

## COMPARATIVE EVALUATION OF EFFICACY AND SAFETY OF INTRAVENOUS FERRIC CARBOXYMALTOSE VERSUS IRON SUCROSE COMPLEX FOR THE TREATMENT OF MODERATE GRADE ANEMIA IN POST CAESAREAN SECTION WOMEN: A RANDOMIZED AND PROSPECTIVE STUDY

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### ABSTRACT

**Objective:** Iron deficiency anemia is common in postpartum women in India. The present study is aimed at comparing the safety and efficacy of intravenous ferric carboxymaltose (FCM) with intravenous iron sucrose complex (ISC) in patients who underwent cesarean section and having moderate grade anemia in postpartum period.

**Methods:** A prospective and comparative study was carried out in 100 post-cesarean section women with moderate grade anemia hemoglobin (Hb 7–9 g%) in Gajra Raja Medical College, Gwalior (M.P.) from February 2019 to August 2020. Subjects were randomly allocated to two groups, namely, FCM and ISC, 50 patients in each group. In group FCM, patients were infused with 1000 mg of FCM in a single dose on 4<sup>th</sup> post-operative day. Patients in ISC group were infused with ISC 200 mg in 100 mL normal saline on 3 alternate days on 4<sup>th</sup>, 6<sup>th</sup>, and 8<sup>th</sup> post-operative day. Mean, Hb mean corpuscular volume (MCV), mean corpuscular Hb (MCH), and MCH concentration (MCHC) were recorded before start of therapy and 15 days after treatment in all study subjects. Mean reticulocyte count was recorded before start of treatment and 2 days after completion of treatment that is on 6<sup>th</sup> and 10<sup>th</sup> post cesarean day in FCM and ISC group, respectively. Adverse drug reactions were recorded during the study period. Statistical analysis was done using Statistical Package for the Social Sciences software.

**Results:** Mean Hb increased by 27% in FCM and by 19% in ISC group and is significant (\* $p < 0.05$ ) from baseline values. FCM showed significantly (\*\* $p < 0.01$ ) better response, than ISC group. Mean reticulocyte percent showed significant increase by 120% and 73% in FCM and ISC group, respectively, from the baseline and change in mean reticulocyte in FCM was significant (\*\*\* $p < 0.001$ ) as compared to ISC. The mean rise in MCV was 12% and 5% and MCH was by 10% and 1% in FCM and ISC group, respectively. FCM groups showed significantly better response ( $p < 0.05$ ) than ISC. However, in MCHC, there were 7% and 4% increase in FCM and ISC group, respectively, and on inter group comparison was not significant ( $p > 0.05$ ). Adverse effects noted during the study were mild and responded to symptomatic treatment. Sixteen percentage of FCM cases and 26% of ISC cases underwent adverse drug reactions that included nausea, vomiting, giddiness, and injection site reactions.

**Conclusion:** FCM is more efficacious and safer than ISC, making it the first line of management in postpartum iron deficiency anemia.

**Keywords:** Iron deficiency anemia, Postpartum anemia, Iron sucrose complex, Ferric carboxymaltose.

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### INTRODUCTION

Iron deficiency anemia is the most common cause of postpartum anemia (PPA), accounting for 50–60% of the cases [1]. PPA has varied adverse effects, both on maternal health as well as neonatal well-being. On one hand, it increases the rates of sepsis, sub-involution, secondary PPH, postpartum depression, lactation failure, and prolonged hospitalization in the mother; on the other hand, poor weight gain, suppression of immunity, and neurocognitive deficits in the neonate [2].

Postpartum iron deficiency anemia (PPIDA) warrants a major concern not only to ensure healthy puerperium, better mother-baby bonding, and building up of iron reserves in the postnatal women to have a better quality of life, but also to keep a check on increasing incidence of anemia in the next pregnancy [3].

Iron replenishment in postpartum period is a must, can be dealt with oral iron preparations and parenteral iron therapy. In most of the cases, oral iron is not enough since the endogenous iron stores are already depleted and less iron is available for sufficient erythropoiesis. Furthermore, orally given iron has adverse effects such as intolerance, nausea, vomiting, epigastric pain, diarrhea, constipation, and

unpredictable absorption, resulting in poor compliance [4]. Parenteral iron therapy is effective modality to treat PPIDA. Conventionally, iron sorbitol or iron dextran is used intramuscularly to avoid oral intolerance [5]. In the recent past, choices have shown a changing trend to give iron intravenously so as to swiftly restore iron stores and obviating the need for blood transfusion. Iron sucrose complex (ISC), a time-tested IV iron preparation, has negligible safety issues with a maximum permissible dose of 600 mg per week. The only disadvantage is limited dose per sitting necessitating multiple visits, adding to total cost of therapy [6,7].

At present, IV ferric carboxymaltose (FCM) is found more convenient to the patients because it is formulated to be administered once a week in a single dose [8]. This novel agent renders better compliance adding to the widespread use of FCM these days [9]. On literature survey, no comparative study is found between FCM and ISC on their effect in post caesarean cases of moderate grade anemia. Therefore, the present study is planned to compare the efficacy of FCM in terms of rise in hemoglobin percentage, change in absolute values of RBC indices, rise in reticulocyte count and safety in terms of adverse drug reaction profiles with that of ISC in patients of postpartum moderate grade anemia after cesarean section.

## METHODS

The prospective and comparative study was conducted in the Department of Obstetrics and Gynecology, Kamla Raja Maternity Wing, JA Group of Hospitals, Gajra Raja Medical College, Gwalior (M.P.) after approval from the Institutional Ethics Committee. (Registration number: 57/IEC-GRMC/2018). A total 100 post-cesarean section women with anemia of moderate grade haemoglobin (Hb 7–9 g%, according to ICMR Classification) were enrolled and using a computer-generated block randomization table divided into two groups in a 1:1 ratio consisting of 50 patients in each group.

In FCM group, 50 cases were treated with IV FCM 1000 mg in 250 mL normal saline (0.9%) over 15 min on post-LSCS day 4. In ISC group, 50 patients were infused with IV ISC 200 mg in 100 mL normal saline over 15 min on alternate 3 post-cesarean day, that is, on 4<sup>th</sup>, 6<sup>th</sup>, and 8<sup>th</sup> day. All emergency measures for resuscitation (adrenaline, oxygen, hydrocortisone, and chlorpheniramine maleate) were kept handy to combat any mishap.

### Inclusion criteria

All post-cesarean section women with anemia of moderate grade (Hb 7–9 g%, according to ICMR Classification) were included in the study.

### Exclusion criteria

The following criteria were excluded from the study:

1. Patients having severe and very severe anemia
2. Known case of folate/B<sub>12</sub> deficiency anemia
3. Sickle cell anemia/Thalassemia
4. Hypersensitivity to IV iron compounds
5. Chronic liver disease
6. Chronic kidney disease
7. Iron overload states, for example, hemosiderosis or hemochromatosis
8. Autoimmune diseases like rheumatoid arthritis and SLE
9. History of recent blood transfusion (within 3 months)
10. Women with weight <35 kg
11. Women with Hb >9g% and <7 g%
12. Anemia due to causes other than IDA
13. Any chronic infections like hepatitis and HIV
14. History of allergic reaction to intravenous iron infusion.

After taking well informed consent, subjects were allotted to IV FCM and IV ISC groups. Detailed medical history was taken. General and systemic examination was done.

### Measurement of efficacy

Therapeutic response to IV FCM and IV ISC was judged on these parameters:

- (1) Hb in g/dL (2) Reticulocyte count (3) RBC indices (a) Mean corpuscular volume (MCV), (b) Mean corpuscular Hb (MCH), (c) MCH concentration (MCHC).

Baseline investigations were recorded before treatment. Reticulocyte count was recorded on post LSCS day 6 in FCM group and post-LSCS day 10 in ICM group. Other investigations were done on day 15 after completion of treatment. All patients were followed for 3 weeks of initiation of treatment.

### Measurement of safety

Adverse drug reactions such as giddiness, nausea, vomiting, hypersensitivity reactions, and injection site reactions, for example, thrombophlebitis, flushing, hypotension, and any other adverse drug reactions with FCM and ICM were noted during treatment period.

### Statistics

The data were analyzed using Statistical Package for the Social Sciences software. The mean changes in hematological parameters between two groups were compared using the Unpaired "t"-test, while the Chi-square test was used to compare baseline categorical

variables/qualitative data. "p"<0.05 was considered as statistically significant.

## RESULTS

The patients' disposal has been depicted in the consolidated standard for reporting trials (CONSORT) style flow diagram in Fig. 1.

Epidemiologically, both groups were comparable on baseline demographic characteristics. Majority of the women were in the age group 18–22 years, primiparous, vegetarian, underwent primary education, had a BMI of 18.5–24.9, and had taken IFA prophylaxis in the antenatal period (Table 1).

### Efficacy assessment

Primary outcome was significant rise in Hb from baseline in both the groups at the end of 2 weeks after treatment. The mean rise in Hb in FCM group 2.3 g/dL (27%) was significantly higher than ISC group 1.61 g/dL (19%) from baseline after 15 days of treatment this shows better efficacy of FCM (\*\*p<0.01). FCM was found superior to ISC in improving Hb level after 2 weeks of treatment (Table 2). The RBC indices: MCV increased by 11.88 fL (10%) and 3.43 fL (1%), respectively, in FCM and ISC group, and is significant (\*p<0.05) from baseline. On intergroup comparison, increase in MCV in FCM group is significant (\*\*p<0.01) as compared to ISC. MCH increased by 2.64 pg (16%) and 0.28 pg (5%), in FCM and ISC group, respectively, and is significant (\*p<0.01) from baseline. FCM showed significantly better response (\*\*p<0.01) as compared to ISC. However, MCHC showed a trivial rise of 2.21g/dL (7%) and 1.35g/dL (4%), respectively, in FCM and ISC group, respectively. On intergroup comparison, it is statistically not significant (p>0.05) (Table 2).

Mean percent reticulocyte count increased by 1.07 and by 0.72 in FSC and ISC group respectively and was significant (p<0.05) from baseline in both the groups. Increase in mean reticulocyte count is by 120% and 72% in FCM and ISC group, respectively, from baseline. On comparison, increase in reticulocyte count with FCM is remarkably significant (\*\*p<0.001) than ISC indicates early and better erythropoiesis with FCM than ISC (Fig. 2).

### Safety assessment

Adverse effects noted during study were mild that include nausea, vomiting, giddiness, flushing, hypotension, and injection site reactions (Table 3). About 16% in FCM group and 26% of patients in ISC group reported adverse effects. One case in FCM group had severe hypersensitivity reaction. The patient had developed hypertensive urgency, mild crepitations in chest, dyspnea, tachycardia, and ran a temperature of 100.6°F. She was given injection chlorpheniramine maleate, hydrocortisone, paracetamol, furosemide, labetalol, and oxygen inhalation among resuscitative measures. Patient responded very well and was stabilized in 2 h.

## DISCUSSION

Anemia is the most common cause of maternal morbidity and mortality, especially in the post-partum period [10]. According to the WHO, anemia accounts for nearly 40% of maternal deaths in the third world. In India, anemia contributes to 10–15% of maternal deaths [11]. Anemia is defined as deficiency of red blood cells or low hemoglobin commonly seen in women of marriage and childbearing age and is more prevalent in rural and economically backward classes. Low socioeconomic status causes poor maternal health because of illiteracy, customary beliefs, refusal for taking nutritional supplements/health services provided by the government, plight of women in society, and lack of personal hygiene all compromising the quality of female life. Iron deficiency anemia in the postpartum period is quite common and deserves special attention because of its potential consequences [12].

Most of the studies regarding use of FCM and ISC in PPIDA have been carried out in western population. The first study on the use of

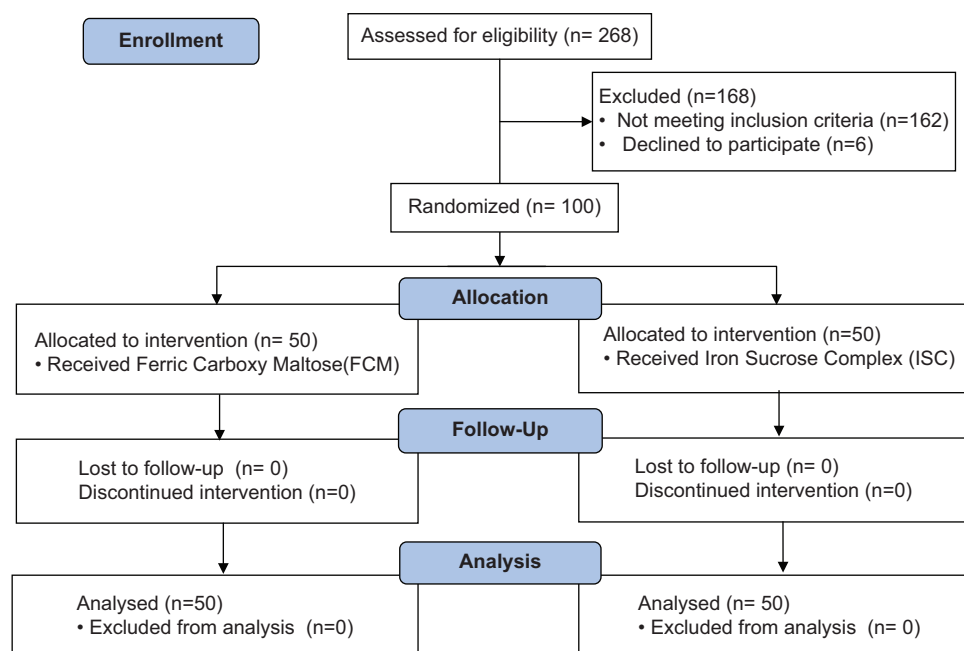


Fig. 1: Consort flow diagram

Table 1: Demographic profile of patients

Epidemiological Data	FCM (%)	ISC (%)
Age( in years)	23.1±3.52	22.5±3.54
Parity		
<3	62	62
≥3	38	38
Residence		
Rural	46	56
Urban	54	44
Literacy level		
Illiterate	16	18
Literate	84	82
Food habits		
Vegetarian	72	78
Non-vegetarian	28	22
Body mass index	21.6±1.4	23.5±1.8
IFA prophylaxis		
Received	74	68
Did not receive	26	32

FCM versus iron sucrose for treatment of iron deficiency anemia in pregnancy was published by Christoph *et al.* [13]. The study concluded comparable safety and tolerability of FCM to ISC, the former offering an advantage of much higher iron dosage at a time reducing the need for repeated administration, thus decreasing patient discomfort.

In our study, mean age of the participant women was 22.8 years with the majority belonging to poorly educated strata. Our results are in accordance with Garg *et al.* [14] who reported 25.30 years as mean age with the majority belonging to poorly educated strata. On the contrary Breymann [15] reported mean age to be 27.7 years and most of the study population belonged to a high literacy stratum in their study on use of ISC in pregnancy and postpartum period.

In our study, the mean rise in Hb was 2.3 g/dL versus 1.61 g/dL; ( $p < 0.001$ ) after 2 weeks of treatment with FCM and ISC, respectively. Our finding was in accordance with several other studies. Garg *et al.* [14] who showed mean Hb to be increased by 2.52 g/dL in FCM group and 1.95 g/dL in iron sucrose groups after 2 weeks of treatment. This result was further supported by that of Patel *et al.* [16]. As per their discourse, mean rise of Hb in FCM group was 4.6 g/dL as compared to

3.5 g/dL in iron sucrose group after 6 weeks of treatment. Van Wyck *et al.* [17] reported increase of mean Hb by 2 g% and 3 g% at 1<sup>st</sup> week and 3–4 weeks, respectively, post-FCM treatment. Patel *et al.* [18] estimated Hb level in pregnant women pre- and post-iron therapy. They observed that Hb levels increased by 2.6 g%/and 1.8 g% in those receiving FCM and ISC, respectively, after 3 weeks of treatment. Rathod *et al.* [19] reported increase of Hb by 2.4 g/dL and 3.4 g/dL after 2 and 6 weeks of FCM therapy.

We also compared RBC indices such as, MCV, MCH, and MCHC in both the groups before and after the therapy. Improvement was observed in these parameters, in both groups after the therapy. The RBC indices MCV and MCH showed significant increase of 16%, 5% and 10%, 1%, respectively, in FCM and ISC groups. Further, the improvement was significant in those patients receiving FCM as compared to ISC. Our results were similar to that of Sumathy and Arulmozhi [20] who showed rise of MCV from 78.94fL to 86.28fL in FCM group and from 80.12fL to 84.22fL in iron sucrose group after 2 weeks of therapy. However, MCHC in the present study showed increase of 7% and 4%, respectively, in FCM and ISC group but failed to rise significantly in any of the groups.

Earliest response to therapy was seen by increase in reticulocyte count in both the groups after 2 days of respective treatments. Reticulocyte percentage was significantly better in FCM group suggesting its better hematopoietic function than ISC. Our results are in accordance to Ikuta *et al.* [21] who also reported significant increase in reticulocyte after 1 week of FCM administration.

Adverse drug reactions do occur with parenteral iron therapy. In our study, 16% of FCM cases and 26% of ISC cases underwent adverse drug reactions. The incidence of adverse reactions reported so far in different studies is between 3% and 24% [9,16,22]. In general, our results were in concordance with other studies which have shown safe and efficient use of FCM in postpartum period as a prospectively better alternative to other complex therapy. Patel *et al.* [18] reported that 6% of patients receiving FCM and 10% of patients receiving ISC showed the side effects. Likewise in the study of Patel *et al.* [16], the incidence of adverse drug reaction was 3% and 7%, respectively. As per Garg *et al.* [14], the percentage of patients showing side effects was 12% for FCM group and 20% of ISC group. On evaluation of the adverse effects post-therapy among the patients in both groups, we found common adverse effects to be nausea, vomiting, pain at injection site, and dizziness.

**Table 2: Effect of IV Ferric carboxymaltose and IV Iron sucrose complex on mean hemoglobin level and RBC indices: MCV, MCH, and MCHC**

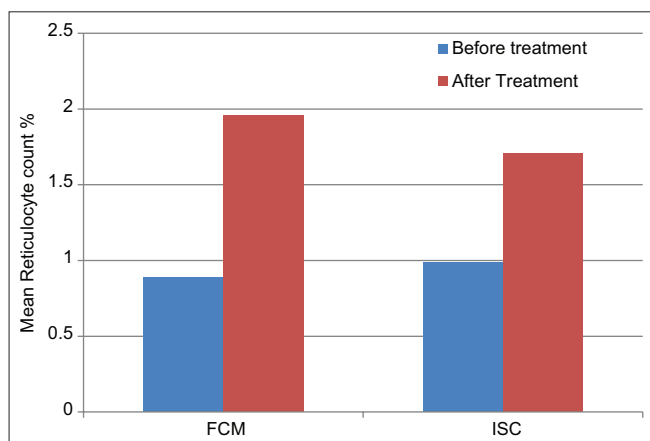
Parameters	FCM		ISC		Inter group "p"-value
	Pre t/t	Post t/t	Pre t/t	Post t/t	
Mean Hb (g/d L)	8.63±0.47	10.93±0.58	8.58±0.55	10.19±0.39	**p<0.01
MCV (f L)	74.25±4.23	86.13±3.79	72.11±5.34	75.54±3.37	***p<0.001
MCH (pg)	27.34±1.52	29.98±1.83	27.86±1.34	28.14±1.69	**p<0.01
MCHC (g/d L)	30.12±1.82	32.33±2.08	29.88±2.08	31.23±1.99	p>0.05

FCM: Ferric carboxymaltose, ISC: Iron sucrose complex, MCV: Mean corpuscular volume, MCH: Mean corpuscular haemoglobin, MCHC: Mean corpuscular haemoglobin concentration

**Table 3: Adverse drug reactions reported after treatment with ferric carboxymaltose and IV iron sucrose complex**

Adverse drug reactions	FCM	ISC
Giddiness	1	1
Nausea	1	3
Vomiting	2	1
Injection site reactions	1	2
Flushing	2	1
Hypotension	0	1
Hypersensitivity reactions	1	4
TOTAL	08	13

FCM: Ferric carboxy maltose, ISC: Iron sucrose complex

**Fig. 2: Effect of IV Ferric carboxymaltose versus IV Iron sucrose complex on mean reticulocyte count percent. FCM: Ferric carboxymaltose, ISC: Iron sucrose complex**

Less adverse reactions due to FCM in our study might be due to the fact that FCM, due to its non-dextran containing molecular structure, is relatively less immunogenic, has a near neutral pH, and possesses physiological osmolarity [17]. However, one case in FCM group in our study had a severe hypersensitivity reaction and was stabilized in 2 h after instituting emergency resuscitative measures. There are very few reports of hypersensitivity reactions with FCM as compared to ISC. Earliar Thanusubramanian *et al.* [23] had reported a single case of hypersensitivity reaction with FCM after test dose whereas Sridhara *et al.* [24] had reported delayed hypersensitivity with subsequent doses of FCM. Overall, FCM appeared to have relatively better tolerance with fewer side effects as compared to ISC. However, larger sample size, long duration of therapy and follow-up, measurements of serum iron, serum ferritin, transferrin saturation, and total iron binding capacity along with marrow iron stores and systematic reviews with meta-analysis are needed for further factual evaluation.

## CONCLUSION

Thus, the authors conclude that treatment of PPIDA using FCM in single large dose is more effective, safe, and promising as compared to other

preparations like ISC which are required in small and multiple doses. Further FCM group patient showed better satisfaction rate and lesser hospital stay. FCM permitting single large dose administration makes it an attractive alternative in terms of safety, efficacy, feasibility, and resource utilization. All these shall add to the widespread acceptance of FCM in near future.

## DECLARATION OF PATIENT CONSENT

The authors certify that they have obtained all appropriate patient consent.

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## AUTHORS CONTRIBUTION

Saroj Kothari: Study design, preparation of data, draft of manuscript, interpretation of results, finalization of manuscript, and revision of manuscript, Shiralee Runwal: Concept, study design, review of literature, interpretation of results, revision of manuscript, and statistical analysis.

## CONFLICTS OF INTEREST OF AUTHORS

There are no conflicts of interest.

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Nil.

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