INTRODUCTION

Iron-deficiency anemia (IDA) is the most common and major hematological, nutritional deficiency but manageable health problem encountered among pregnant women globally but more common in developing countries, especially in tropics like India, especially in underprivileged population. According to the World Health Organization, about 591,000 perinatal deaths and 115,000 maternal deaths globally are due to IDA directly or indirectly [1]. India alone contributes to about 80% of the maternal deaths due to anemia in South Asia. The prevalence of anemia in pregnant women in India is 50% in the National Family Health Survey-4 [2]. The Indian Council of Medical Research has categorized anemia during pregnancy as - mild anemia - Hb - 10–10.9 g%, moderate anemia - Hb - 7–9.9 g%, severe anemia - Hb - 4–6.9 g%, and very severe anemia - Hb - <4 g% [1]. Iron deficiency in post-partum women reflects IDA that existed in women during their pregnancy. Building up iron stores and correcting IDA in post-partum period will improve health of mother and will also decrease the complication in subsequent pregnancy. Iron supplementation in post-partum period will improve the prognosis in the subsequent pregnancies and decrease the incidence of anemia pre-term deliveries, morbidity, and mortality [3].

A single IV iron infusion is an effective and safe option for treatment of post-partum IDA. Iron sucrose and ferric carboxymaltose (FCM) are dextran-free iron preparation for parenteral therapy. Iron sucrose in November 2000 got FDA-approved forming iron hydroxide-sucrose complex in water with 34,000–60,000 Dalton molecular weight [4]. It is administered as infusion in 200 mL normal saline over 15–20 min and maximum daily dosage of 200 mg, not more than thrice a week [5].

Recently, a new parenteral iron preparation, FCM, was developed to facilitate the effective treatment of IDA. FCM is novel non-dextran which is administered in dose of 15 mg/kg as intravenous infusion [6]. Maximum dose per sitting should not exceed 1000 mg. While IV iron in pregnancy improves hematological parameters, there is an absence of evidence for improvements in important maternal or perinatal outcomes. The current IV iron preparation of choice is largely determined by cost and convenience of administration. This study was designed to test the efficacy of FCM versus iron sucrose in treating post-partum anemia.

Aim

The aim of this study was to compare the efficacy, compliance, and safety of the administered intravenous FCM versus intravenous iron sucrose in post-partum women with IDA.

METHODS

This was a hospital-based prospective randomized controlled study, comprises of 100 post-natal women with IDA with hemoglobin level <11 g/dL, were enrolled after full filling selection criteria and giving valid consent admitted to post-natal ward of Obstetrics and Gynecology department in SP Medical College, Bikaner, from June 2021 to May 2022. In age, residence, socioeconomic status, the incidence of IDA in both the groups were comparable and is more among rural areas, low socioeconomic status. Improvement in hemoglobin, serum ferritin, and blood indices in both the iron sucrose and FCM groups, but it was faster and greater with ferric carboxymaltose when compared with iron sucrose. Other advantages are large dose administration at 1 time, therefore, lesser total number of doses required in the FCM group as compared to the IS group.

Conclusion: FCM is well tolerated, safer, and effective than iron sucrose in treatment of post-natal IDA.

Keywords: Iron-deficiency anemia, Ferric carboxymaltose, Iron sucrose.

ABSTRACT

Objectives: The objective of this study was to compare intravenous ferric carboxymaltose (FCM) versus intravenous iron sucrose in post-partum women with iron-deficiency anemia (IDA).

Methods: This was a hospital-based prospective randomized controlled study, comprising 100 post-natal women with IDA with hemoglobin level <11 g/dL admitted in post-natal ward of the Obstetrics and Gynecology Department in SP Medical College, Bikaner, from June 2021 to May 2022.

Results: In age, residence, socioeconomic status, the incidence of IDA in both the groups were comparable and is more among rural areas, low socioeconomic status. Improvement in hemoglobin, serum ferritin, and blood indices in both the iron sucrose and FCM groups, but it was faster and greater with ferric carboxymaltose when compared with iron sucrose. Other advantages are large dose administration at 1 time, therefore, lesser total number of doses required in the FCM group as compared to the IS group.

Conclusion: FCM is well tolerated, safer, and effective than iron sucrose in treatment of post-natal IDA.

Keywords: Iron-deficiency anemia, Ferric carboxymaltose, Iron sucrose.
Karwasara et al.

Ganzoni formula
Total iron deficit (mg) = Body weight (kg) × (target Hb-actual Hb) × 2.4 + depot iron (mg)
Depot iron = 500 mg if body weight >35 kg,
15 mg/kg if body weight <35 kg
Target Hb level was taken as 11 g/dL.

The patient was randomly divided into two groups; in the iron sucrose group (Group A), the dose of iron sucrose was 200 mg intravenously in 200 mL 0.9% normal saline over a period of 30 min on alternate days until the total dose was administered, not to exceed 600 mg/week. In the FCM group (Group B), intravenous infusion was given in 200 mL 0.9% normal saline immediately after dilution over 15 min. Maximum dose of FCM per sitting was 1000 mg or 15 mg/kg. Subsequent doses if needed were planned at 1-week intervals (on the 7th and 14th days).

Dilution should not be lower than 2 mg/mL to ensure stability. The general condition of patients, blood pressure, and pulse rate were noted before and after infusion. Any minor and major adverse effects such as rash, vomiting, headache, or any other anaphylactic reaction was noted.

Patients were followed up at 3 and 6 weeks of parenteral therapy, with CBC and serum ferritin levels. Pre-treatment and 3rd- and 6-week post-partum investigations were done for both the groups, and the results were compared on the basis of hemoglobin, mean corpuscular volume (MCV), and serum ferritin.

The investigation was started after receiving ethical approval from the institute. Written informed consent was obtained from all the study subjects.

Statistical analysis
Data were recorded as per pro forma. The data analysis was computer based; SPSS-22 was used for analysis. Serum ferritin values were obtained from Unicel DXL 800 access immunoassay system. For category variables, Chi-square test was used. For continuous variables, independent sample’s unpaired t-test was used. p<0.05 was considered significant.

RESULTS

Maximum number of patients 23 (46%) and 31 (62%) were in the age group of 21–25 years in Group A and Group B, respectively. Thirty-one (62%) in Group A and 33 (66%) in Group B belonged to rural area and in lower socioeconomic status.

Maximum women 21 (42%) belonged to P2 (Para 2) in Group A whereas maximum 22 (44%) belonged to p1 in Group B (p<0.05) (Table 1). Thirty-nine (78%) were lower segment cesarean section (LSCS) operated in Group A (FCM) whereas 35 (70%) were LSCS operated in Group B (IS).

According to mode of delivery, 11 (22%) patients were normal vaginally delivered and 39 (78%) were LSCS operated in Group A (FCM). Fifteen (30%) patients were normal vaginally delivered and 35 (70%) were LSCS operated in Group B (IS) (p>0.05).

Improvement of Hb in the FCM group was from pre-treatment mean Hb 8.66 g/dL to 10.25 g/dL at 3 weeks and 11.56 g/dL at 6 weeks while improvement of Hb in the IS group from pre-treatment mean Hb 8.58 g/dL to 9.36 g/dL at 3 weeks and 10.60 g/dL at 6 weeks (Fig. 1).

Improvement of MCV in the FCM group was from pre-treatment mean MCV 77.18 fl to 82.16 fl at 3 weeks and 88.24 fl at 6 weeks while improvement of MCV in the IS group was from pre-treatment mean MCV

![Fig. 1: According to pre and after Hb level](image-url)
In our study, the mean age was 25.72 years in the FCM group and 25.25 years in the IS group and maximum number of patients 62% belonged to rural area. Other studies like Wajid et al. [7] also show a mean age group comparable to our study that was 26.16 years in the IS group and 26.86 years in the FCM group.

In our study, the distribution of patients according to parity was as follows: 11 (22%) belonged to p1, 21 (42%) belonged to p2, 17 (34%) belonged to p3, and 1 (2%) belonged to p4 in Group A (FCM). Twenty-two (44%) patients belonged to p1, 18 (36%) belonged to p2, 4 (8%) belonged to p3, and 6 (12%) belonged to p4 in Group B (IS) which were in contrast to the study findings reported by Wajid et al. [7], in which out of 80 patients, 61 (76.2%) were para <3 in the IS group and 55 (68.8%) in the FCM group. 3 or more para in 19 (23.8%) in the IS group and 44 (27.5%) in the FCM group.

In our study improvement of Hb in the FCM group from pre-treatment mean Hb 8.66 g/dL to 10.25 g/dL at 3 weeks and 11.56 g/dL at 6 weeks while improvement of Hb in the iron sucrose group from pre-treatment mean Hb 8.58 g/dL to 9.36 g/dL at 3 weeks and 10.60 g/dL at 6 weeks. It shows that in the FCM group, the average increase is about 1.59 g/dL at 3 weeks and 2.9 g/dL at 6 weeks, while in the iron sucrose group, the average increase is about 0.78 g/dL at 3 weeks and 2.02 g/dL at 6 weeks.

Similar findings were evident in an earlier study in India conducted by Kumari et al. [8], in which patients when received iron sucrose hemoglobin increased from 8.27 g/dL to 9.17 g/dL and 10.48 g/dL post-therapy at 2 weeks and 4 weeks, respectively, while in the FCM group, Hb increased from 8.3 g/dL to 10.177 g and 11.83 g/dL at 2 weeks and 4 weeks, respectively, post-infusion therapy. It shows that in the FCM group, the average increase is about 1.87 g/dL at 2 weeks and 3.53 g/dL at 4 weeks, while in the iron sucrose group, the average increase is about 1.44 g/dL at 2 weeks and 3.53 g/dL at 6 weeks. Results were further supported by a study conducted by Rathod et al. [9], in which Hb improved from baseline 7.71 g/dL to 10.87 g/dL at 2 weeks and 12.11 g/dL at 6 weeks after FCM infusion; similarly, Hb improved from baseline 8.05 g/dL to 10.41 g/dL at 2 weeks and 11.40 g/dL at 6 weeks after iron sucrose therapy. Similarly higher efficacy of FCM was reported in studies done by Smita et al. [8], Lunagariya et al. [10], and Sharma et al. [11]. Our study results were also comparable with a study of Modi et al. [12] who found that the average baseline Hb was 7.82±0.04 g/dL which was significantly increased up to 12.4±1.33 g/dL at 6 weeks (p<0.05). In a study of Sumathy and Arulmozhi [13] among the iron sucrose group, an increase in level of Hb was observed by 1.65 g/dL and 2.35 g/dL after 2 and 4 weeks of treatment. Similarly, in case of the FCM group, they observed an increase in 2.04 g/dL and 2.83 g/dL at 2 and 4 weeks of treatment.

In our study, serum ferritin which indicates iron status of body increased more significantly in the FCM group from pre-treatment mean serum ferritin 37.73 ng/dL to 217.57 ng/dL at 3 weeks and 180.79 ng/dL at 6 weeks while changes in serum ferritin in the iron sucrose group from pre-treatment mean serum ferritin 42.47 ng/dL to 151.99 ng/dL at 3 weeks and 130.18 ng/dL at 6 weeks. The difference between the two groups was comparable at baseline and on follow-up improvement in Hb level, MCV and ferritin was faster and greater in the FCM group as compared to the IS group and was found to be statistically significant at 3 and 6 weeks (Table 2).

In the iron sucrose group, total 4 patients complained of minor reactions: 2 patients (nausea, vomiting), 1 patient (pain at injection site), and 1 patient (fever) (Table 3). Apart from few minor reactions, no major adverse reactions were seen in both the groups.

**DISCUSSION**

In our study, the mean age was 25.72 years in the FCM group and 25.25 years in the IS group and maximum number of patients...
3 weeks and 11.6 fl at 6 weeks. In the iron sucrose group, the average increase is about 2.24 fl at 3 weeks and 7 fl at 6 weeks. Similar result were found in Smita et al. [8] who reported an increase in MCV from 71.55 fl to 74.05 fl in iron sucrose and from 71.62 fl to 77.57 fl in the FCM group after 4 weeks. Wajid et al. [7] also reported more improvement of MCV in the FCM group as compared to the iron sucrose group as MCV level increase from 66.82 fl to 80.38 fl in iron sucrose and 64.08 fl to 81.33 fl in the FCM group at 3 weeks. Furthermore, our study results were also similar to that of other studies like Lunagariya et al. [10] and Sumathy and Arulmozhi [13].

We also compared the safety of both intravenous drugs and found that the FCM group reported with less side effect, as in our study, only one patient in the FCM group complained of nausea vomiting while in the iron sucrose group, total 4 patients complained of minor reactions: 2 - nausea and vomiting, 1 patient - pain at injection site, and 1 patient - fever. Apart from few minor reactions, no major adverse reactions were seen in both the groups.

Likewise in case of a study of Lunagariya et al. [10], 16 patients in the iron sucrose group showed minor adverse reaction: 6 - pain at injection site, 3 - itching and rash, 3 - headache, 2 - abdominal pain, and 2 - nausea and vomiting. While, in the FCM group, 12 patients showed adverse effect: 5 - pain at injection site, 2 - itching and rash, 3 - headache, 2 - abdominal pain, and 2 - nausea and vomiting, and it was 32% and 24% with both the IS and FCM groups, respectively.

**CONCLUSION**

This study compared the efficacy of FCM versus iron sucrose in the management of post-natal iron-deficiency anemia. Although our results showed improvement in hemoglobin, serum ferritin, and blood indices in both the iron sucrose and FCM groups, it was faster and greater with ferric carboxymaltose when compared with iron sucrose. Other advantages are large dose administration at 1 time therefore lesser total number of doses required in the FCM group as compared to the IS group. This not only saves hospital resources but also improves patient satisfaction. Adverse reactions were also low in the FCM group as compared to iron sucrose; therefore, FCM is well tolerated, safer, and effective than iron sucrose in treatment of post-natal IDA.

**ACKNOWLEDGMENT**

We owe a debt of gratitude to the Sardar Patel Medical College, Bikaner, for assistance during the course of the research.

**AUTHORS' CONTRIBUTION**

All the authors have contributed equally.

**CONFLICT OF INTEREST**

The authors declare no conflicts of interest.

**AUTHOR'S FUNDING**

The authors hereby state that they did not get any financial assistance for their research, writing, or publication of this paper.

**REFERENCES**


doi: 10.1007/s00277-011-1279-z, PMID 21710167


