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COMPARATIVE STUDY OF INTRAVENOUS FERRIC CARBOXYMALTOSE AND IRON SUCROSE IN THE MANAGEMENT OF IRON DEFICIENCY ANEMIA

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ABSTRACT

This study was conducted to compare the efficacy of ferric carboxymaltose and iron sucrose in the treatment of postnatal iron deficiency anaemia. This was a prospective study involving 100 Postnatal women with haemoglobin between 8-10gm% in the age group of 15 to 25 yrs placed randomly into two groups. The study was conducted in Govt RSRM Lying Hospital ,Stanley Medical College, Chennai during year August 2015 – 2016.One group of 50 postnatal mother received iron sucrose while the other 50 postnatal mother received Ferric carboxymaltose.

KEYWORDS FMCG, GST, Patanjali Ayurvedic LTd.

INTRODUCTION

Anaemia is defined as decreased oxygen carrying capacity of blood. It is one of the major illness affecting more than 50% of antenatal and postnatal women in developing countries like India leading to increased maternal mortality and morbidity. Most common type is the nutritional anaemia - IRON DEFICIENCY ANAEMIA.

CAUSES:

- Increased blood loss during delivery (In normal vaginal delivery >500ml, caesarean>1000 ml)
- Iron malabsorption due to vomiting, or due to gastrointestinal disease
- Due to intake of iron deficient foods.
- Due to hookworm infestations

WHO defines postnatal anaemia as haemoglobin less than 11gm.

GRADES OF ANAEMIA:

Mild 8.0-10.9
Moderate 5.0-7.9
Severe Less than 5

STAGES OF IRON DEFICIENCY ANAEMIA:

There are three stages of development of iron deficiency anaemia.

1. storage iron depletion
2. Iron deficient erythropoiesis
3. Iron deficiency anaemia.

CATEGORIES OF IRON DEFICIENCY:

Degrees of iron deficiency	Haemoglobin	Serum ferritin
Iron Deficient not anemic	>11gm/dl	<12ng/ml
Iron deficiency anemia	<11gm/dl	< 12ng/ml

PARAMETERS	NORMAL RANGE	IDA
Serum iron µg/dl	60-120	<60
Serum iron ng/dl	15-150	<15
TIBC µg/dl	325-400	>400
Tranferrin saturation	20-50%	<15
Tfr mg/dl	5.8	8.8
ZPP µg/dl	<40	<70

Postnatal iron deficiency anemia can be diagnosed clinically and confirmed by laboratory parameters like haemoglobin, peripheral smear, blood indices and serum ferritin. Various modes of treatment are available to treat postnatal iron deficiency anaemia.

They are Oral iron
- Parenteral iron
- Blood transfusion

Due to poor compliance to oral iron and its gastrointestinal side effects and because of inherent risks following blood transfusion, parenteral iron has gain more importance to treat iron efficiency anaemia in clinical practice.Among them second generation intravenous iron sucrose is most commonly used. Upcoming is the third generation injection ferric carboxymaltose.

MATERIALS AND METHODS:

The study was conducted in Govt RSRM Lying Hospital – Stanley Medical College, Chennai during year August 2015 – 2016. 100 Postnatal women with hemoglobin between 8-10gm% were selected and placed randomly into two groups. One group of 50 postnatal mother received iron sucrose while the other 50 postnatal mother received Ferric carboxymaltose.

INCLUSION CRITERIA:

Postnatal women with IDA with HB 8-10gm.

EXCLUSION CRITERIA:

H/O Allergy to iron compound, Chronic kidney disease, Anaemia due to other causes(Including postpartum Haemorrhage), Hematological disorder, Bronchial asthma, Hepatitis, HIV, Heart disease, H/O recent blood transfusion.

DOSE CALCULATION:

In postnatal women 24 hrs after delivery Haemoglobin estimation, blood indices, peripheral smear and serum ferritin should be done. Patient with iron deficiency anaemia with HB between 8 to 10gm were selected. Required iron dose is calculated using the formula below.

Target HB is 12 gm.

2.4 x Body weight in Kg x (Target HB - Actual HB) +500 gm.

IRON SUCROSE: (No test dose is required)

1) It is given by IV injection according to the iron dose calculated and rounded up to the nearest multiple of 100 for each individual.
2) 200 mg elemental iron diluted in 200 ml 0.9% normal Saline is the maximum dose given over 15 to 20 min and repeated on alternate days as required.

FERRIC CARBOXYMALTOSE: (No test dose is required)

1) It is given by IV injection according to the iron dose calculated

and rounded up to the nearest multiple of 100 for each individual

2) Maximum single dose of 1000 mg diluted in 250 ml of 0.9% 3. normal Saline given over 15 minutes and not more than once a week.

OBSERVATION AND RESULTS

AGE DEMOGRAPHY IN IRON SUCROSE Vs FERRIC CARBO XYMALTOSE:

AGE	IRON SUCROSE		FCM	
	COUNT	PERCENTAGE	COUNT	PERCENTAGE
15-20	15	30%	14	28%
21-25	22	44%	23	46%
26-30	12	24%	11	22%
31-35	1	2%	2	4%

PARITY IN IRON SUCROSE Vs FERRIC CARBOXYMALTOSE:

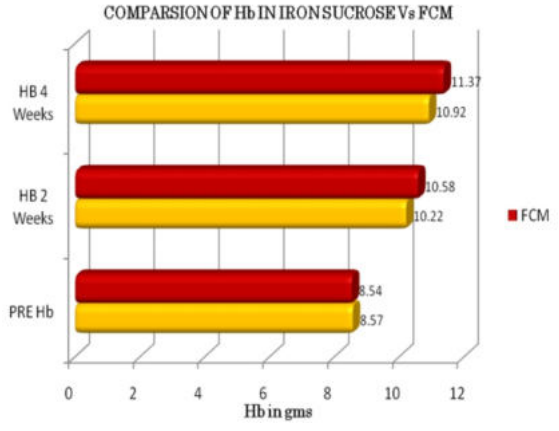
PARITY	IRON SUCROSE		FCM	
	COUNT	PERCENTAGE	COUNT	PERCENTAGE
P_1L_1	18	36%	17	42%
P_2L_2	26	52%	26	44%
P_3L_3	4	8%	6	12%
P_4L_4	2	4%	1	2%

MODE OF DELIVERY (MOD) IN IRON SUCROSE Vs FERRIC CARBOXYMALTOSE:

MOD. Code	IRON SUCROSE	FCM
Labour Natural	11	10
Labour Natural with Episiotomy	17	17
Labour Natural with LP	3	3
FORCEPS	2	1
Emergency LSCS	8	8
Emergency Repeat LSCS	3	4
Emergency Repeat LSCS ST	6	6
VABC	0	1

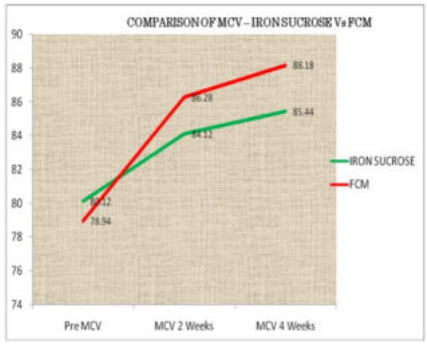
COMPARISON OF EFFICACY OF IRON SUCROSE Vs FCM USING MEAN PLOT COMPARISON OF Hb IN IRON SUCROSE vs FCM

	IRON SUCROSE	FCM
PRE Hb	8.57	8.54
Hb 2 Weeks	10.22	10.58
Hb 4 Weeks	10.92	11.37



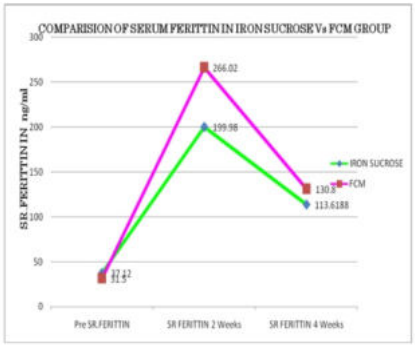
COMPARISON OF MCV – IRON SUCROSE Vs FCM

	IRON SUCROSE	FCM
PRE MCV	80.12	78.94
MCV 2 Weeks	84.22	86.28
MCV 4 Weeks	85.44	88.18



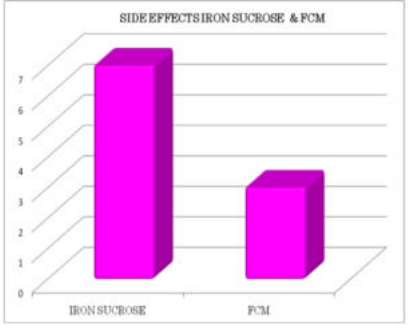
COMPARSION OF SR.FERRITIN – IRON SUCROSE Vs FCM

	IRON SUCROSE	FCM
Pre SR.FERITTIN	37.12	31.5
SR.FERITTIN 2 Weeks	199.98	266.02
SR.FERITTIN 4 Weeks	133.6188	130.8



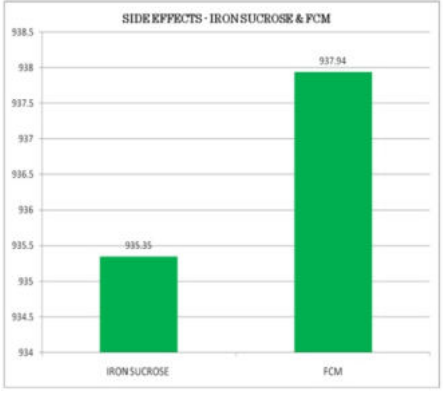
COMPARISION OF SIDE EFFECTS

IRON SUCROSE	FCM
7	3



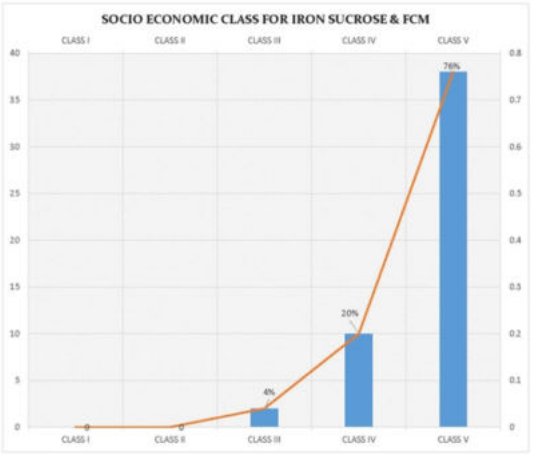
DOSE REQUIREMENT FOR IRON SUCROSE & FCM

	IRON SUCROSE	FCM
DOSE	935.53	937.94



SOCIO ECONOMIC STATUS

SOCIO ECONOMIC CLASS	COUNT	PERCENTAGE
CLASS I	-	-
CLASS II	-	-
CLASS III	2	4%
CLASS IV	10	20%
CLASS V	38	76%



DISCUSSION

Post-partum iron deficiency anaemia can be treated by oral and intravenous iron. With both of these iron therapies hemoglobin levels increase by 2.4 to 4.6 gm/dl. David B[6] et al study has shown increase in hemoglobin levels by 2 gm/dl within 7 days and 4gm/dl within 2-4 weeks in patients receiving ferric carboxymaltose. Serum ferritin also increased promptly in IV FCM patients.

Giannoulis[21] et al reported increase of hemoglobin by 4-6 gm/dl in patients receiving iron sucrose. Setu Rathod[5] et al has showed increased in hemoglobin 0f about 2.4gm/dl and 3.4 gm/dl at 2 weeks and 6 weeks respectively. In our study hemoglobin level increased by 1.65 gm/dl;2.35g/dl in iron sucrose group and 2.04 gm/dl;2.83g/dl from FCM group at 2 weeks and 4 weeks of post treatment.

Seid[8] et al reported that ferritin level increases in 6 weeks about 238 ng/ml in FCM group while there was reported that an increase in serum ferritin in oral iron group as 21ng/ml. Christian breymann[17] et al serum ferritin from 39.9 ng/ml from baseline to 568.2 ng/ml at week 1, 161.2ng/ml at 12 weeks (p<.001 when compared to margin increase in ferritin level with ferrous sulphate group 32.4 from baseline to 34.8ng/ml and 43.3ng/ml at 2 weeks and 12 weeks respectively. Prasanth S Kharde[9] et al showed that mean increase in serum ferritin level from11.47ng/ml from baseline to 47.69 ng/ml at 2 weeks and 53.47 ng/ml at 6 weeks. In our study the mean improvement in serum ferritin level from baseline of 37.12 ng/ml to 113.61 ng/ml at 4 weeks following iron sucrose and among FCM group there is improvement from31.5 ng/ml of baseline to 130.8 ng/ml at 4 weeks.

Van Wyck et al has shown a significant increase in MCV among FCM patients. Dede et al had shown increase in mean MCV of 33.3 fl from pre treatment following iron sucrose therapy. Khurshid shabir Raja et al had shown a mean increase in MCV 0f 10 fl from baseline. Our studyshows mean improvement in MCV following iron sucrose therapy is from 80.12 fl to 85.44 fl at 4 weeks and among FCM group the mean increase is 88.18 fl at 4 weeks from 78.94 fl.There is no serious adverse reactions among the iron sucrose as well as FCM groups. The incidence of adverse effects reported so far is between 6.8% and 24.2%. in our study there is milder adverse reactions like nausea, giddiness and urticarial was reported with incidence of 6% among FCM group and 14% in iron sucrose group.

SUMMARY

In this study I randomly selected 100 postnatal women with IRON DEFICIENCY ANAEMIA with haemoglobin level between 8 to 10 gm. Iron deficit is calculated using formula with the aim of target haemoglobin 12gm.After getting the consent, and after explaining the risks and benefits, 50 postnatal women received iron sucrose and 50 women received FCM. The dose required is almost 1000mg in both the groups. For iron sucrose per sitting only 200mg can be administered. So patients in iron sucrose group needs at least five visits to receive the required dose. Whereas in FCM group 1000 mg can be administered as a single dose. The outcomes are compared and analysed using paired T test and by Independence T test. The investigations used are haemoglobin, serum ferritin, blood indices, and peripheral smear before and after treatment. The results are summarized below.

In age and parity the incidence of iron deficiency anaemia in both groups were comparable and is more among young age group (15-25) and in multiparas .People belonging to low socioeconomic group is also at increased risk.

The average increase in haemoglobin in FCM group is faster and greater. The average haemoglobin increase is about 10.92(2.35g/dl) at 4 weeks in iron sucrose group from baseline value of 8.57g where as in FCM group Hb increase is about 11.37(2.83g/dl) from 8.54. MCV increases about 85.44(fl) from baseline of 80.12(fl) in iron sucrose group whereas in FCM it increases to about 88.18(fl) from 78.94.So there is significant improvement in blood indices following FCM injection.Among iron sucrose group serum ferritin increases from baseline (37.2 to 199.98 at 2weeks; 113.61 at 4 weeks). But the improvement is greater among FCM GROUP.(31.5 to 266.02 at 2 weeks and 130.8 at 4 weeks).the ferritin fall at 4th week is due to iron redistribution in haemoglobin formation.

Adverse reactions following both groups were milder .Following iron sucrose 14%(n=7) developed side effects like nausea, vomiting, urticaria whereas in FCM group only 6% developed nausea, giddiness and arthralgia.

CONCLUSION

This study compared the efficacy of ferric carboxymaltose over iron sucrose in the management of postnatal iron deficiency anaemia.Though our results showed improvement in hemoglobin, serum ferritin, and blood indices in both iron sucrose and FCM group but it was faster and greater with ferric caboxymaltose when compared with iron sucrose. Other advantages are more dose can be administered at a single visit and the hospitalization duration of the patients are reduced greater. The quality of life is also better with FCM group. FCM lacks dextran and less immunogenic so adverse reactions are also low. So out of two intravenous iron FCM seems to be clinically better and statistically significant than iron sucrose in treatment of postnatal iron deficiency anaemia.

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