



A COMPARITIVE STUDY OF FERRIC CARBOXY MALTOSE VERSUS IRON SUCROSE FOR ANEMIA IN PREGNANCY

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ABSTRACT

A comparative study of ferric carboxymaltose versus iron Sucrose for anemia in pregnancy

AIMS & OBJECTIVES: To assess and compare the efficacy, safety and compliance of IV ferric carboxy maltose and iron sucrose in pregnant females with iron deficiency anemia.

MATERIALS & METHODS:

INCLUSION CRITERIA: Pregnant women more than 18 years of age with definitive diagnosis of iron deficiency anemia with haemoglobin level 6-10g/dl

EXCLUSION CRITERIA: Women who don't want to participate, Women with serious medical and surgical illness, Women with other causes of anemia (excluding dimorphic anemia) & Women with previous h/o reactions to parenteral iron & Women who are hemodynamically unstable.

RESULTS: Among 70 subjects, 70% had microcytic hypochromic anemia, 0.9% had dimorphic anemia, 35.64% had moderate anemia (Hb 6.7-9g/dl). Serum ferritin levels raised by 33.1% & 60.2% respectively at 2 and 4 weeks with FCM.

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 & 4 weeks after treatment. Side effects in mild form occurred in 6.2% of the subjects.

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

KEYWORDS :

INTRODUCTION

- Anemia is one of the world's leading cause of disability and it is one among the most serious public health hazards(1).
- Anemia 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 in its widest sense(3). It is found more commonly among women of child-bearing age, during pregnancy and lactation.
- It is one of the major contributing factors in maternal mortality and morbidity in the third world countries & according to WHO, it contributes to 20% of the total maternal deaths(4).
- The WHO proposes that "anaemia or deficiency should be considered to exist" when the haemoglobin is below the following levels(3).

| AGE/ SEX | g/dl (venous blood) | MCHC (percent) |
|-------------------------------|---------------------|----------------|
| Adult females(non-pregnant) | 13 | 34 |
| Adult females(pregnant) | 11 | 34 |
| Adult males | 13 | 34 |
| Children(6 months to 6 years) | 11 | 34 |
| Children 6 to 14 years | 12 | 34 |

- WHO has defined anaemia as haemoglobin less than 11g/dl during pregnancy and post partum period.
- During pregnancy, plasma volume expands resulting in haemoglobin dilution. For this reason, haemoglobin level less than 10g/dl is considered anaemia.
- Peri-partum iron deficiency anaemia is associated with significant maternal, fetal morbidity. Poor outcomes for the fetus include preterm birth, fetal growth restriction, intrauterine fetal demise, low APGAR scores and

infection.

- Women with iron deficiency are also at risk of adverse effects requiring medical interventions such as blood transfusion, cardiovascular complications, reduced physical and cognitive performance and reduced immune function.
- Factors responsible for iron deficiency in India include early marriage, teenage pregnancy, multiple pregnancies, less birth spacing, low iron and folic acid intake and high incidence of hook worm infestations in Indian population.

OBJECTIVES OF THE STUDY

To assess the efficacy and safety and to compare the efficacy, safety and compliance of intravenous ferric carboxy maltose and iron sucrose in the treatment of iron deficiency anemia in pregnant women in the second and third trimesters of pregnancy.

METHODOLOGY

- STUDY DESIGN:** A hospital based, Prospective, Comparative study.
- STUDY SAMPLE:** pregnant women admitted in GEMS Hospital during a period of two months (26th November 2019 to 23rd january 2020) are involved in the current study.
- SOURCE OF DATA:** pregnant women admitted in GEMS Hospital, Srikakulam
- SAMPLING STRATEGY:**

INCLUSION CRITERIA: Pregnant women more than 18 years of age with definitive diagnosis of iron deficient anaemia with haemoglobin between 6-10 g/dl.

Pregnant women with gestational age more than 20 weeks upto 36 completed weeks.

METHODS OF COLLECTION OF DATA:

- Maternal parameters including age, obstetric index, gestational age, body weight, severity of anaemia,

cumulative iron deficit and parenteral iron dose was collected from the inpatient medical records .

- Follow up was done at 2 weeks and 4 weeks post treatment and repeat haemoglobin and serum ferritin levels were recorded.

SAMPLING METHOD: Using the convenient sampling, the sample size of 120 antenatal mothers was taken with 60 subjects each in both the ferric carboxy maltose and iron sucrose groups.

Patients were randomly categorized to receive either Iron sucrose or FCM.

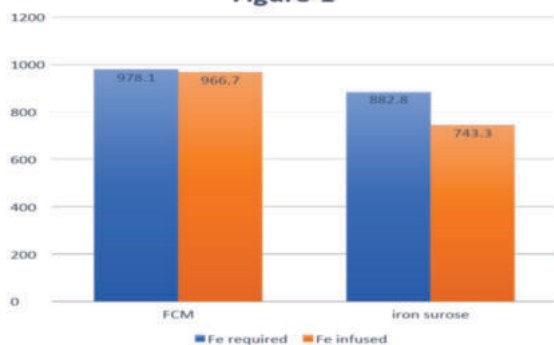
Group-1 for FCM and Group-2 for Iron sucrose.

RESULTS

Iron required and Iron infused for study participants.

- Participants in FCM group were seen to have an average iron requirement of 978.1mg whereas the average dose of iron infused was 966.7mg.
- In Group-2, the average iron requirement was slightly lesser i.e; 882.8mg, 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.

Figure-1



Hb level comparison at various time points of study participants)

- Figure-2 shows the comparison of Hb increase post treatment in both the groups.
- It was observed that at 2 weeks post treatment, the mean Hb did not show a statistically significant difference.
- However, the mean Hb at 4 weeks post treatment when compared in both groups, there was a statistically significant difference, implying that patients in group-1 had more increase in mean Hb after 4 weeks.

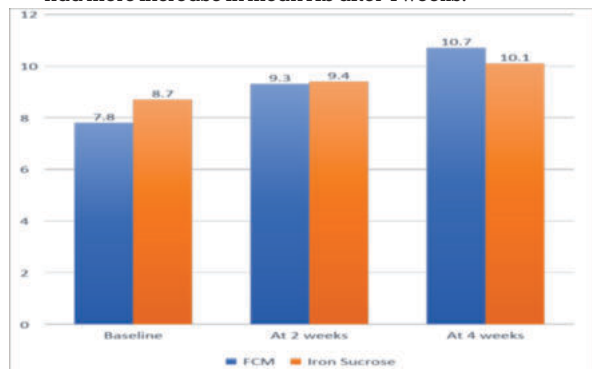


Figure -2 : showing the comparison of Hb increase post treatment in both groups

COMPARISON OF SERUM FERRITIN AND SERUM IRON LEVELS

Serum ferritin seems to be higher in those who received Iron

sucrose as seen in figure-3.

As seen in figure-4 mean serum iron was lesser in those receiving FCM

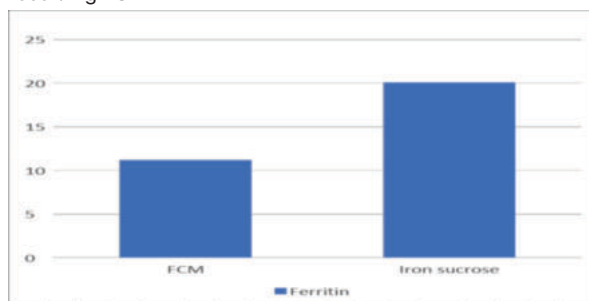


Figure -3 :showing serum ferritin levels

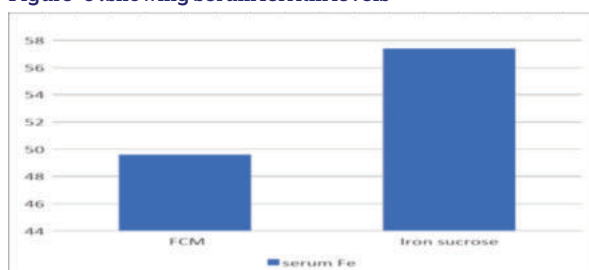
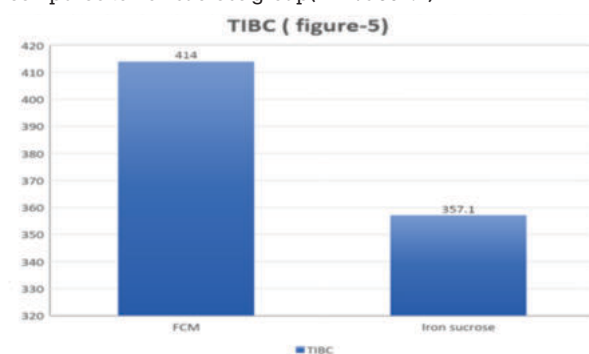


Figure -4 : showing serum iron levels

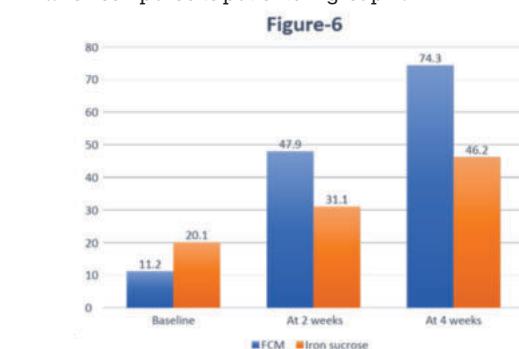
COMPARISON OF SERUM TIBC LEVELS

As seen in figure-5, TIBC levels were higher in FCM group as compared to iron sucrose group(414 vs 357.1)



FERRITIN LEVEL COMPARISON AT VARIOUS TIME POINTS OF STUDY PARTICIPANTS

- Figure-6 depicts the overall comparison in terms of serum ferritin levels pre & post infusion in both the groups
- 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.



COMPLIANCE:

The main disadvantage of 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. Hence iron sucrose showed poor compliance as compared to FCM.

- Hence, this study, shows that rapid delivery of 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 formulation that have limits of low and multiple doses.
- SAFETY:** Hypersensitivity reactions including some fatal events are seen to occur to some extent with all IV formulations(5).
- It is also necessary to monitor patients for signs and symptoms of hypersensitivity during and after IV iron administration for at least 30 minutes.
- Such agents should be administered only when personnel and emergency drugs for treatment of hypersensitivity reactions are immediately available.

SIDE-EFFECTS DEVELOPED BY THE STUDY PARTICIPANTS

| | | | | | |
|---|-----------------|----|------|----|-------|
| 1 | Fever & Chills | 1 | 1.7% | 4 | 6.7% |
| 2 | Rashes | 0 | 0 | 1 | 1.7% |
| 3 | Giddiness | 1 | 1.7% | 0 | 0 |
| 4 | Hypotension | 0 | 0 | 2 | 3.3% |
| 5 | No Side Effects | 58 | 96.7 | 53 | 88.3% |

CONCLUSION

- Our study, like several other similar ones, proves that FCM is simple, effective and safe alternative to several other iron preparations that are being used till date, be it oral or parenteral iron.
- Iron sucrose, ofcourse, has the advantage of being easily available and being less expensive. But the cost effectiveness of FCM over shadows 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 dose or not.
- Thus, when used in pregnant women, the hazard of anaemia is not only tackled, but might also be prevented in the post partum period.
- In conclusion, FCM not only offers a rapid correction of Hb, but also provides replenishment of iron stores of the body, without major adverse effects.
- 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.

SUMMARY

- Thus study is a prospective, hospital based, comparative study of the efficacy and safety profile of the novel parenteral IV iron preparation Ferric carboxy Maltose to older IV preparation being commonly used i.e; iron sucrose.
- Over a period of 60 days (2 months), 120 pregnant women in their second and third trimesters, with Iron deficiency anemia were treated with parenteral iron, either FCM or iron sucrose.
- Iron sucrose was seen to have slightly more number of adverse effects . Compliance was also lesser with iron sucrose due to incomplete adherence to treatment.
- Thus, FCM in all aspects is an effective tool to combat iron deficiency and anemia in pregnancy.

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