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Comparative Efficacy of Iron Sucrose and Ferric Carboxymaltose in Iron Deficiency Anemia: A Randomized Controlled Study

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ABSTRACT
Background: Anemia is recognized as the most prevalent hematological condition worldwide, affecting nearly one-fourth of the global population. Iron deficiency anemia alone impacts almost one billion individuals. In view of this high burden, the current study aimed to assess and compare the efficacy of intravenous iron sucrose and ferric carboxymaltose in postpartum women.
Methods: This two-year randomized controlled trial was carried out in the Department of Obstetrics and Gynecology at Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR), Burla, between November 2017 and October 2019. A total of 123 women diagnosed with iron deficiency anemia were enrolled in the study.
Result- The mean age of participants of the iron sucrose therapy group was 24.5±11.3 and that of the FCM group was 25.6±10.1. Mean BMI in the iron sucrose-treated group was 20.16±2.51 and in the FCM-treated group was 20.11±3.4. In the injectable iron sucrose therapy-treated group, at the 6th week, the mean hemoglobin was 9.96±0.74. In the group treated with injectable ferric carboxymaltose (FCM), the mean value was 101.85 ± 1.14. Ferric carboxymaltose demonstrated significantly greater effectiveness than iron sucrose in the management of postpartum iron deficiency anemia, with a p-value <0.001, indicating a highly significant difference.
Conclusion- Ferric carboxymaltose showed superior effectiveness over iron sucrose in the treatment of postpartum women with iron deficiency anemia. Its use was linked to a lower incidence of adverse effects and higher patient adherence, suggesting that it is a more favorable treatment option in this population

Key-words: Iron sucrose, Ferric carboxy maltose, Anemia, Iron deficiency anemia, Post-partum, Pregnancy.

INTRODUCTION
Anemia is recognized as a significant contributor to maternal morbidity and mortality worldwide. The World Health Organization (WHO) estimates that around 20% of maternal deaths are linked to anemia, which remains highly prevalent in developing countries, including India [1].

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This condition is characterized by a diminished oxygen-carrying capacity of red blood cells, leading to inadequate tissue oxygenation. Postpartum anemia often develops due to pre-existing anemia during pregnancy, which is further aggravated by acute blood loss during delivery [2].

The World Health Organization (WHO) defines anemia during pregnancy as a hemoglobin (Hb) concentration of less than 11 g/dL. In India, the Indian Council of Medical Research (ICMR) classifies anemia in pregnant women as mild (Hb 10.0–10.9 g/dL), moderate (Hb 7.0–9.9 g/dL), severe (Hb 4.0–6.9 g/dL), and very severe (Hb <4.0 g/dL) [3]. When other confounding conditions are absent, a serum ferritin level below 12–15 µg/L is considered indicative of iron deficiency [4].

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Postpartum anemia, defined as a hemoglobin concentration under 11 g/dL, is a common obstetric complication, typically resulting from a combination of pre-existing iron deficiency and blood loss during childbirth [5]. Globally, of the approximately 500,000 maternal deaths occurring annually in relation to delivery, nearly 20% are attributed to peripartum hemorrhage and anemia. Iron deficiency during pregnancy, compounded by delivery-related blood loss, constitutes the primary cause of postpartum anemia. While normal peripartum blood loss averages around 300 mL, excessive bleeding exceeding 500 mL is reported in approximately 15% of women [6].

Currently, there is no uniform consensus on the management of postpartum anaemia, and clinical practices vary across institutions. In most settings, iron supplementation remains the mainstay of treatment, while blood transfusion is reserved for severe cases. However, blood transfusion is associated with several potential risks, including transfusion of incompatible blood, anaphylactic reactions, and transmission of infections, all of which can pose serious hazards for young mothers. In addition, the limited availability of blood products at a national level further necessitates that transfusion be considered a last resort in otherwise healthy postpartum women [7]. Parenteral iron therapy has been shown to achieve a more rapid and pronounced increase in hemoglobin levels than oral iron supplementation, while minimizing the risks associated with blood transfusion. Therefore, parenteral iron therapy is indicated when oral iron is contraindicated due to GI side effects [8].

Iron dextran and iron sorbitol citric acid have been in use for many years; however, concerns regarding unpredictable anaphylactic reactions associated with these conventional formulations have limited their widespread utilization [9]. Iron sucrose has long been employed for intravenous treatment of postpartum iron-deficiency anemia. Its administration, however, is restricted to smaller doses because higher doses are associated with an increased risk of both local and systemic adverse effects [8]. More recently, ferric carboxymaltose has become available, offering the advantage of delivering larger doses more rapidly. Its physiological osmolarity and near-neutral pH (5.0–7.0) allow higher single doses to be safely administered over a shorter infusion time [10]. Both are newer parenteral iron formulations. As they lack the dextran moiety, the incidence of anaphylactic reactions associated with their use is significantly lower [11].

The present study aimed to compare the increase in hemoglobin levels between postpartum women receiving iron sucrose and those treated with ferric carboxymaltose (FCM) injections for iron-deficiency anemia. Additionally, the study sought to assess the demographic characteristics of the anemic patients.

MATERIALS AND METHODS

Study Design- This research was a randomized controlled trial conducted in the Department of Obstetrics and Gynecology at Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR), Burla. The study was conducted over two years, from November 2017 to October 2019.

Study population- A Total of 123 patients with Hb level <10 gm/dl on day 2 of post-partum period post-partum anemia was enrolled in the study. So, the patients included were women with IDA with Hb level of <10g/dl on day 2 of post-partum period who cannot tolerate oral iron. The excluded participants were patients with History of anemia due to causes other than iron deficiency, such as patients suffering from chronic kidney disease or rheumatoid arthritis, or currently on myelosuppression therapy, or treated with erythropoietin within 30 days, or those who are hypertensive to inj. FCM or inj. Iron Sucrose, or hemodynamically unstable patients or patients suffering from renal disease, liver disease, sickle-cell anemia, hemochromatosis or other iron storage disorders.

Data collection- Informed consent has been obtained from the individuals participating in the study. Demographics such as name, age, rural/urban residence, height, weight, and diet preferences were collected. In addition, variables such as birth order, birth spacing, and number of parities were recorded.

Study procedure- Participants were randomly allocated into two groups: one receiving iron sucrose therapy and the other receiving ferric carboxymaltose (FCM) therapy. In the iron sucrose group, the total iron requirement for each patient was calculated and rounded to the nearest 100 mg. A 200 mg dose of iron sucrose was prepared by diluting it in 200 mL of 0.9% normal saline and

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administered intravenously over 15 minutes. Additional doses were given on alternate days as needed, ensuring that the total weekly dose did not exceed 800 mg.

In the FCM group, the ferric carboxymaltose dose was determined according to the calculated iron deficit, rounded to the nearest 100 mg. The calculated dose was then diluted in 250 mL of normal saline and administered intravenously over 15 minutes. The maximum single dose allowed was 1000 mg, which could be given either daily or weekly. The iron deficit for all participants was determined using the Ganzoni formula.

{Body weight in kg× (Target Hb-Current Hb) ×2.4} +500

The factor 2.4 is calculated based on the average blood volume, which constitutes approximately 7% of body weight, and the iron content of hemoglobin, estimated at 0.34%. Accordingly, the calculation is expressed as 0.07 × 0.0034 × 100 = 2.4, representing the conversion from g/dL to mg.

Statistical Analysis- Data analysis was carried out using SPSS version 24 (SPSS Inc., Chicago, IL, USA). Continuous variables were reported as mean ± standard deviation, whereas categorical variables were summarized as frequencies and percentages. Differences in mean values across groups were evaluated using analysis of variance (ANOVA), and p-values<0.05 were considered statistically significant.

Ethical Clearance- The study protocol received ethical clearance from the Institutional Ethics Committee, VIREC, Burla.

RESULTS

Table 1 comprises details of demographic factors. The mean age of participants in the iron sucrose therapy group was 24.5±11.3, and that of the FCM group was 25.6±10.1. The number of females who gave birth for the first time (i.e., primipara) was 21 (30%) in the iron sucrose therapy group and 17 (32%) in the FCM group. In addition, BMI, place of residence, level of education, and baseline laboratory parameters such as hemoglobin and ferritin have also been provided.

Table 1: Patient Demographics

Parameters	Iron sucrose therapy group (n=70)	FCM group (n=53)
Age (in years)	24.5±11.3	25.6±10.1
BMI (kg/m^2)	20.16±2.51	20.1±3.4
Rural habitat	49 (70%)	27 (51%)
Urban habitat	21 (30%)	26 (49%)
Primi Para	21 (30%)	17 (32%)
Multi Para	49 (70%)	36 (68%)
Level of Education		
Illiterate	23(32.8%)	12(22.6%)
Primary	19(27.1%)	24(45.2%)
Secondary	15(21.4%)	8(15.0%)
Graduate and above	13(18.5%)	9(16.9%)
Baseline Haemoglobin (gm/dl)	8.32±0.56	8.16±0.74
Baseline Ferritin (mg/dl)	33.72±20.42	26.31±20.71

Data is presented as either mean±SD or n (%)

Fig. 1 shows the age-wise distribution of patients in two intervention groups. Most patients were 26–30 years old, followed by 21–25 years, with fewer in the <20 and >30 years age groups. Blue bars: IV Iron Sucrose; Orange bars: IV FCM.

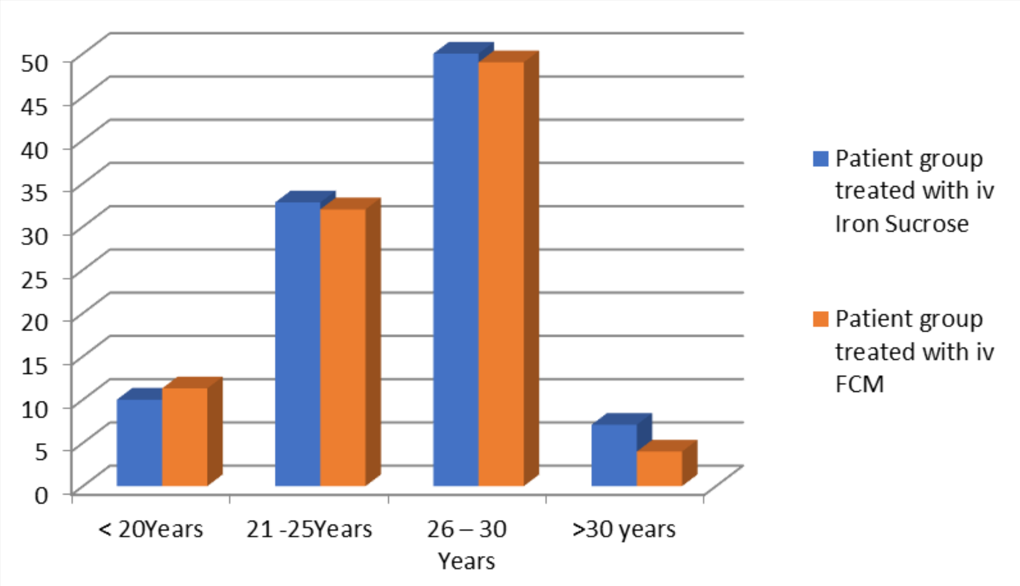

Fig. 1: Distribution of patients according to age in both intervention groups

Details of the comparison of changes in laboratory parameters, such as hemoglobin and ferritin, at day 2 and at the end of the 6th week in participants receiving iron sucrose therapy have been provided in Table 2. Changes in both parameters were significant at p<0.001.

Table 2: Comparison of changes in parameters in group of iron sucrose therapy

Parameters in Injectable Iron Sucrose Group (n=70)	Measure at Day 2	Measure at 6th Week	p-value
Hemoglobin(gm/dl)	8.3±0.5	9.9±0.7	<0.001
Ferritin(mg/dl)	33.7±20.4	102.6±28.4	<0.001

Data is presented as either mean±SD or n (%); ANOVA was used to obtain p-value
p-value<0.05 was regarded as statistically significant.

Comparison of changes in parameters such as hemoglobin and ferritin in the FCM group is presented in Table 3. Changes in both parameters were significant at p<0.001.

Table 3: Comparison of changes in parameters in FCM group

Parameters in Injectable FCM Group (n=53)	Measure at Day 2	Measure at 6th Week	p-value
Hemoglobin(gm/dl)	8.1±0.7	10.8±1.1	<0.001
Ferritin(mg/dl)	26.3±20.7	185.4±33.2	<0.001

Data is presented as either mean±SD or n (%); ANOVA was used to obtain p-value
p-value<0.05 was regarded as statistically significant

DISCUSSION

In our study, demographics were compared between the injectable iron sucrose therapy group and the injectable FCM therapy group with respect to age and BMI.

Anemia was most prevalent among women aged 26–30 years (49.6%) and least prevalent in those over 30 years. A similar observation was reported by Yadav UK *et al.*, who found the highest prevalence of anemia in the 20–24-year age group [12]. Similar results were obtained from the research of Gautam et al. and Kisioglu *et al.* [13,14].

Of 123 patients, 69.1% were multipara, and 30.89% were primipara and anemic. Similar results were conducted by Bodnar in the USA [15]. A study conducted by Ayesha

Farooq in Islamabad in 2011 showed that nearly 72% of multiparous subjects had iron deficiency with serum ferritin <20 µg/mL [16]. Between the groups, anaemia was more common in the iron sucrose group (70%) than in the FCM therapy group (68%).

The study showed that anaemia was more prevalent in the illiterate and primary education groups, i.e., 32.8% and 27.1% in the iron sucrose therapy group and 22.2% and 45.2% in the FCM therapy group. Similar results were reported by Singh *et al*., who found a high incidence of anemia among illiterate and primary education groups [17]. So, lack of education also contributed to the prevalence of anaemia.

Comparison of changes in parameters such as hemoglobin and serum ferritin at the 6th week of the postpartum period relative to baseline showed highly significant differences between the iron sucrose and FCM therapy groups. A randomized controlled trial assessing ferric carboxymaltose (FCM) in postpartum anemia found that patients receiving FCM reached hemoglobin levels above 12 g/dL more quickly, maintained these levels by day 42, achieved a hemoglobin rise of 3 g/dL or greater in a shorter period, and exhibited higher serum ferritin and transferrin saturation compared to other treatments [11]. Similarly, Rathod *et al.* reported greater improvements in hemoglobin and serum ferritin in patients receiving FCM compared with those treated with iron sucrose [18].

In the current study, patients treated with ferric carboxymaltose (FCM) demonstrated significantly higher mean hemoglobin and serum ferritin levels compared to those receiving injectable iron sucrose (p<0.001). Similar findings were observed by Singh *et al.* [19], who reported that among 200 postpartum women with anemia, a substantially greater proportion in the FCM group attained hemoglobin levels exceeding 11 g/dL. By day 21 post-treatment, 88 women in the FCM group exhibited a hemoglobin increase of 2 g/dL. In contrast, only 24 women in the iron sucrose group achieved a comparable rise, a statistically significant difference (p<0.001). Both groups also demonstrated increased mean baseline hemoglobin and ferritin at six weeks (p=0.0). In the present study, while serum ferritin showed a greater rise, hemoglobin increment was comparatively smaller.

Patel *et al.* [20] observed a similar trend, reporting notable increases in hemoglobin and ferritin at six weeks postpartum. These findings indicate that intravenous ferric carboxymaltose leads to faster hemoglobin restoration than iron sucrose during the postpartum period.

The study emphasized that both prevention and management of postpartum anemia are vital for lowering maternal mortality and morbidity, improving overall quality of life, and promoting stronger mother-child bonding. The study's limitation was its sample size, as a larger sample would have helped confirm the results more reliably. Another limitation is the study's specific design. A better design may have helped in the configuration of results.

CONCLUSIONS

The study demonstrated that both ferric carboxymaltose (FCM) and iron sucrose led to significant improvements in hemoglobin and serum ferritin levels during the postpartum period. Notably, patients treated with FCM experienced a comparatively greater rise in both hemoglobin and ferritin compared to those receiving iron sucrose. Additionally, FCM was observed to replenish iron stores more rapidly, supporting its use as a safe and effective alternative to blood transfusion in postpartum women.

CONTRIBUTION OF AUTHORS

Research concept- Anima Kumari Sethy, Smruti Ranjan Beher

Research design- Lipsa Patra, Rabindra Naik

Supervision- Anima Kumari Sethy, Rabindra Naik

Materials- Anima Kumari Sethy, Smruti Ranjan Beher

Data collection- Lipsa Patra, Rabindra Naik

Data analysis and interpretation- Anima Kumari Sethy, Rabindra Naik

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Article editing- Anima Kumari Sethy, Smruti Ranjan Beher

Final approval- Lipsa Patra, Rabindra Naik

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