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Comparision of intravenous iron sucrose and intravenous ferric carboxymaltose for treatment of iron deficiency anemia in pregnant women: in a tertiary care hospital in Chengalpattu district

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ABSTRACT

Background: Anaemia is the most common manageable problem among pregnant women worldwide, which contribute to maternal and perinatal mortality.
The aim is to compare the efficacy, safety and compliance of intravenous ferric carboxymaltose with intravenous iron sucrose in the treatment of iron deficiency anaemia in pregnancy.
Materials and Methods: It is a randomized prospective study conducted in department of obstetrics and Gynecology at Shri Sathya Sai Medical College, constituting of 100 pregnant women. 50 pregnant anemic patients were treated with intravenous ferric carboxymaltose and other 50 patients were treated with intravenous iron sucrose. Hemoglobin, packed cell volume and blood indices were measured before and 3 weeks after treatment. The efficacy and safety of both intravenous compounds were studied.
Results: Anaemia in pregnancy was more prevalent among 20-24 years of age groups, it is more common in multigravida in 22-28 weeks of gestational age. The mean difference of hemoglobin 3 weeks after treatment was 2.34 g/dl for ferric carboxymaltose and 1.32g/dl for iron sucrose. The other parameters also increased significantly for ferric carboxymaltose than iron sucrose.
Conclusions: ferric carboxymaltose is an efficient and better alternative in iron deficiency anaemia in pregnancy with fewer side effects and has the added advantage of single dose regime.

1. Introduction

Anaemia is one of the world's leading causes of disability and it is one of the most serious public health hazards.[1] Anaemia refers to a state wherein the level of haemoglobin in the blood is below the reference range appropriate for that particular age and sex.[2]

Nutritional anaemia being the most common variant worldwide, can be described as a disease syndrome caused by malnutrition.[3] It is found more commonly among women of childbearing age, children and during pregnancy and lactation. Nearly two-thirds of pregnant and one-half of non-pregnant women from the developing countries are seen to be affected by some form of nutritional anaemia.[4]

The developed countries though less affected, are not completely free of anaemia, and a significant percentage of women of child-bearing age i.e. about 4-12% suffer from anemia.[5] Globally, nutritional anaemia affects nearly half of pregnant women, with iron deficiency being recognized as the most common nutritional deficiency among women of childbearing age, in both developed and developing countries.[1,6] It is one of the major contributing factors in maternal morbidity and mortality in third world countries and according to the WHO, it contributes to 20% of the total maternal deaths.[7]

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In India, about 20-40% of maternal deaths are due to anaemia. It is estimated that one in every two women in our country suffers from some form of anaemia.[8] The prevalence of anaemia in pregnancy in India as per the National Family Health Survey (NFHS)-3 findings is 55.3%, with a prevalence of 57.4% and 50.9% in rural and urban areas respectively.[9–11]

The WHO proposes that "anaemia deficiency should be considered to exist" when the haemoglobin is below the following levels.[12,13]

Table 1: Hb levels for anaemia

Age/sex	Hb-g/dl (venous blood)	MCHC (percent)
Adult males	13	34
Adult females (non-pregnant)	12	34
Adult females (pregnant)	11	34
Children, 6 months to 6 Years	11	34
Children, 6 to 14 years	12	34

The normal MCHC should be 34 irrespective of the age group, any value below being considered abnormal.[14,15]

2. Methodology

A hospital-based, randomized, comparative study was conducted on all antenatal women attending Department of Obstetrics and Gynecology, Shri Sathya Sai Medical College and Hospital were studied over 18 months. Based on the previous study[14] the proportion of iron sucrose and ferric carboxymaltose groups are 86% and 14%, using 5% level of significance, 80% power. The total sample size is 100 antenatal women, 50 in each group. The Study was conducted after obtaining ethical clearance from IEC. Patients will be selected according to inclusion and exclusion criteria.

2.1. Inclusion criteria

All Antenatal women with iron deficiency anaemia with Hb 6-10gm and peripheral smear suggestive of iron deficiency anaemia.

1. Gestational age 16-35 weeks.
2. Age group between 18-35years.

2.2. Exclusion criteria

1. History of parenteral iron intolerance
2. Chronic Kidney disease
3. Haematological disorder
4. Vitamin B12 and folate deficiency
5. Deep vein thrombosis, thrombocytosis
6. Having Thalassemia or sickle cell disease
7. H/o recent blood transfusion

The study protocol comprised the following activities:

1. Screening
2. Consent
3. Measurement of pre-treatment Hemoglobin and calculation of total required dose of iron
4. Randomization
5. Administration of the Intervention
6. Measurement of post-treatment (3 weeks Hemoglobin

2.3. Randomisation

Randomisation was done by computer-generated random numbers assigning patients to both groups-iron sucrose or iron carboxymaltose group.

2.4. Intervention

Ferric Carboxymaltose was given as per the total required dose in normal saline infusion as follows:

Iv drip infusion: Dilute in 0 9% sodium chloride / 500 to 1000mg: 250 ml NS - 15 min duration

Not exceeding the maximum dose of 1000 mg /day/ week.

Iron sucrose was given in a dose of 200 mg intravenously in 100ml normalsaline over a period of 15-20 min on alternate days until the required total dose was administered; to the maximum dose of 600 mg/week.

Ganzoni formula:

Deficit = (Target hb{12gm/dl} -Hemoglobin of the patient) × 2.4 × Weight in kg (pre pregnancy) + 1000 (storage).

Follow up

They were followed up after three weeks, for haemoglobin estimation to note the rise in haemogloin values.

3. Results and Observations

Table 2: Distribution of patients according to the severity of anemia

Hb level	No. of cases	Percentage
Mild anemia	7	7.0
Moderate anemia	93	93.0
Total	100	100.0

Table 2 is showing 93% of patients were belongs to moderate anaemia.

Table 3 is showing 59.0% of anemic patients were belongs to the age group of 2-24 years, in that 52.0% of cases were moderate anemia and 7.0% of were mild anemia.

Table 4 is showing 43.0% of anemic patients were belongs to upper middle class and 57.0% of patients were

Table 3: Correlation between age and severity of anemia

Age (years)	Moderate anemia	Mild anemia	No. of cases	Percentage
<20	3	-	3	3.0
20-24	52	7	59	59.0
25-29	26	1	27	27.0
30-34	11	-	11	11.0
Total	92	8	100	100.0

Table 4: Correlation between socioeconomic status and severity of anemia

SES	Moderate anemia	Mild anemia	Total no cases	%
Upper middle class	39	4	43	43.0
Lower middle class	53	4	57	57.0
Total	92	8	100	100.0
Chi-Square Test & P-value		$\chi^2 = 0.175$,	P = 0.932,	NS

belongs to the lower middle class, so according to our study anemia patients were more common in the lower middle class.

Table 5 is showing that anemia was more common in multigravida patients, that were 61.0% and 39.0% patients were primi gravida.

Table 6 shows that 63.0% of anemic patients were in the gestational age group of 22-28 weeks because of hemodiluation.

Study observed that, majority of the cases 93 (93.0%) were belongs to the moderate (7-9%) Hb% level and 7 (7.0%) were belongs to the mild Hb% level. There was no statistical significant difference of Hb% level between the groups FCM and Iron sucrose (P>0.05).

Study reveals that, there was no statistical significant difference of adverse effects between the groups of FCM and Iron Sucrose (P>0.05).

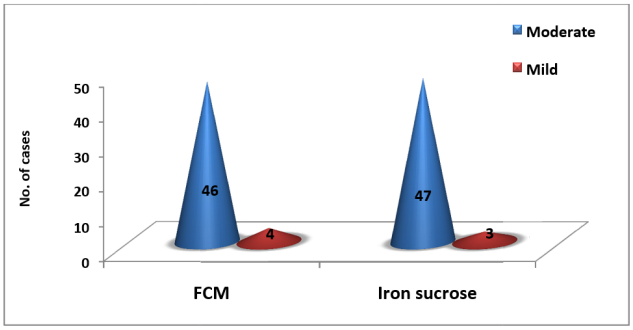

Fig. 1: Multiple bar diagram represents Hb% level wise distribution of cases

Study reveals that, there was statistically very highly significant difference of mean Hb% level before and after the treatment in FCM and Iron sucrose groups respectively (P<0.001).

After the treatment the mean HB% level has significantly increased in both the groups, therefore the treatment was effective in both the groups (P<0.001). But FCM group showed more increase the Hb% level as compare to Iron sucrose group.

4. Discussion

Nutritional anemia in pregnancy is a public health problem especially in developing countries and the commonest is iron deficiency anemia. Anemia in pregnancy is significantly associated with both fetal and maternal morbidity. Rapid improvement of Hb and iron stores in pregnancy will improve the general health status of the patient and decrease complications.

The patients in our study belonged to the age group of 18-35 years. The Majority of them were of the age group of 19-24 years in both study groups. The mean age was found to be slightly lesser in our study (24.8±4.4 and 24.5±3.1 years) when compared to other studies such as Christoph P et al.[12] (29 and 29.9 years) and Patel J et al.,[13] (29,1±2.4 and 28.4±3.7 yrs). This might suggest early marriage and pregnancy in patients in our study. Other maternal data such as Obstetric Index and gestational age though showed slight variations in either group were not significant as in other studies. Mean body weight (48.6 kg and 49.7 kg) was also significantly lower in our study as compared to prior studies (73.1 and 69.3 kg) by Christoph et al.,[12] which suggests that patients in our study were poorly nourished.

Baseline Hb in our study was 7.8±1.2 g/dl in group 1 and 8.7±0.9g/dl in group 2, thus group 2 had anaemia to a slightly lesser degree. However, this did not account for bias as the patients received iron infusion depending on the dose calculated based on their respective Hb levels. The baseline Hb in other studies were slightly higher 9.7±0.9 and 9.5±4.9 g/dl in Christoph P et al., and 8.7±3.1 and 8.9±2.3 g/dl in Patel J et al.,.[12,13] This again suggests that our study population had slightly higher grades of anaemia and required more vigorous management. Serum ferritin levels were however comparable to other studies

Table 5: Correlation between gravidity and severity of anemia

Gravidity	Moderate anemia	Mild anemia	No of cases	%
Primi	33	6	39	39.0%
multi	59	2	61	61.0%
Total	92	8	100	100.0
Chi-Square Test & P-value		$\chi^2 = 4.73$,	P = 0.039, S	

Table 6: Correlation between gestational age and severity of anemia

Gestational agein weeks	Moderate anemia	Mild anemia	No. of cases	%
15-21	20	-	20	20.0
22-28	56	7	63	63.0
29-35	16	1	17	17.0
Total	92	8	100	100.0

Table 7: Distribution of cases according to Hb level

Hb% level	FCM		Iron sucrose		Total	
	No.	%	No.	%	No.	%
Moderate 7–9	46	92.0	47	94.0	93	93.0
Mild 9–10	4	8.0		6.0	7	7.0
Total	50	100.0	50	100.0	100	100.0
Mean ± SD	8.28 ± 1.16		8.26 ± 1.13		8.27 ± 1.14	
t-test value P-value	t = 0.023, P = 0.962, NS					

NS= Not significant, S= Significant, HS= Highly significant, VHS= Very highly significant

Table 8: Distribution of cases according to adverse effect

Adverse Effect	FCM		Iron sucrose		Total	
	No.	%	No.	%	No.	%
No Adverse effect	48	96.0	49	98.0	97	97.0
Rashes	1	2.0	1	2.0	2	2.0
Vomiting	1	2.0	0	0.0	1	1.0
Total	50	100.0	50	100.0	100	100.0
Chi-Square Test & P-value	$\chi^2_{yates} = 0.343$, P = 0.937, NS					

Table 9: Comparison of mean Hb% level before treatment and after 3 weeks treatment and also comparison between the groups

Groups	Before Treatment Mean ± SD	After Treatment Mean ± SD	Mean difference	Pairedt-test P- value & Significance
FCM	8.28 ± 0.39	10.62 ± 0.66	2.34	t = 31.97 P = 0.000, VHS
Iron sucrose	8.26 ± 0.34	9.57 ± 0.46	1.32	t = 24.77 P = 0.000, VHS
Mean difference	0.02	1.05	–	–
Unpaired t-Test	t = 0.69	t = 9.155	—	—-
P- value & Significance	P = 0.778 NS	P = 0.000 VHS	–	–

(12.8±29.1 mcg/L Christoph P et al.,) in group 1,11.2±7.9 mcg/L. Group 2 however owing to a lesser degree of anaemia had raised baseline serum ferritin levels (20.1±13.6 mcg/L versus 7±5.65 mcg/L in Christoph P et al.,).[12] Other iron parameters such as serum iron and TIBC were also significantly better in group 2(57.4 mcg/dl and 357.1 mcg/dl respectively).

The mean iron required in group 1 of the present study was significantly higher than group 2 (978.1 versus 882.8 mg). Likewise, the total iron infused was also more in group 1(966.7 versus 743.3mg).

Christoph P et al.[12] also showed similar differences in iron infused (933 versus 402 mg). Thus, our study population had iron deficiency and thus anaemia of higher severity.

In regards to the type of anaemia histologically, the majority of our patients had microcytic, hypochromic blood picture in both groups (65%) suggesting that majority had severe grades of iron deficiency.

The present comparative study investigated the efficacy and safety of FCM and iron sucrose in IDA of pregnancy. It was seen that both IV iron preparations were effective in treating IDA in pregnancy. FCM therapy efficiently increased Hb, at the end of 3 weeks following treatment. The Hb rise with FCM was 1.5±0.1g/dl at 3 weeks.

These results are in line with several other studies. A study by Christoph P et al.,[12] on 206 pregnant women with IDA showed a Hb increase of 1.5±1.1g/dl at the end of 3 weeks. A similar study by Pels A et al., in the Netherlands showed Hb increase of 2.3 g% in 3 weeks. Patel J et al.,[13] had Hb increase of 5.2 g/dl,15 days post treatment whereas the ferritin levels improved by 9.2 mcg/L.

Hb and ferritin values also improved after treatment with iron sucrose. Our study at the end of 3 weeks showed Hb increment of 0.7 -1.4 mg/dl. Christoph P et al.[12] showed similar rise in Hb of 1.1g/dl in 4 weeks, whereas Patel J et al.,[13] an Indian study, showed a rise of 3.7g/dl in 15 days. The ferritin increase in this previous Indian study was 9.2 mcg/L. Thus, in terms of efficiency, both FCM and iron sucrose showed improved results in our study as compared to several previous studies.

However, our study aimed to also compare the efficacy of FCM therapy to iron sucrose. At the end of 3 weeks, FCM showed significantly increased Hb and ferritin as compared to iron sucrose, post treatment.

Thus, our study shows, that FCM is well tolerated in pregnant women and has fewer number of side effects as compared to iron sucrose even when given as a large dose.

5. Conclusion

In conclusion, FCM not only offers a rapid correction of Hb levels but also provides replenishment of iron stores in the body, without major adverse effects. Thus, when used in pregnant women in their second or third trimesters the hazard of anaemia is not only tackled in pregnancy but might also be prevented in the post-partum period. At the end, we have a healthy mother with a healthy baby, which is a birth right of every woman. At the national level, this will tremendously reduce the burden of maternal morbidity and mortality and improve the quality of life. Hence, all the health care providers, hospital administration and the government should take measures to make FCM easily available and affordable to the women who are in actual need of it and make use of this boon to eradicate.

6. Source of Funding

None.

7. Conflict of Interest

None.

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