare to iron sucreose. FCM is safe and effective intravenous treatment for iron deficiency anemia in pregnancy. FCM has the advantages of single large dose administration and fewer hospital visit. FCM is most suitable drug for the treatment of patients with IDA who required quick replenishment of iron stores.

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