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Original Research Article

Comparative Study of Efficacy and Safety of Intravenous Ferric Carboxy Maltose versus Iron Sucrose in Treatment of Postpartum Iron Deficiency Anemia

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Abstract

Background: As postpartum iron deficiency anemia is observed in about 65% of women in India, it is the major contributing factor and indirect cause of maternal death. 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 safety and efficacy of intravenous FCM versus iron sucrose in treatment of postpartum iron deficiency anemia.

Methods: It was a prospective observational study of postpartum women (within 10 days of delivery) with iron deficiency anemia who delivered in Guru Gobind Singh Govt. Hospital, Jamnagar. A sample size of 194 women was estimated based on prevalence of anemia which is 65% among postpartum women in India including dropout rate of 10% which were further divided into 2 groups. Group 1: iron sucrose group, Group 2: ferric carboxy maltose group.

Results: FCM has greater rise in Hb, less side effects, and easy administration of dose as compared to iron sucrose. The rise in Hb with FCM as compared to iron sucrose is (4.6 versus 3.5 respectively).

Conclusions: FCM has more safety and efficacy as compared to iron sucrose in treatment of postpartum iron deficiency anemia.

Keywords: Ferric carboxy maltose, Hemoglobin, Iron sucrose, Iron therapy, Postpartum Iron Deficiency Anemia.

Introduction

Postpartum anemia is a prevalent complication affecting women in the early puerperium, with iron deficiency being the most common underlying cause. It is estimated that 20–40% of postpartum women, particularly in developing countries, experience hemoglobin levels below normal due to peripartum blood loss, pre-existing antenatal iron deficiency, and inadequate nutritional replenishment.

Oral iron therapy, while widely used, is often limited by gastrointestinal side effects, poor compliance, and slow replenishment of iron stores, making intravenous (IV) iron preparations a preferred option in moderate to severe anemia or when rapid correction is required. Among IV iron formulations, Iron Sucrose has been in use for many years and is considered safe, but it requires multiple small-dose infusions due to dose limitations per sitting. In contrast, Ferric Carboxymaltose (FCM) is a newer preparation that allows administration of larger single doses with a favorable safety profile, enabling quicker restoration of iron stores and improved patient convenience.

Given the importance of rapid and safe correction of iron deficiency in the postpartum period, comparative evaluation of the efficacy and safety of these two commonly used IV iron formulations is essential. This study aims to compare Ferric Carboxymaltose and Iron Sucrose in terms of their ability to improve hematological parameters, replenish iron stores, and their associated adverse

event profiles in postpartum iron deficiency anaemia

Methods

It was a prospective observational study of postpartum women (within 10 days of delivery) with iron deficiency anemia (mild to moderate) who delivered in Guru Gobind Singh Govt. Hospital, Jamnagar. A sample size of 194 women was estimated based on prevalence of anemia which is 65% among postpartum women in India (Ministry of Health and Family Welfare. National Iron+ Initiative: Guidelines for Control of Iron Deficiency Anaemia, Adolescent Division, Ministry of Health and Family Welfare, Government of India, New Delhi; 2013) including dropout rate of 10%.

The sample size of 194 women were divided into two groups: 1) Iron sucrose group (200 mg/day in 100 ml 0.9% normal saline over 30minutes on 0, 2, 4, 6 and 8 day). 2) Ferric carboxy maltose (FCM) group (1000 mg in 100 ml 0.9 % normal saline over 30 minutes).

Diagnosis was confirmed by CBC and blood indices.

Follow up was scheduled after 6 weeks coinciding with 1st day of her baby's immunization schedule on an OPD basis for CBC investigation.

Any side effects (pain at injection site, itching and rash, abdominal pain, palpitation, headache, nausea, vomiting, and anaphylactic shock) and compliance were noted.

Written informed consent was obtained from all patients enrolled in the study.

Calculation of iron requirement: 2.4 x body weight (target Hb - actual Hb) + 500 mg

Inclusion criteria

- 18–40 years old.
- Postpartum (within 10 days of delivery) with iron deficiency anemia (hemoglobin 7–10.9 gm/dl).
- Hemodynamically stable at the time of enrollment.
- No history of significant vaginal bleeding in the last 24 hours.
- No active infection at the time of enrollment.
- Intolerance or non-compliance to oral iron therapy.
- Serum ferritin <30 ng/ml and/or transferrin saturation <20% (if available, for confirmation of iron deficiency).
- Single live birth (to minimize confounders related to twin/triplet deliveries).
- Agreed to comply with follow-up visits and laboratory investigations.

Exclusion criteria

- History of parenteral iron intolerance
- Having thalassemia or sickle cell disease
- History of bleeding disorders
- Non iron deficiency anemia
- Recent treatment with iron, blood transfusion or erythropoietin within 3 months
- Postpartum hemorrhage
- History of asthma or cardio vascular disease.

Results

Out of the 194 patients treated for postpartum anemia 94 from iron sucrose group and 100 from FCM group completed the protocol. Those who completed protocol and came for follow up were included for study and statistical analysis.

Epidemiologically both groups were compared with age and parity.

Table 1: Distribution of subjects based on obstetric profile among two groups.

Iron sucrose group			Ferric carboxy maltose group	
Parity	**n**	**%**	**n**	**%**
Multi gravida	66	70.3	70	70
Primi gravida	28	29.7	30	30
Total	94	100	100	100

Postpartum iron deficiency anemia was more common in multigravida patients than in primigravida (Table 1).

Table 2: Age wise distribution of study subjects among two groups.

Age group	Iron sucrose group		Ferric carboxy maltose group	
	Frequency	**Percent**	**Frequency**	**Percent**
18-25	66	70.3	70	70
26-30	18	19.2	22	22
>30	10	10.6	08	8
Total	94	100	100	100
Mean	31.33±4.41		33.33±4.62	

The most common age group affected with iron deficiency anemia was 18-25 years of women (Table 2).

Table 3: Comparison of Iron Sucrose vs. Ferric Carboxymaltose in Mild and Moderate Iron Deficiency Anaemia

Parameter	Mild degree iron deficiency anemia (n=64)		Moderate degree iron deficiency anemia (n=130)	
	Iron Sucrose (n=32)	Ferric Carboxymaltose (n=32)	Iron Sucrose (n=65)	Ferric Carboxymaltose (n=65)
Baseline Hb (g/dl)	~10–10.9	~10–10.9	~7–9.9	~7–9.9
Mean Hb rise at 6 weeks (g/dl)	1.5–2.0	2.5–3.0	2.0–2.5	3.0–3.5
Serum Ferritin rise (ng/ml)	50–70	100–150	60–90	150–200
Dosing schedule	Multiple small divided doses 2–3×/week)	Single infusion (1000 mg)	Multiple doses required	Single dose
Time to replenish stores	3–4 weeks	1–2 weeks	4–6 weeks	2–3 weeks
Adverse events	More frequent (hypotension, infusion reactions, multiple venipunctures)	Less frequent (well tolerated, mild GI symptoms, headache)	Same pattern, but higher frequency due to more doses	Same, generally better tolerated
Compliance & Convenience	Less (requires multiple visits)	High (single visit)	Less (many infusions)	High

Ferric Carboxymaltose (FCM) gives faster hemoglobin rise, higher ferritin levels, and requires fewer hospital visits, which improves compliance. Iron Sucrose (IS) is effective but slower, with more infusions needed, leading to less convenience.

Table 4: Comparison of haemoglobin level among two groups.

Hb levels	Iron sucrose group	Ferric carboxy maltose
	Mean±SD	Mean±SD
Pre treatment	7.79±0.69	8.23±0.55
Post treatment	11.36±1.17	12.84±1.04
Hb difference	3.5±1.12	4.6±0.96

Sufficient rise in Hb (4.6 versus 3.5) was seen in patients receiving FCM as compared to iron sucrose (Table 4).

Table 5: Comparison of Adverse Effects

Adverse Effect	Ferric Carboxymaltose (FCM)	Iron Sucrose (IS)
Injection site reactions (pain, swelling, phlebitis)	Less common	More common
Nausea / Vomiting	Occasional	Occasional to frequent
Headache / Dizziness	Mild, transient	Mild, transient
Flushing	Rare	More frequent
Metallic taste / Dysgeusia	Rare	Reported
Hypotension (transient, infusion-related)	Rare	More common
Allergic / Hypersensitivity reaction	Very rare (<1%)	Rare but possible
Fever / Chills	Uncommon	More common
Musculoskeletal pain (back pain, arthralgia, myalgia)	Reported in few cases	Reported, sometimes more frequent
Serious adverse events	Very rare	Very rare

Less side effects (pain at injection site, itching and rash, abdominal pain, nausea, vomiting, palpitation, anaphylactic shock) were seen with administration of FCM (only 3 patients) as compared to iron sucrose (Figure 1).

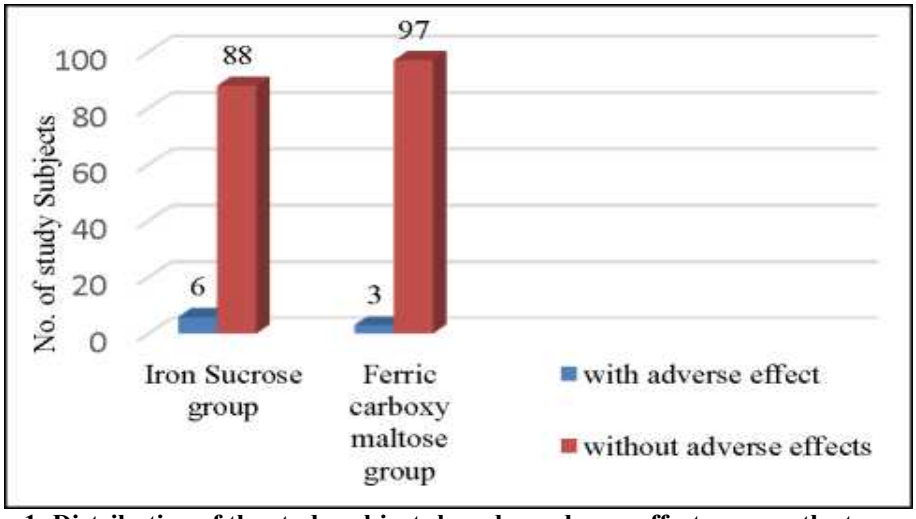

Figure 1: Distribution of the study subjects based on adverse effects among the two groups.

FCM is safer than ferric carboxy maltose as only 3% of study subjects of FCM group suffered from adverse effects as compared to 6.3% in iron sucrose group. Since FCM is a single dose therapy as compared to iron sucrose (5 doses), hospital stay of patients receiving FCM is less as compared to patients receiving iron sucrose.

Discussion

Postpartum anemia is a major public health problem and is observed in 65% of women in India. Postpartum anemia arises frequently and imposes a substantial disease burden during the critical period of maternal- infant interactions. Anemic women have a longer average length of hospital stay, are more likely to receive a blood transfusion and incur higher hospitalization costs, Hence, postpartum IDA require attention and high quality care. [5]

Traditional treatments i.e. oral iron therapy and blood transfusion involves significant drawbacks. To overcome this problem IV iron preparations were used. [6] Our study indicates that postpartum anemia can be treated effectively by FCM (ferric carboxy maltose) as compared to iron sucrose with additional advantage of single infusion, less side effects and better patient compliance.

In our study total 194 postpartum women with iron deficiency anemia were divided randomly in two groups, iron sucrose (group 1) and ferric carboxy maltose (group 2). Both groups were given deworming therapy, baseline investigations done, follow up was done at 6 weeks and Hb level repeated.

Singh et al in their study on postpartum patients with Anemia and observed that there was mean rise of Hb was 2.086 gm for FCM group and 1.766 gm for iron sucrose group and Patel et al in their study showed the mean rise of hemoglobin value in Ferric carboxy maltose injection in the treatment of postpartum iron deficiency anemia was 5.2 gm/dl for ferric carboxy maltose and 4.1 gm/dl for iron sucrose in pregnant women. [7,8] In our study mean rise of Hb in FCM group was 4.6 and in iron sucrose group was 3.5 which was significant.

Joshi et al in their study, most common age group affected was 18-25 years and Lunagariya et al study, most common age group was 20-25 years, in our study also most common age group is 18-25 years. [9,10] Joshi et al in their study, postpartum anemia was more common in multiparous women (70-75% in both the groups). [9] In our study also postpartum anemia was more common in multiparous women which accounts for nearly 70 % in both groups.In Joshi et al study, adverse effects were seen in 7.2% of iron sucrose group and 3.3% of FCM group whereas in our study 6.3 % of patients of iron sucrose group and 3% of patients of FCM group developed side effects. [9]

Registered adverse effects were mild and quickly reversible and mostly restricted to local reaction at the infusion site. There was no treatment related serious adverse events. No anaphylactic reaction was detected. No venous thrombosis was registered. Most common adverse effect in iron sucrose group was urticarial. [11]

Intra venous iron supplementation is highly effective in treating postpartum iron deficiency anemia, resulting in a much rapid resolution of iron deficiency anemia, has minimal side effects, and because it is administered intravenously, it circumvents problem of compliance. [12]

Conclusion

From our study we concluded that ferric carboxy maltose is safe and efficient in treatment of iron deficiency anemia in postpartum women as compared to iron sucrose, with lesser adverse effects and better patient compliance. Iron Sucrose is cheaper per dose, but requires multiple hospital visits (increasing indirect costs and inconvenience).

Due to ultrashort duration of treatment i.e. ability to administer 1000mg dosage in a single sitting, fewer adverse effects, better compliance and decreased hospital stay in patients makes FCM the first line drug in management of postpartum iron deficiency anemia causing faster and higher replenishment of iron store and correction of Hb level.

It increases patient compliance and decreases bed occupancy and burden on health facility in developing country like India.

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