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Comparing the Efficacy of Iron sucrose with Ferric carboxy maltose in Post partum iron deficiency anemia -A Prospective Observational Study

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KEYWORDS

Iron sucrose, Ferric carboxy maltose, Iron deficiency anemia (IDA), Post-partum, Pregnancy, Post-partum anemia

ABSTRACT:

Introduction: Anaemia is the most common disorders of blood, affecting about a quarter of the people globally. Iron deficiency anaemia affects nearly one billion people. So, the study was conducted to compare efficacy of iron sucrose therapy with ferric carboxymaltose intravenously in post-partum iron deficiency anemia.

Objectives: To compare the effect of iron sucrose with ferric carboxy maltose in postpartum iron deficiency anemia.

Methods: It was a prospective observational study conducted in the Department of obstetrics and gynecology, Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR), Burla, Odisha, India. The study was held from November 2017 to October 2019. Total 123 patients with iron deficiency anemia on postpartum day 2 were enrolled in the study.

Results: The mean age of participants of iron sucrose therapy group was 24.5±11.3 and that of FCM group was 25.6±10.1. Mean BMI in iron sucrose treated group was 20.16 ± 2.51and in FCM treated group was 20.11 ± 3.4. In injectable iron sucrose therapy group on 6th week, mean haemoglobin was 9.96±0.74 and in injectable FCM therapy group it was 101.85±1.14 with p-value <0.001. Similarly, the mean serum ferritin level in the iron sucrose therapy group was 102.67 ± 28.42, compared to 185.43 ± 33.25 in the FCM therapy group, also with a p-value of < 0.001. The mean haemoglobin and serum ferritin levels in the FCM therapy group were significantly higher than those in the iron sucrose therapy group (p < 0.001) which was statistically significant.

Conclusions: From our study we concluded that, Ferric carboxy maltose was more effective in correcting postpartum IDA than iron sucrose.

1. Introduction

Anemia is one of the major contributing factors in maternal mortality and morbidity. According to WHO it contributes to 20% of maternal deaths and is widely prevalent in developing countries like India [1]. Anemia is a pathological condition in which the oxygen carrying capacity of the red blood cells is insufficient to meet the body's needs. The major causes of postpartum anemia are anemia during pregnancy combined with acute blood loss at delivery [2].

WHO defines anaemia in pregnancy as haemoglobin (Hb) <11gm/dl. In India, the ICMR classification of anaemia in pregnancy is: 10.9-10 gm% as mild,9.9-7 gm % as moderate and 6.9-4 gm% as severe anaemia and very severe anaemia is Hb <4 gm/dl [3]. In absence of interfering factors, serum ferritin <12-15 µg/l is considered as iron deficiency [4].

According to WHO, postpartum anaemia (PPA) is haemoglobin level <11gm/dl at 1week postdelivery, and this is a very common obstetric problem usually due to combination of blood loss during delivery and preexisting iron deficiency [5]. As per ICMR immediate postpartum anemia is Hb level below 10 g/dl within the first 48 hours after delivery and Postpartum anemia at 1week is Hb< 11gm% at 1 week after delivery [3]. It has been estimated that of the ~500,000 maternal deaths occurring each year on a global scale in association with delivery, 20% are caused by peripartum haemorrhage and anaemia. Major cause of postpartum anaemia is iron deficiency during pregnancy in association with blood

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loss during delivery. Normal peripartum blood losses are approximately 300 ml, but blood loss >500 ml occurs in 15% of the women [6].

At the present time there is no consensus on the management of Postpartum anaemia and clinical practice varies from one clinic to another. The standard approach to treatment in the majority institutions is iron supplementation while blood transfusion reserved for more severe cases. But there are a number of hazards of blood transfusion including transfusion of wrong blood, anaphylaxis and risk of infections any of which would be hazardous for the young mother. These hazards, together with the national shortage of blood products, mean that transfusion should be viewed as a last resort in otherwise young and healthy women [7]. Parenteral iron has been shown to produce a faster and greater increase in Hb concentration than oral supplementation without the risks associated with a blood transfusion. Therefore, parenteral iron therapy is possible in cases where oral iron is contraindicated due to its gastrointestinal side effects [8].

Iron dextran and iron sorbitol citric acid are widely used since a long time however threat of unpredictable anaphylaxis due to these conventional preparations prevents their widespread use [9]. Iron sucrose has been used for years in the post-partum period for parenteral therapy of iron deficiency anaemia. However, its use is limited to lower doses due to local and systemic side effects at higher doses [8]. Recently, ferric carboxy maltose (FCM) has been introduced which can be used both at high doses and at a rapid rate as it has physiological osmolarity and neutral PH (5.0-7.0) which makes it possible to administer its higher single dose over shorter period [10]. Both of these are newer parenteral iron products which do not contain the dextran moiety and incidence of anaphylaxis with these products is markedly lower [11].

This study was done to compare the rise in haemoglobin between injection iron sucrose versus injection FCM group in postpartum iron deficiency anemia. Also, to evaluate the demographic profile of patients with anemia.

2. Objectives

Primary objective was to compare the rise in haemoglobin and serum ferritin level in women receiving injection iron sucrose and injection FCM in postpartum iron deficiency anaemia. Secondary objectives were to know the predisposing factors of anaemia and to know the demographic profile of participants in both the groups with anaemia

3. Methods

Study Design- This study was a prospective observational study conducted in the Department of obstetrics and gynaecology, Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR), Burla, Odisha, India. The study was held from November 2017 to October 2019.

Study population- Total 123 patients with Hb level <10 gm/dl on day 2 of post-partum period were enrolled in the study. So, the patient included were women with IDA with Hb level of <10g/dl on day 2 of post-partum period those cannot tolerate oral iron. The excluded participants were patients with History of anemia due to causes other than iron deficiency such as patient suffering from chronic kidney disease or rheumatoid arthritis, or currently on myelosuppression therapy, or treated with erythropoietin within 30 days, or those who are hypersensitive 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 disorder.

Data collection- Informed consent was obtained from the individuals for participation in the study. Demographics details such as name, age, rural/urban habitat, height, weight, socioeconomic status, diet preference was collected. Other than this, variables such as birth orders and birth spacing along with number of parities were recorded.

Study procedure- The enrolled participants were randomly allocated into two groups naming Iron sucrose therapy group (n=70) and FCM therapy groups (n=53). Patients of iron sucrose therapy group received intravenous infusion as per calculated deficit and rounded to nearest multiple of 100. Two hundred milligram of iron sucrose was diluted in 200ml of 0.9% normal saline and given over 15 minutes. Repeat dose if needed was given in alternate days keeping in mind that maximum dose of iron should not exceed more than 800mg/week. While patients of FCM therapy group received injection ferric carboxy maltose as per calculated iron deficit and rounded to nearest multiple of

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100. Calculated dose was diluted in 250ml normal saline wand was given over 15 mins. Single maximum dose of 1000mg can be given per day/week. Iron deficit was calculated using GANZONI's formula.

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

The factor 2.4 is derived from blood volume, which is 7% of body weight and iron content of Hb, which is 0.34%. 0.07 × 0.0034 × 100 = 2.4 (conversion from g/dL to mg).

Outcome measures- The changes in Hb and serum ferritin levels, patient's compliance at 6th weeks after treatment was measured

Statistical analysis- Data analysis was conducted using the SPSS v.24 software (SPSS Inc., Chicago, IL, USA). Continuous variables are presented as mean ± SD or n (%). Analysis of variance (ANOVA) was used to compare mean values of the respective groups. p-value was considered significant at <0.05.

Ethical clearance- Ethical approval was obtained from Institutional Ethics Committee, VIREC, Burla dated 28.11.2019. Approval number- 2017/I-F-CT-01/048.

4. Results

The mean age of participants in the iron sucrose therapy group was 24.5 ± 11.3 years, while the mean age in the ferric carboxymaltose (FCM) group was 25.6 ± 10.1 years. The number of females who had given birth once (primipara) was 21 (30%) in the iron sucrose therapy group and 17 (32%) in the FCM group, indicating comparable figures between the two groups. Mean BMI in KG/m2 in iron sucrose treated group was 20.16 ± 2.51and in FCM treated group was 20.11 ± 3.4.

In iron sucrose group, 49 patients i.e. 70% belong to rural population and 21 patients i.e.30% belongs to urban population. In FCM group, 27 patients i.e. 51% belong to rural population and 26 patients i.e.49% belongs to urban population. Most of the women were of age group 26-30 years i.e. 49.6%, 32.5% of age group 21-25 years, 10.6% in the age group of <20 years and 7.3% in the age group of >30 years.

According to modified Kuppuswammy classification out of 123 cases, 17.1% (i.e. 21) were from upper middle class,16.2% (i.e.20) from lower middle class, 54.5% (i.e. 67) from upper lower class and 12.2% (i.e. 15) from lower socioeconomic status. None of the women from was from upper socioeconomic status. In the iron sucrose group 23(32.8%) were illiterate, 19(27.1%) had primary education, 15(21.4%) had secondary education,13(18.5%) were graduated. In the FCM group 12(22.6%) were illiterate, 24(45.2%) had primary education, 8(15.0%) had secondary education,9(16.9%) were graduated.

Table 1: Baseline Haemoglobin (Hb) and Ferritin levels in both groups:

Parameters	**Iron Sucrose (n=70) group**	**FCM (n=53) group**
Baseline Hb(gm/dl)	8.32 ± 0.56	8.16 ± 0.74
Baseline Ferritin(mg/dl)	33.72 ± 20.42	26.31±20.71

Table 2 and 3 below show the details on the comparison of changes in laboratory parameters, such as haemoglobin and ferritin, at day 2 and at the end of the 6th week post-delivery for participants receiving iron sucrose and FCM therapy respectively. Changes in both parameters were found to be significant with a p-value of <0.001.

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

Iron Sucrose Group (n=70)	**Measure at Day 2**	**Measure at 6th Week**	**p-value**
Haemoglobin (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 was considered significant at <0.05

Table 3. Comparison of changes in parameters in FCM group:

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FCM Group (n=53)	Measure at Day 2	Measure at 6th Week	p-value
Haemoglobin (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 was considered significant at <0.05

In the group receiving injectable iron sucrose therapy, the mean haemoglobin level at the 6th week was 9.96 ± 0.74, while in the group receiving injectable ferric carboxymaltose (FCM) therapy, it was 101.85 ± 1.14, with a p-value of < 0.001. Similarly, the mean serum ferritin level in the iron sucrose therapy group was 102.67 ± 28.42, compared to 185.43 ± 33.25 in the FCM therapy group, also with a p-value of < 0.001. The mean haemoglobin and serum ferritin levels in the FCM therapy group were significantly higher than those in the iron sucrose therapy group (p < 0.001) (**Table 4**)

Table 4: comparison of changes in parameters compared between both the intervention groups at 6th week of post-partum:

Parameters at end of 6th Week	Iron Sucrose group (n=70)	FCM group (n=53)	p-value
Haemoglobin (gm/dl)	9.96 ± 0.74	10.85 ±1.14	***<0.001***
Ferritin (mg/dl)	102.67 ± 28.42	185.43± 33.25	***<0.001***

5. Discussion

Anemia in the postpartum period may be associated with an increased prevalence of breathlessness, tiredness, palpitation and maternal infections, particularly of the urinary tract. Such symptoms may cause women to experience difficulty in caring for their baby, and may influence the emotional bond the mother has with her baby. Treatment of postpartum anaemia is very important to build up iron reserves in the puerperium, to have better quality of life and to minimize incidence of anaemia in next pregnancy. So, the following study was done to see whether giving iron by intravenous route in form of ferric carboxymaltose to women with postpartum anemia results in higher haemoglobin concentrations and improved iron stores than using inj. iron sucrose

In our study, anemia was most prevalent in the age group of 26-30 years, accounting for 49.6%, while the least prevalence was observed in those over 30 years. A similar study conducted by Yadav UK et al. in 2021 reported that the highest prevalence of anemia was in the 20-24 age group [12]. Comparable results were also found in the study conducted by Gautam et al. and Kisioglu et al [13, 14].

Out of 123 patients, 69.1% were multiparous, and 30.89% of primipara were anaemic. Similar results were reported by Bodnar in the USA [15]. In a study conducted by Ayesha Farooq in Islamabad in 2011, nearly 72% of multiparous women had iron deficiency, with serum ferritin levels below 20 µg/mL [16]. When comparing the two groups in our study, anemia was found to be more prevalent among multiparous patients in the iron sucrose group (70%) as well as in ferric carboxymaltose (FCM) therapy group (68%).

The present study showed a higher prevalence of anemia among the uneducated and primary education groups, with 32.8% and 27.1% in the iron sucrose therapy group, and 22.2% and 45.2% in the FCM therapy group, respectively. Similar findings were reported by AB Singh et al. in 2009, where a higher incidence of anemia was observed in the illiterate and primary education groups [17]. These results suggest that a lack of education may also contribute to the prevalence of anemia.

The comparison of changes in parameters such as haemoglobin and serum ferritin at the 6th week postpartum, from baseline levels in both the iron sucrose therapy and FCM therapy groups, was found to be highly significant. In the group receiving injectable iron sucrose therapy, the mean haemoglobin level at the 6th week was 9.96 ± 0.74, while in the group receiving injectable ferric carboxymaltose (FCM) therapy, it was 101.85 ± 1.14, with a p-value of < 0.001. Similarly, the mean serum

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ferritin level in the iron sucrose therapy group was 102.67 ± 28.42, compared to 185.43 ± 33.25 in the FCM therapy group, also with a p-value of < 0.001.

A randomized controlled trial on ferric carboxymaltose (FCM) injection for postpartum anemia showed that patients treated with FCM were significantly more likely to achieve a haemoglobin level greater than 12 g/dL in a shorter period, with sustained haemoglobin levels >12 g/dL at day 42. They also reached a haemoglobin rise of 3 g/dL or more quickly and attained higher serum transferrin saturation and ferritin levels [11]. A similar study by Rathod S et al. demonstrated a greater rise and replenishment of haemoglobin and serum ferritin levels with FCM compared to iron sucrose [18].

The mean haemoglobin and serum ferritin levels in the FCM therapy group were higher than those in the injectable iron sucrose therapy group, with a p-value <0.001, indicating high statistical significance. Research conducted by Singh et al. in 2016, involving 200 patients with postpartum anemia, revealed that a significantly higher number of women in the FCM group achieved haemoglobin levels >11 g/dL. On the 21st day after therapy, 88 women in the FCM group showed a haemoglobin rise of 2 g/dL, compared to only 24 women in the iron sucrose group, which was also highly significant with a p-value <0.001. The mean baseline haemoglobin and ferritin levels in both the iron sucrose therapy group and the FCM group increased by the 6th week, with a p-value of 0.001. In our study, we observed a greater rise in serum ferritin but a smaller rise in haemoglobin compared to this study [19].

Similar results were observed in a study by Patel J et al. in 2020, where an increase in haemoglobin and ferritin levels was noted at the 6th week of the postpartum period. The study concluded that intravenous ferric carboxymaltose increases haemoglobin levels more rapidly compared to iron sucrose during the postpartum period [20].

The prevention and treatment of postpartum anemia are essential for reducing maternal mortality and morbidity, improving quality of life, and strengthening mother-child bonding. One limitation of the study was its sample size; a larger number of participants could have provided better confirmation of the results. Another limitation was the specific design of the study, as an improved study design may have yielded more robust results.

6. Conclusion

The study concluded that both FCM and iron sucrose have a positive effect on haemoglobin and serum ferritin levels in the postpartum period. The FCM group showed a greater increase in both haemoglobin and serum ferritin compared to the iron sucrose group. FCM also replenishes iron stores more rapidly than iron sucrose and can be considered a safe and effective alternative to blood transfusion during the postpartum period.

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