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Comparative Study of IV FCM and Iron Sucrose to Assess Efficacy, Cost-Effectiveness, and Compliance in Iron-Deficiency Postpartum Anaemia Patients



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ABSTRACT

Background: Iron deficiency anemia is common among post partum patients. Postpartum anemia may lead to postpartum depression, stress, anxiety and cognitive impairment. Adequate treatment of anemia in postpartum period will have improved life quality in women in child bearing age so this study was designed with the objective to compare the FCM and Iron sucrose to assess its efficacy, cost effectiveness and compliance in the Iron deficiency anaemia in post partum women. **Material and method:** 80 patients of post partum anaemia patients were included in study and divided into 2 groups. Group A received Iron sucrose and Group B received FCM and monitored for 4 weeks. **Results:** The results show that the FCM had more increase in level of Hb, more cost effective and compliance to medication as compared with the Iron sucrose group of patients. **Conclusion:** FCM is more effective, safe and cost-effective as compared to Iron Sucrose preparation in post partum iron deficiency anaemia women.

INTRODUCTION

Anemia affects more than 2 billion people globally, accounting for over 30% of the world's population which is the most common public health problem particularly in developing countries occurring at all stages of the life cycle. [1,2] Changes in the red cell indices is the good indicator of iron deficiency.[3] Mean cell volume (MCV), Mean cell hemoglobin (MCH), and mean cell hemoglobin concentration are all reduced. Iron deficiency anemia is managed by oral iron, intramuscular iron, intravenous iron, and blood transfusion depending on the severity of anemia.[4-7] Intravenous iron preparations have been used for treating IDA, with promising result and avoiding blood transfusion as well as side effects of the oral iron preparation. During transfusion the patient should be continuously monitored by blood pressure, pulse rate and for any adverse reactions.[8] Both IS and FCM require special care and close monitoring in administration, hence all of the recruited patients purchased parenteral iron supplement. Treatment with iron preparations is used routinely in pregnancy.[9] However, oral iron supplementation often leads to adverse side effects, such as constipation, abdominal pain and other gastrointestinal symptoms. Several study [10-12] shows the significant increase in Hb and serum ferritin were observed in all three groups but the increase in FCM group was significantly higher ($p < 0.00001$) than conventional iron sucrose and oral iron group. Patel et al also shows the Ferric carboxymaltose is associated with fewer side effects as compared to iron sucrose in postpartum women.[13] In the current study the efficacy, compliance and cost effectiveness was measure between IV FCM and Iron Sucrose in post natal women.

MATERIAL AND METHODS

The study was performed in 80 post natal women suffered from Iron deficiency anemia. One group of 40 patients received iron sucrose while the other 40 patients received Ferric carboxymaltose. The patients deficient with iron and with Hb level 8-10 gm were included and those patients were excluded having allergic to iron, chronic kidney disease, anaemia due to other cause, bronchial asthma, heart disease. Iron sucrose of 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. FCM was given by IV injection according to the iron dose calculated and rounded up to the nearest multiple of 100 for each individual. Cost Effective Analysis: Cost effectiveness of the both was calculated by considering resource expenditure on medication, nursing and bed in hospital was compared in both group. Compliance

Analysis: The compliance of medication in both group of patients was observed. Adverse Monitoring was reported in both groups. In this study the data was collected, assembled, analyzed, tested individually. To compare the means of parameters of both the groups, independent Student t test was performed. A 95% limit and 5% level of significance were adopted.

RESULTS

In the study, the total 80 patients of data were collected and compared with both the group of patients. The age group distribution observed in the Iron sucrose was maximum in 25-29 years of patients (47%), 20-24 having 11 patients (28%) and 30-34 having 9 patients (22%) while in the group B the patients receiving FCM drug the age of 25- 29 is maximum having (50%), 30- 34 age group observed 10 patients (25%) and 20-24 was 9 patients (22%) as shown in table 1.

Table 1: Age distribution in Iron Sucrose group A and FCM group B

Age (years)	Group A No (%)	Group B No (%)
15-19	00 (00)	01 (3)
20-24	11 (28)	9 (22)
25-29	19(47)	20 (50)
30-34	9 (22)	10(25)
35-39	1(3)	0
Total	40	40
Mean ± SD (years)	24.56 ± 3.53	25.58 ± 3.70
Statistical inference	t= 1.4792, p= 0.142 (not significant)	

Mean age was similar and not significantly different (p= 0.142).

The dose requirement in both the group was noted is not much difference in Iron sucrose was required 936.73mg while in FCM was 937.94mg as shown in table 2.

Table 2: Dose Requirement for Iron Sucrose & FCM

	IRON SUCROSE	FCM
DOSE	936.73	937.94

Haemoglobin increase in FCM group is faster and greater. The haemoglobin increase is about 10.92 at 4 weeks in iron sucrose group from baseline value of 8.57g where as in FCM group Hb increase is about 11.37 from 8.54 as mentioned in table 3.

Table 3 Comparison of Hb in Iron Sucrose and FCM in post natal anaemic patients

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

No serious side effects were reported in any group. Mild adverse effects like nausea, vomiting, diarrhea, constipation etc. were observed in 67% patients in Group A, and 42% patients in Group B. Adverse reactions following both groups were milder as shown in table 4.

Table 4: Comparison of adverse effect in Iron sucrose group A and FCM group B

Adverse drug reactions	Group A No (%)	Group B No (%)
Diarrhea	2(5)	2(5)
Nausea	2(5)	1(2.5)
Constipation	4(10)	3(7)
Abdominal pain	2(5)	0
Injection site reactions	4(10)	1(2.5)
Headache	6(15)	3(7)
Dysgeusia	2(5)	0
Skin discoloration	2(5)	6(15)
Vomiting	3(7)	1(3)
Hypersensitivity reaction	0	0
Hypertension	0	0
Hot flushing	0	0
Hypotension	0	0
Total	27(67%)	17(42%)

The cost of the Iron sucrose and FC treated group were compared as the total cost shows less

in FCM group of patients as compared with the Iron sucrose group.

Table 5: Comparison of cost-effectiveness in Iron Sucrose and FCM in patients

		Ferric carboxymaltose (n=40)	Iron sucrose (n = 40)	p value
Medication cost	Mean ± SD	720.20 ± 228.80	110.52 ± 56.81	0.0001
	95% CI	(697.60–742.81)	(104.69–116.35)	
	Median (IQR)	800.00 (400.00)	104.00 (65.00)	
Bed cost	Mean ± SD	90.86 ± 34.30	399.40 ± 194.66	0.0001
	95% CI	(87.47–94.25)	(379.42–419.38)	
	Median (IQR)	70.00 (70.00)	350.00 (350.00)	
Nursing cost	Mean ± SD	104.43 ± 33.18	492.53 ± 253.34	0.0001
	95% CI	(101.15–107.71)	(466.58–518.50)	
	Median (IQR)	116.00 (58.00)	464.00 (290.00)	
Total cost	Mean ± SD	915.49 ± 280.18	1002.99 ± 473.03	0.0001
	95% CI	(887.58–943.17)	(954.44–1051.55)	
	Median (IQR)	986.00 (528.00)	989.00 (633.00)	

The patients receiving the FCM (98%) were more compliance to the drug as compared with the Group A received the Iron Sucrose (87%). the frequency of administered of Iron sucrose was more as compared with FCM administration and patients discomfort leads to the less compliance in Group A Iron sucrose patients compared with FCM patients.

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 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.[14] Ferric carboxymaltose is non-dextran iron complex that consists of a ferric hydroxide core stabilized by a carbohydrate shell. [15] The design of the macromolecular ferric hydroxide carbohydrate complex permits guarded delivery of iron to the cells of the reticuloendothelial system and subsequent delivery to the iron-binding

proteins, ferritin and transferrin, with negligible risk of large amounts of ionic iron being released into the serum.

Giannoulis et al reported increase of hemoglobin by 4-6 gm/dl in patients receiving iron sucrose. Setu Rathod et al has showed increased in hemoglobin of 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. [16,17]

Seid 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.[18] Christian breymann et al serum ferritin from 39.9 ng/ml from baseline to 568.2 91 ng/ml at week 1, 161.2ng/ml at 12 weeks ($p<0.001$ 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. [19]

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%. Mild adverse effects like nausea, vomiting, diarrhea, constipation etc were observed in 67% patients in Group A, and 42% patients in Group B.

CONCLUSION

This study 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 thus reduces the cost of hospital stay in FCM patients. The quality of life is also better with FCM group shows greater compliance. 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 the treatment of postnatal iron deficiency anemia.

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