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Post transfusion serum iron parameters-Comparision of two intravenous iron preparations

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Abstract

In pregnancy, the demands for iron exceed the body's ability to absorb iron from the diet. During this period, iron stores become depleted. The serum ferritin and serum iron begins to fall. Once the transferrin saturation falls to 15–20%, hemoglobin synthesis becomes impaired. Hence, iron parameters reflect the stores. The objective of the study was to compare the post transfusion serum iron parameters of two intravenous iron preparations in moderate Anaemia of pregnancy. Fifty women in group A were given injection ferric carboxymaltose and 50 in group B were given injection iron sucrose as per calculated dose. Serum iron parameters were noted at baseline, 3 and 12 weeks. All data was statistically analysed and conclusions drawn.

We observed higher increase in both serum ferritin and serum iron in FCM group than iron sucrose group at each point of measurement, however, in both groups, ferritin and iron levels had fallen at 12 weeks as compared to those at 3 weeks. To conclude, FCM gave a higher rise in iron stores but these stores should be continuously monitored, to determine iron deficiency in future antenatal visits and monitor further therapy.

Keywords: Ferritin, Ferric Carboxytmaltose, Iron Sucrose, Transferrin Saturation

Introduction

India has the highest prevalence of Anaemia (65-75%).[1] India contributes to about 80% of the maternal deaths due to Anaemia in South Asia. India's contribution both to the prevalence of Anaemia in pregnancy and maternal deaths due to Anaemia is higher than warranted by the size of its population.[2]

In pregnancy, the demands for iron exceed the body's ability to absorb iron from the diet. During this period, iron stores, reflected by the serum ferritin level or the appearance of stainable iron on bone marrow aspirations decrease. As long as iron stores are present and can be mobilized, the serum iron, total iron-binding capacity (TIBC), and red cell protoporphyrin levels remain within

normal limits, red cell morphology and indices remain normal.[3]

When iron stores become depleted, the serum iron begins to fall, TIBC increases, once the transferrin saturation falls to 15–20%, hemoglobin synthesis becomes impaired. Gradually, the hemoglobin and hematocrit begin to fall. The transferrin saturation at this point is 10–15%.[3] Signs related to iron deficiency depend on the severity and chronicity of the Anaemia Iron deficiency Anaemia in pregnancy needs acute corrective measures because of its related considerable morbidity and mortality.

Objective

To compare the post transfusion serum iron parameters of two intravenous iron preparations in moderate Anaemia of pregnancy.

Methods

The randomized comparative hospital based study was done at a referral centre over six months. 100 pregnant women with moderate Anaemia were included in the study after taking informed consent. They were divided into two groups with 50 women in each group. Women in group A were given injection ferric carboxymaltose and those in group B were given injection iron sucrose. FCM was given in one or two sittings depending on iron requirement and iron sucrose was given in divided doses. Serum iron parameters were recorded at baseline, 3 and 12 weeks. All the observations were tabulated and statistically analysed.

Results

There were 50 women in both groups. The basal value of S. ferritin was 6.84 ± 3.29µg/L in FCM group and 7.53 ± 3.81µg/L in iron sucrose group, the difference was statistically not significant. The serum ferritin levels were very low in our population reflecting poor stores.

We observed higher increase in serum ferritin in FCM group than iron sucrose group at each point of measurement. The rise in mean serum ferritin values from baseline in the FCM group was 129.18 ± 12.73 at 3 weeks, 110.48 ± 13.86 at 12 weeks compared to iron sucrose group, which was 119.19 ± 13.29 at 3 weeks, and 98.91± 12.24 at 12 weeks. This rise was statistically significant in both groups ($p<0.001$) and difference in rise in serum ferritin between both the groups also significant ($p<0.001$).However, in both groups, ferritin levels had fallen at 12 weeks as compared to those at 3 weeks. Table 1

In the study, baseline mean serum iron was statistically comparable in both groups 13.45± 8.28µg/dl in FCM group and 11.53 ± 5.02µg/dl in iron sucrose group .

We observed higher increase in serum iron in FCM group than iron sucrose group at each point of measurement. The serum iron values in the FCM group were 112.04±11.95 µg/dL at 3 weeks, 90.59±10.39µg/dl at 12 weeks compared to iron sucrose group, 101.67±9.53µg at 3 weeks, and 79.91±8.01µg/dL) at 12 weeks. This was statistically significant in both groups ($p<0.001$) the difference in rise in serum iron between both the groups also significant ($p<0.001$).Table 1.

However, in both groups, similar to ferritin, serum iron levels too had fallen as compared to those at 3 weeks.

Table 1: S. Ferritin and S. Iron Baseline and Post treatment Values

Parameter			FCM group	Iron sucrose group	P value
S. Ferritin	Baseline	Mean Ferritin ± SD	6.84±3.29	7.49±3.80	t =0.91 P=0.363,NS
	3 wks	Mean Ferritin ±SD	136.03±13.73 Pair t =71.73 P <.001,Sig	126.68±13.7 Pair t =63.41 P <.001,Sig	t =3.40 P<0.01 Sig
		Rise Mean Ferritin ± SD	129.18±12.73	119.19±13.29	t =3.83 P<0.01Sig
	12 Wks	Mean Ferritin ±SD	117.38±15.86 Pair t =33.82 P <.001,Sig	106.40±12.69 Pair t =57.12 P <.001,Sig	t =3.82 p<0.001,Sig
		Rise Mean Ferritin ± SD	110.48±13.86	98.91 ±12.24	t =4.42 p<0.001,Sig
S.Iron	Base line	Mean Iron ±SD	13.45±8.27	11.53±5.02	t =1.40 P=0.163,NS
	3 Wks	Mean Iron ±SD	112.04±11.95 Pair t =34.82 P <0.001,Sig	101.67 ±9.53 Pair t =56.58 P <0.001,Sig	t =4.79 p<0.001,Sig
		Rise Mean Iron ± SD	98.46±13.86	90.14±11.26	t =3.29 p<0.001,Sig
	12 wks	Mean Iron ±SD	90.59±10.39 Pair t =38.10 P <.001,Sig	79.91±8.01 Pair t =51.48 P <.001,Sig	t =5.75 p<0.001,Sig
		Rise Mean Iron ± SD	77.12±13.89	68.38±9.39	t =3.68 p<0.001,Sig

In our study, there was increase in transferrin saturation in both groups at each point of measurement. The transferrin saturation values in the FCM group were 25.66±3.58 at 3 weeks, 33.06±3.85 at 12 weeks compared to iron sucrose group, which was 25.24±3.69 at 3 weeks and 33.24±3.39 at 12 weeks. The rise was statistically significant in both groups but there was no significant difference in rise in transferrin saturation between both the groups. Table 2

Table 2 S.Transferrin Saturation and TIBC Baseline and Posttreatment Values

Parameter			FCM group	Iron sucrose group	P value
Transferrin satration	Base line	Mean Transferrin saturation ±SD	3.24±2.58	3.86±2.71	t =1.17 P=0.09 NS
	3 wks	Mean Transferrin saturation ±SD	25.66±3.58 t=37.02 p<0.01,Sig	25.24±3.69 t=34.37 p<0.01,Sig	t =0.576 P=0.565,NS
		Rise Mean T. saturation ± SD	22.42±4.28	21.38±4.40	t =1.198 P=0.233,NS
	12wks	Mean Transferrin saturation ±SD	33.06±3.85 t=47.50 p<0.001,Sig	33.24±3.39 t=45.09 p<0.001,Sig	t =0.247 P=0.804, NS
		Rise Mean T. saturation ± SD	29.82±4.44	29.38 ±3.10	t =0.574 P=0.566, NS
TIBC	Base line	Mean TIBC ±SD	553.44±90.63	533.30±76.21	t =1.202 P=0.232, NS
	3wks	Mean TIBC ±SD	416.90±59.24 t=-11.86 p<0.001,Sig	411.98±55.27 t=-13.37 p<0.001,Sig	t =0.48 P=0.669, NS
		Decrease Mean TIBC ± SD	-136.54±81.38	-121.32±61.82	t =-1.094 P=0.276, NS
	12 wks	Mean TIBC ± SD	298.52±41.72 t=-19.55 p<0.001,Sig	317.02±56.81 t=-22.04 p<0.001,Sig	t =1.85 P=0.06, NS
		Decrease Mean TIBC ± SD	-254.64±79.84	-216.28±69.37	t =-2.564 P=0.01,Sig

In our study we observed higher decrease in TIBC in FCM group than iron sucrose group at each point of measurement. The change in TIBC values from baseline in the FCM group was -136.54 ± 81.38 at 3 weeks, -254.64 ± 79.84 at 12 weeks compared to iron sucrose group, which was -121.32 ± 61.82 at 3 weeks and - 216.28 ± 69.37 at 12 weeks. The decrease was statistically significant in both the groups (P<.001) and there was significant difference in decrease in TIBC between both the groups at 12 weeks (p=0.01). Table 2

Discussion

Mean serum ferritin found by most authors, before start of supplementation was low (ranging from 8.45b µg/l, Ambily Jose et al[4] to 16.03 ± 5.95 µg/L, Aakanksha Mahajan A et al[5])

Other authors, Swetha T et al[6] , Shabina Khan et al[7],Ambily Jose et al[4] all observed a significant rise in serum ferritin levels from baseline in 3 to 4 weeks in both groups, but the increase in FCM group was more than iron sucrose group at each point of measurement ($p < 0.001$).

This may be due to the rapid replenishment of iron stores by FCM given in single dose as compared to iron sucrose which was given in divided doses.

In the study by Ambily Jose et al[4] mean serum iron was 30.25 µg/dl before initiation of therapy, higher than the present study and levels changed significantly across after 3weeks treatment in both the FCM 178µg/dL ($p<0.001$) and iron sucrose group 187µg/dL ($p<0.001$) Serum iron levels were higher in the iron sucrose group, than in the FCM group. This study was contrary to the present study.

We observed that as compared to levels at 3 weeks,the serum ferritin and iron levels both had fallen at 12 weeks.Similar observations were made by Ambily Jose et al[4].

It was observed by Aakanksha Mahajan et al[5] that mean ferritin values rose at 3 weeks but fell at 6 weeks.

Similar findings were noted by Ambily Jose et al[4] ,who also reported that mean serum iron levels had decreased after 12 weeks treatment in both the FCM 112µg/dL ($p< 0.001$) and iron sucrose group 107µg/dL ($p< 0.001$).

Our study demonstrated superiority of FCM in replenishment of stores as observed by highly significant difference in ferritin rise between both the groups. All iron indices showing more improvement with FCM than iron sucrose. Higher increase in ferritin with ferric carboxytmaltose (FCM) may be due to the property of Type-I polynuclear iron (III)-hydroxide carbohydrate complex that produces a slow and controlled release iron to endogenous iron binding sites.[8]

Ambily Jose et al[4] also found transferrin saturation to be higher in FCM group than iron sucrose at 12wks post treatment.

A fall in serum ferritin and iron levels at 12 weeks was observed as compared to those at 3 weeks. Post transfusion monitoring is done only by haemoglobin levels by most, and hence fails to detect the fall in iron stores if any. Iron supplementation should be emphasized on after intravenous iron to continue replenishing the stores. Serum iron parameters should be monitored as well in follow-up visits.[9] another session of intravenous iron may be planned if levels fall despite oral iron intake.

Conclusion

After intravenous iron therapy,laboratory measures of iron stores should be utilized to determine iron deficiency in antenatal visits and monitor further therapy. The iron stores thus will be replenished and will prevent anaemia in the postpartum period.

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