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Original Research Article

A comparative study of ferric carboxy maltose versus iron sucrose for iron deficiency anaemia in pregnancy

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ABSTRACT

Background: Anaemia is a major contributor to maternal morbidity and mortality worldwide. Ferric carboxy maltose is a novel iron preparation which can treat anaemia faster and more effectively. Thus, this study aimed to evaluate the efficacy and safety of FCM in pregnancy and also to compare the same with Iron sucrose in pregnancy.

Methods: This was a Prospective, Hospital based, Comparative study performed on 120 women who attended the department of obstetrics and gynaecology at KIMS, Hubli for a duration of one and a half years (2017-18). The patients received either FCM or Iron sucrose, with 60 participants in each group.

Results: Among 120 subjects, 75% of the patients had microcytic, hypochromic anaemia, 1.4% had dimorphic anaemia. 38.33% of patients had moderate anaemia (Hb 6-7.9g/dl). After FCM infusion, rise in Hb at 2 weeks was 1.5g/dl and at 4 weeks was 2.9 g/dl. Serum ferritin levels raised by 36.7 and 63.1 mcg/l at 2 and 4 weeks with FCM respectively. On comparison with Iron sucrose, the Hb rise was statistically better with FCM at 4 weeks, whereas the ferritin levels were significantly improved with FCM at both 2 and 4 weeks after treatment. Side effects in mild form occurred in 7.5% of the subjects.

Conclusions: FCM is a safe, effective alternative to other parenteral iron therapies, offering faster correction of anaemia and iron replenishment. Its use in pregnancy will significantly reduce the burden of maternal mortality and morbidity.

Keywords: Anaemia, Ferric carboxy maltose, Iron sucrose, Iron deficiency

INTRODUCTION

Anaemia is one of the world's leading cause of disability and it is one among 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, it can be described as a disease syndrome caused by malnutrition in its widest sense.³ It is found more commonly among women of child-bearing 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 anemia.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 anemia affects nearly half of the pregnant women, with iron deficiency being recognized as the most common nutritional deficiency among women of child-bearing age, in both developed and developing countries.^{1,6} It is one of the major contributing factors in maternal mortality and morbidity in the third world countries and according to the World Health Organization, it contributes to 20% of the total maternal deaths.⁷ 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. In Karnataka, as per the findings of National Family Health Survey (NFHS)-4, the prevalence of anaemia in pregnancy is 39.6% in urban areas and 48.7% in rural areas.^{9,10} Studies have found the median time to achieve anaemia correction to be shorter with FCM compared to Iron Sucrose (3.4 vs 4.3 weeks).¹¹⁻¹³ This study was conducted to compare the efficacy, safety and compliance of IV ferric carboxymaltose and iron sucrose in pregnant females with iron deficiency anaemia in the second and third trimester of pregnancy.

METHODS

This was a hospital-based, prospective, comparative study carried out over one and half years (January 2017 to July 2018) on pregnant women aged 18 yrs or above with gestational age between 20 weeks to 36 completed weeks admitted as inpatients in the department of Obstetrics and Gynaecology at Karnataka Institute of Medical Sciences, Hubli, with definitive diagnosis of iron deficiency anemia and with haemoglobin levels between 6 and 10g/dl. Using convenient sampling, the sample size was taken as 120 and the patients were randomly categorized to receive either iron sucrose or FCM with 60 subjects in each group. The study participants were briefed about the purpose of the study, the drugs, its effect and all possible adverse effects. Informed and written consent was taken. Maternal parameters including age, obstetric index, gestational age, body weight, severity of anemia (haemoglobin and serum ferritin levels), cumulative iron deficit and parenteral iron dose were collected from the inpatient medical records of the patient. Follow up was done at 2 weeks and 4 weeks post treatment and repeat haemoglobin and serum ferritin levels were recorded. Pregnant women having serious medical or surgical illness or with other types of anaemia excluding dimorphic anaemia, previous history of adverse reaction to parenteral iron or haemodynamically unstable were excluded from the study. Data collected was entered in Microsoft Excel and analyzed using SPSS software

version 22. The results of the study were analyzed using Student's t-test, Chi-square test and other tests of significance as applicable, $p < 0.05$ was taken as the significance level. Iron deficiency was diagnosed based on blood parameters: Serum Haemoglobin, peripheral smear, serum iron, serum total iron binding capacity and serum ferritin levels. Total dose of parenteral iron requirement was calculated on the basis of haemoglobin deficit and body weight using the Ganzoni formula:

$$\begin{aligned} \text{Cumulative iron deficit (mg)} \\ &= \text{body weight (kg)} * \text{target Hb} \\ &- \text{actual Hb g/dl} * 2.4 \\ &+ \text{iron storage depot (500mg)}. \end{aligned}$$

Iron sucrose was administered as slow IV infusion: 200 mg iron sucrose diluted in 200 ml of normal saline (0.9%) as the maximum dose in a single infusion over 30 minutes and was repeated on alternate days as per the requirement. Ferric carboxy maltose was infused as slow IV infusion: maximum single dose of 1000mg (15mg/kg) diluted in 250 ml of normal saline (0.9%) over 15 minutes not more than once a week. Pulse, blood pressure and foetal heart rate were monitored at 5 minutes intervals with FCM and 15 minutes intervals with Iron sucrose and noted during each infusion. Adverse effects which occurred were managed accordingly and noted. Post treatment, serum Hb and ferritin levels were reassessed. The end point of treatment with iron sucrose was taken as the date when she received her last dose.

RESULTS

A total of 120 patients participated in the study. After being diagnosed with IDA patients were randomly categorized to receive FCM-Group 1 or Iron Sucrose-Group 2. There were 60 participants in each study group. 7.5 % of the patients were lost for follow up at the end of 4 weeks. The (Table 1) shows that majority of the women belonged to the age group of 19 to 24 years, with an average of 53.3% and 51.7% in either group respectively. Both the study groups were comparable in terms of age distribution.

Table 1: Age distribution of study participants.

Age category (years)	Group-1 (N=60)		Group-2 (N=60)		P value
	Frequency	%	Frequency	%	
19-24	32	53.3	31	51.7	0.85
25-35	28	46.7	29	48.3	

P value based on Chi-square test

Table 2: Obstetric Index of study participants.

Gravida	Group-1 (N=60)		Group-2 (N=60)		P value
	Frequency	%	Frequency	%	
Primi	27	45	21	35	0.08
Gravida 2	11	18.3	22	36.7	
Gravida 3 and above	22	36.7	17	28.3	

P value based on Chi-square test

Table 3: Gestational age of study participants.

Gestational age (weeks)	Group-1 (N=60)		Group-2 (N=60)		P value
	Frequency	%	Frequency	%	
<30	27	45	31	51.7	0.46
>30	33	55	29	48.3	

P value based on Chi-square test

The (Table 2) shows the parity-wise distribution. In group, 1 it was seen that majority of the patients were primigravidae (45%), followed by Gravida 3 and above (36.7%). Whereas, in group 2, Gravida 2 occupied the majority (36.7%) followed by primigravidae (35%). On comparing either group, there were no statistically significant differences in terms of Obstetric Index.

Table 4: Age and baseline weight of study participants.

Parameter	Group-1 (N=60)		Group-2 (N=60)		P value
	Mean	SD	Mean	SD	
Age (years)	24.8	4.4	24.5	3.1	0.62
Weight (kg)	48.6	6.9	49.7	6.4	0.39

P value based on t test.

Table 5: Pre-transfusion iron parameters of study participants.

Parameter	Group-1 (N=57)		Group-2 (N=57)		P value
	Mean	SD	Mean	SD	
Ferritin (mcg/l)	11.2	7.9	20.1	13.6	0.001*
Iron (mcg%)	49.6	12.2	57.4	6.2	0.001*
TIBC (mcg%)	414	74.2	357.1	47.8	0.001*

P value based on t test, *statistically significant (p<0.05).

As shown in (Table 3), 55% of the patients belonging to group 1, had gestational age more than 30 weeks (30 weeks+1 day and above). On the contrary most of the patients in group 2 were of gestational age of less than 30 weeks (51.7%). There was no statistically significant difference (p=0.46) on comparing gestational age of both groups. The (Table 4) shows the age and baseline body weight comparison of the participants in either group. Both the groups showed comparable mean age (24.8 years and 24.5 years) as well as mean body weight (48.6 kg and 49.7 kg).

The (Table 5) depicts the pretransfusion blood parameters used to diagnose iron deficiency, namely serum ferritin, serum iron and serum TIBC. All the three parameters showed statistically significant differences between the two groups, with group 2 showing slightly improved values. As seen in Table 5 mean serum iron was lesser in group 1 (49.6 versus 57.4 mcg/dl). TIBC levels were

higher in group 1 as compared to group 2 (414 versus 357.1 mcg/dl). The baseline Hb levels in either group also showed a statistically significant difference (p value of 0.001). The mean Hb levels were higher in group 2 by 0.9 g/dl. MCHC type of anaemia was the most common in both the groups (63.5 and 61.7%) respectively. This was followed by NCNC (25 and 33.3% respectively) and Dimorphic (DM) anaemia (11.7 and 5% respectively).

Table 6: Iron required and infused for study participants.

Parameter	Group-1 (N=60)		Group-2 (N=60)		P value
	Mean	SD	Mean	SD	
Iron required (mg)	978.1	140	882.8	103.9	0.001*
Iron transfused (mg)	966.7	125.7	743.3	188.1	0.001*

P value based on t test, *statistically significant (p<0.05).

Table 7: Hb level at various time points of study participants.

Parameters	Group-1		Group-2		P value
	Mean	SD	Mean	SD	
Baseline	7.8	1.2	8.7	0.9	0.001*
At 2 wks	9.3	1.3	9.4	0.9	0.65
At 4 wks	10.7	1.4	10.1	0.8	0.004*

P value based on t test, *statistically significant (p<0.05).

As shown in (Table 6), participants in group 1 were seen to have an average iron requirement of 978.1mg whereas the average dosage of iron infused was 966.7 mg. In group 2, the average iron requirement was slightly lesser, i.e., 882.8 mg, and the patients in this group received an average dose of 743.3 mg of iron as infusion. So, the patients in group 2 received about 139.5 mg lesser iron than the calculated dosage.

As shown in (Tables 7-9), following treatment, Hb and Ferritin levels significantly improved in both groups. The mean Hb increase after FCM infusion at 2 weeks post treatment was 1.5 g/dl, whereas at the end of 4 weeks post treatment the mean Hb increased by 2.9 g/dl (from 7.8 to 10.7 g/dl in 4 weeks). The mean Hb after iron sucrose infusion increased from 8.7 g/dl to 9.4 g/dl at the end of 2 weeks of treatment (mean Hb rise of 0.7g/dl). After 4 weeks of infusion the mean Hb levels were 10.1g/dl (mean rise of 1.4g/dl in 4 weeks).

Table 8: Iron parameters before and after treatment of Group-1 participants.

Parameter	Baseline		At 2 wks		At 4 wks		P value
	Mean	SD	Mean	SD	Mean	SD	
Hb	7.8	1.2	8.7	0.9	10.3	1.4	0.001*
Ferritin	10.8	8.1	48.0	14.6	70.2	17.1	0.001*

P value based on repeated measures ANOVA test, *statistically significant ($p < 0.05$).

Table 9: Iron parameters before and after treatment of Group-2 participants.

Parameter	Baseline		At 2 wks		At 4 wks		P value
	Mean	SD	Mean	SD	Mean	SD	
Hb	8.7	0.9	9.0	0.9	9.7	0.9	0.001*
Ferritin	19.7	13.6	31.1	12.8	45.8	12.0	0.001*

P value based on repeated measures ANOVA test, *statistically significant ($p < 0.05$).

Table 10: Ferritin level at various time points of study participants.

Parameter	Group-1		Group-2		P value
	Mean	SD	Mean	SD	
Baseline	11.2	7.9	20.1	13.6	0.001*
At 2 wks	47.9	14.5	31.1	12.7	0.001*
At 4 wks	74.3	13.6	46.2	11.9	0.001*

P value based on t test, *statistically significant ($p < 0.05$).

It was seen that at 2 weeks post treatment the mean Hb did not show a statistically significant difference (p value of 0.65). However, the mean Hb at 4 weeks post treatment when compared in both groups, there was a statistically significant difference (p value of 0.004), implying that patients in group 1 had more increase in mean Hb after 4 weeks.

The (Table 10) shows the comparison of serum ferritin levels at 2 and 4 weeks post treatment. It was seen that serum ferritin levels showed a significant increase in group 1 as compared to group 2 (p value of 0.001), both at 2 weeks and 4 weeks post infusion. This shows that group 1 patients had better improvement in ferritin levels than group 2 patients. Ferritin levels increased by a mean of 36.7mcg/l and 63.1mcg/l at 2 and 4 weeks respectively. The increase in serum ferritin levels after iron sucrose treatment was 11mcg/l and 26.1 mcg/l at the end of 2 and 4 weeks respectively. It was seen that patients in group 1 showed a significantly higher improvement in ferritin levels both at 2 and 4 weeks when compared to patients in group 2 (p value of 0.001).

Among 60 participants in group 1, 2 patients complained of mild side effects whereas in group 2, 7 amongst 60 participants had minor side effects. This difference was however, not statistically significant. In the FCM group 96.66% of patients showed no side effects whereas in the Iron sucrose group, 88.33% patients had no side effects. Overall, 7.5% of the study population had some kind of side effects. 2 participants from each group received additional treatment for anaemia. Two patients in group 1 also received blood in addition to FCM and two in group 2 received injection vitamin B12.

DISCUSSION

Being a tertiary care centre, the influx of pregnant women attending the department of OBG with different causes and grades of anaemia was naturally very high and almost every 2nd pregnant woman attending the ANC clinic was found to clinically have some amount of pallor. On history and examination, almost 90% of these women had inadequate dietary intake, thus making nutritional anaemia the most common cause. Local food habits which were lacking in foods rich in iron, folate and vitamin B12, might have been the root cause for this. After diagnosis of anaemia in the outpatient department, patients were counselled regarding the need for either oral or parenteral iron therapy, as well as blood transfusion, depending on the type and severity of anaemia. It was observed that pregnant women and their kin were generally hesitant for blood transfusion and required further counselling about the risks of not treating severe anaemia. Patients who required parenteral iron infusion were given admission and further investigations obtained. Those diagnosed with IDA were recruited into the study after informed, valid and written consent. A total of 60 participants each entered the study in each group. Group 1 received injection FCM infusion as a single dose. Group 2 received iron sucrose infusions of 200mg each on alternate days till the required dose was reached. In group 1, 3 patients were lost for follow up both at 2 and 4 weeks and 1 patient did not follow up at 4 weeks. In group 2, 5 patients did not follow up at both 2 and 4 weeks. Thus, the actual number of patients at the completion of the study were 56 in group 1 and 55 in group 2, with 9 (7.5%) being lost for follow up. The patients in our study belonged to the age group of 19-35 years.

Table 11: Results of several similar comparative studies of Hb:FCM versus iron sucrose.

Name	Hb FCM		Hb rise	Hb IS		Hb rise IS	Follow up duration	P value
	Pre	Post	FCM	Pre	Post			
Present study	7.8±1.2	10.7±1.4	2.9±0.2	8.7±0.9	10.1	1.4	4 weeks	0.004*
Christoph et al¹⁴	9.8±1.09	11.13±1.2	1.54±1.1	9.56±1.2	11.04±1.1	1.17	4-6 weeks	0.08
Patel et al¹⁵	7.5±3	12.7±2.4	5.2	7.9±2.7	11.6±1.3	3.7	15 days	0.04*
Mishra et al¹⁷	8.97±1.05	11.34±0.9	2.37	-	-	-	3 weeks	<0.001*
Pels et al¹⁶	8.4	10.7	2.3	-	-	-	4 weeks	NA
Froessler et al¹⁸	9	11.5	2.5	-	-	-	6 weeks	<0.001
Rodrigues et al¹⁹	8.5	11	2.5	-	-	-	4-6 weeks	<0.05*

*statistically significant

Table 12: Results of several similar comparative studies of ferritin:FCM versus iron sucrose.

Name of study	Pre-ferritin FCM	Post- ferritin FCM	Ferritin rise FCM	Pre-ferritin IS	Postferritin IS	Ferritin rise IS	Followup duration	P value
Present study	11.2±7.9	74.3±13.6	63.1	20.1±13.6	46.2±11.9	26.1	4 weeks	0.001*
Patel et al¹⁵	11.4±6.7	20.6±3.8	9.2	10.9±7.8	20.1±3.4	9.2	15 days	NS
Mishra et al¹⁷	18.30±16.39	104.10±32.46	86	-	-	-	3 weeks	<0.001*
Froessler et al¹⁸	6.5	194	187.5	-	-	-	6 weeks	<0.05*

*Statistically significant

Majority of them were of the age group of 19-24 years in both the study groups. The mean age was found to be slightly lesser in our study (24.8±4.4 and 24.5±3.1 yrs) when compared to other studies such as Christoph et al (29 and 29.9 yrs) and Patel et al (29.1±2.4 and 28.4±3.7 yrs).^{14,15} 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 which suggests that patients in our study were poorly nourished.^{14,15}

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 anemia to a slightly lesser degree. However, this did not account for bias as the patients received iron infusion depending on 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 et al and 8.7±3.1 and 8.9±2.3 g/dl in Patel et al.^{14,15} 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 (12.8±29.1 mcg/l Christoph et al) in group 1, 11.2±7.9 mcg/l. Group 2 however owing to lesser degree of anemia had raised baseline serum ferritin levels (20.1±13.6 mcg/l versus 7±5.65 mcg/l in Christoph et al).¹⁴ 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 et al also showed similar differences in iron infused (933 versus 402 mg).¹⁴ Thus our study population had iron deficiency and thus anaemia of higher severity as compared to other studies conducted both in India and other countries. In regards to the type of anaemia histologically, majority of our patients had microcytic, hypochromic blood picture in both groups (65%) suggesting that majority had severe grades of iron deficiency. Dimorphic anemia was only seen in 10 % of our population contrary to the findings in general where dimorphic anemia is the most common variant.

Efficacy

The present comparative study investigated the efficacy and safety of FCM and iron sucrose in IDA of pregnancy. It was seen that both the IV iron preparations were effective in treating IDA in pregnancy. FCM therapy efficiently increased Hb as well as serum ferritin at the end of both 2- and 4-weeks following treatment. The Hb rise with FCM was 1.5±0.1g/dl at 2 weeks and 2.9±0.2g/dl at 4 weeks in our study. Similarly, serum ferritin levels also significantly improved after FCM, with an increase of 36.7 and 63.1 mcg/l at 2 and 4 weeks respectively. These results are in line with several other studies. A study by Christoph

et al on 206 pregnant women with IDA showed a Hb increase of 1.5 ± 1.1 g/dl at the end of 4 weeks.¹⁴ A similar study by Pels et al in the Netherlands showed Hb increase of 2.3 g% in 4 weeks.¹⁶ Patel et al had Hb increase of 5.2 g/dl, 15 days post treatment whereas the ferritin levels improved by 9.2 mcg/l.¹⁵

Hb and ferritin values also improved after treatment with iron sucrose. Our study at the end of 2 and 4 weeks showed Hb increment of 0.7 and 1.4 mg/dl and a ferritin increment of 11 and 26.1 mcg/l respectively. Christoph et al showed similar rise in Hb of 1.1 g/dl in 4 weeks, whereas Patel et al an Indian study, showed a rise of 3.7 g/dl in 15 days.^{14,15} The ferritin increase in this previous Indian study was 9.2 mcg/l.¹⁵ 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 2 weeks, the present study did not show a significant difference in rise of Hb levels between both groups. FCM showed significantly increased Hb as compared to iron sucrose, at 4 weeks post treatment. But the ferritin levels showed significant increase with FCM as compared to iron sucrose after 2 weeks as well as 4 weeks.

In the present study, two patients who received FCM also required additional blood transfusion and two patients who received iron sucrose also received vitamin B12 injections. Hence 3.3% of patients in each group have benefited from additional therapy for anaemia.

Compliance

The main disadvantage with iron sucrose is that it takes multiple injections of smaller doses and hence the duration of treatment is prolonged. Hence, adherence to complete treatment cannot be guaranteed. As expected, our study showed that 5 % of the patients who were treated with iron sucrose did not continue after the 2nd dose and 65 % and 13 % did not keep up appointments for scheduled injections after the 3rd and 4th dose respectively. Thus only 37 % of the patients received the required dose of iron and completed their treatment. Whereas in the FCM group, 4 patients failed to receive adequate dose as they were given injections from vials containing 500 mg and they failed to come for the second dose.

This was because FCM was available as only 1000 and 500 mg per vial and 4 patients had to be given 500 mg as 1000 mg vials were unavailable at the time of their treatment. Hence 93.3% of participants received adequate dose of FCM. Thus, iron sucrose therapy showed poor compliance as compared to FCM in our study. Hence, this study like other studies, suggest that the rapid delivery of a large, single dose of FCM is a promising treatment option for pregnant women who need correction of iron deficiency and anaemia, over other parenteral iron formulations, that have limits of low and multiple dosages.

Safety

Hypersensitivity reactions, including some fatal events are seen to occur to some extent with all IV iron formulations.²⁰ Hence it is essential for standard warning texts to be included in all the prescribing information of all these preparations. It is also necessary to monitor patients for signs and symptoms of hypersensitivity during and after IV iron administration for at least 30 minutes. In addition, such agents should be administered only when personnel and emergency drugs for the treatment of hypersensitivity reactions are immediately available.²⁰ The present study was done abiding to all these precautions. In two primary FCM trials of 750 mg, serious anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of patients receiving FCM and 0.1% (1/1783) of subjects receiving a comparator.²¹ So far, in all the previous studies only a single case of fatality has been reported with FCM.²² In the current study, hypersensitivity reactions with FCM was 1.6% (1/60) whereas with iron sucrose it was 11.6% (7/60). This difference could be due to the smaller sample size as compared to the previous FCM trials. These reactions were managed with anti-allergy medications and supportive therapy. There were no serious adverse events. Injection site reactions were not observed, as seen with several other studies like Christoph et al and Patel et al (2.9%/2.9% and 13%/30%).^{14,15}

The maternal vital parameters such as pulse rate and systolic and diastolic blood pressure, showed a statistically significant variation before and after therapy with both FCM and iron sucrose in the present study, as opposed to other prior studies.^{14,15} This can be explained as being due to the larger sample size and standard deviation changes. The same applied to the foetal heart rate before and after therapy. However, no detrimental effects were observed due to these changes in both the mother and the foetus in both groups. The use of FCM for anaemia in postpartum period and its safety, has been studied extensively in previous studies. These showed no safety concerns in breastfed infants of mothers who received FCM.²³ Hence, though the patients were not followed up till delivery and postpartum and thereafter, the likelihood of serious adverse effects on the newborn is negligible, based on older studies. Thus, this 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.

Limitations

Limitations were though our study showed no detrimental effects on the foetus while used in the second and third trimesters, large scale RCTs are needed to further evaluate the longterm effects of FCM on the foetus.

CONCLUSION

Even if provided with a whole armamentarium to treat iron deficiency, it is seen that due to reasons that can be totally

overcome, utilization of these solutions in developing countries is not even half of expected. IDA is preventable by proper communication and awareness about antenatal care and nutrition. Our study like several other similar ones, proves that FCM is a simple, effective and safe alternative to several other iron preparations that are being used till date, be it oral or parenteral iron. Iron sucrose of course has the advantage of being easily available and being less expensive. But the cost effectiveness of FCM overshadows this. In our study FCM was well accepted by the patients. There were no serious adverse events and even those which occurred, were of mild nature. Treating patients with iron sucrose left us uncertain as to whether the woman will be returning to receive her next required dose or not. Especially in a country like ours, where the likelihood of a woman, pregnant or otherwise receiving essential treatment depends on various factors and people surrounding her, FCM appears to be the perfect one step solution for anaemia, being as simple as a vaccination. 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 anaemia.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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