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Original Research Article

Comparing Outcome of IV Iron Sucrose Versus IV Ferric Carboxymaltose in the Treatment of Iron Deficiency Anaemia in Pregnancy

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Abstract: ***Background:*** Pregnancy-associated iron deficiency anaemia is a widespread complication, which is linked with high morbidity in mothers and their newborns, especially in low- and middle-income countries. The use of intravenous iron therapy is becoming more common as an alternative to oral iron where this approach is ineffective or poorly tolerated but comparative evidence on its use in pregnancy is less well established. ***Aim:*** To compare the efficacy and safety of intravenous iron sucrose and ferric carboxymaltose in the treatment of iron deficiency anaemia among pregnant women. ***Methods:*** This randomised controlled trial was undertaken in the Department of Obstetrics and Gynecology, District Headquarters Hospital, Gujranwala. One hundred and eighty pregnant women with iron deficiency anaemia between 20 and 26 weeks of pregnancy were selected randomly to receive intravenous iron solution in the form of iron sucrose (n=90) or ferric carboxymaltose (n=90). Hemoglobin and serum ferritin levels, which are hematological parameters, were evaluated at baseline and 12 weeks. Clinical outcomes and adverse effects were noted and they were statistically analyzed by using SPSS version 24. ***Results***: The ferric carboxymaltose group had a much higher mean hemoglobin level (11.6 ± 0.8 g/dL) than the iron sucrose group (10.3 ± 0.9 g/dl; $p<0.001$) at the age of 12 weeks. The average increase in hemoglobin was higher with ferric carboxyl maltose (3.3 ± 0.9 g/dL vs. 2.1 ± 0.8 g/dL; $p<0.001$), and the serum levels of ferritin were significantly better (72.4 ± 12.5 ng/mL vs. 48.7 ± 10.2 ng/mL; $p< 0.001$). Fatigue resolution was more common in the ferric carboxymaltose group (84.4% vs. 64.4; $p=0.004$), whereas the necessity to repeat infusion was much less (10.0% vs. 40.0; $p<0.001$). Conclusion: In comparison to iron sucrose, ferric carboxymaltose found to be more convenient and effective intravenous iron preparation for iron deficiency anaemia during pregnancy. It showed better hematological corrective and clinical effects with the same level of safety.

Keywords: Iron deficiency anaemia; pregnancy; ferric carboxymaltose; iron sucrose; intravenous iron; hemoglobin.

INTRODUCTION

Iron deficiency anaemia (IDA) is the most prevalent micronutrient deficiency globally and is disproportionately rampant in pregnant women as they are subject to growth-inductive physiological iron needs (Gamde and Obeagu, 2023). One in every 36-40 pregnant women worldwide is anemic, and iron deficiency is the cause in half of all cases, especially in low- and middle-income nations (Kebede et al., 2025). The growth in iron needs in the course of pregnancy is motivated by growth in maternal red blood cell mass, placental development, and fetal rise which makes women susceptible to iron deposits depletion (Benson et al., 2022). Mechanistically, iron deficiency interferes with haemoglobin production and decreases oxygen delivery to the tissues, which leads to decreased oxygenation of the mother and fetus (Zhao et al., 2022). It is epidemiologically proven that severity of anaemia has a dose-response relationship with the risk of adverse perinatal outcomes (Kebede et al., 2025).

Oral iron supplementation is the initial treatment of mild iron deficiency anaemia, but its usefulness in pregnancy is regularly undermined by gastrointestinal intolerance and impaired absorption (Zhang et al., 2021). Poor adherence is usually caused by nausea, constipation and epigastric discomfort especially during the second and third trimesters of the pregnancy. Also, oral iron bioavailability in pregnant women might be further decreased by inflammatory conditions, as well as the iron regulation involving hepcidin (Benson et al., 2024). Intravenous iron (IVI) makes iron stores fast and predictable to respond to iron and is especially effective during late pregnancy when haemoglobin needs replenishment within a short period before childbirth (Garzon et al., 2020).

Iron sucrose has a favorable safety profile and was utilized in obstetric practice over a number of decades (Govindappagari and Burwick, 2019). However, its usage is restricted with regard to the maximum doses that should be given per infusion in order to have the entire replacement of iron, this requires frequent visits to the hospital (Karakoc et al., 2022). In the case of pregnant populations, the clinical studies have shown that intravenous iron is superior in haemoglobin correction when compared to oral preparations (Cantor et al., 2024). In addition, intravenous treatment eliminates the necessity to receive blood transfusion, thus reducing the dangers of transfusion during the peripartum period (Garzon et al., 2020). Recent preparations such as ferric carboxymaltose allow the administration of big single doses because it consists of stable iron carbohydrate complex. This pharmacokinetic action enables replenishment of iron stores more quickly and a better treatment convenience (Govindappagari and Burwick, 2019).

Although intravenous iron is increasingly used in pregnancy, the clinical practice still lacks uniformity in terms of the formulation used, dosage regimen, and time of administration (Garzon et al., 2020). The available comparative evidence on iron versus ferric carboxymaltose is based on heterogeneous study designs and has been mostly performed in different populations with different baseline level of anaemia (Zhang et al., 2021). Numerous studies in the market are based on laboratory findings like haemoglobin and ferritin concentrations and little is done to determine more generalized maternal or neonatal outcomes (Benson et al., 2021; Raut and Hiwale, 2022). Also, the accessibility of resources and various healthcare facilities might affect the practicability and efficacy of a particular intravenous iron therapy. Lack of consistent outcome measures makes differences between formulations more difficult to interpret (Hansen et al., 2023).

In Pakistan, maternal iron deficiency anaemia is a significant health issue, and its prevalence is estimated at more than 40% in pregnant women (Shahzad et al., 2025). Among the factors, there are poor eating of iron, high fertility rates, short birth intervals, and small access to quality antenatal care services (Zulfiqar et al., 2021). Pakistan has strongly linked maternal anaemia with elevated chances of maternal morbidity, low birth weight, and perinatal mortality (Naz et al., 2024). Even though oral iron supplementation is habitually prescribed, noncompliance and late representation often lead to intravenous iron treatment in tertiary care units. The evidence-based choice of intravenous iron preparations is especially important in Pakistan since the country has a high burden of disease and limited healthcare resources. The purpose of this primary research is therefore to compare the clinical outcomes of iron deficiency anaemia in pregnant women receiving iron sucrose versus ferric carboxymaltose in the Pakistani healthcare setting.

Material and Methods

Study Design and Setting

This research was designed as a randomized controlled trial at the Department of Obstetrics and Gynecology in the Gujranwala Medical College and District Headquarters Hospital, Gujranwala. The hospital is a big tertiary care referral center, which offers antenatal care to a big and heterogeneous population. Randomized controlled design was chosen because it would enable the researchers to directly compare the results between the two intravenous iron preparations and reduce selection bias. The research was conducted after the research synopsis has been approved by the concerned authorities. The study lasted at least six months after the ethical approval was received.

Sample Size Determination

The sample size was determined by the average increase in hemoglobin in the previous studies where in the ferric carboxymaltose group the mean increase in hemoglobin was 3.96 ± 4.19 g/dL and in the iron sucrose group was 2.11 ± 1.72 g/dL with a statistically significant difference at a p-value of less than 0.05. According to these parameters a sample size of 180 patients was calculated, 90 of them were taken in each treatment group. The study power was established at 80% and the level of significance was established at 5% to ensure that there is enough power to support a significant difference between the two interventions.

Sampling Technique and Study Population

The strategy used to recruit eligible participants was non-probability consecutive sampling. The women who became pregnant and had iron deficiency anaemia diagnosed in the ante-partum phase were put on the list of those to be enrolled based on a set of inclusive and exclusion criteria. The inclusion criteria included women aged 18-45years, whose gestational age (calculated since the last menstrual period) was in the range of 20-26 weeks, and non-responsive or

intolerant to oral iron therapy. Patients who had pre-existing anaemia prior to pregnancy, which was characterized by a haemoglobin level below 10 g/dl and those who did not want to give informed consent were excluded. Also, patients with comorbidities like diabetes mellitus, gestational diabetes, hypertension, chronic hepatic, pulmonary, or ischemic heart disease and metabolic or endocrine disorders and coagulation abnormalities were ruled out on the basis of medical record.

Data Collection

After receiving the consent of the Ethical Review Committee, qualified patients were assessed and evaluated in terms of the clinics and laboratory protocols. Complete blood counts were performed on the venous blood samples, analyzed with an automated analyzer and flow cytometry, and serum ferritin levels were determined in the laboratory of the hospital. The lottery method was used to randomly assign the participants to the two equal groups; Group A and Group B. Group A and B were given intravenous iron sucrose and intravenous ferric carboxymaltose respectively. Every patient was administered a test dose before it could be administered so that the reaction could be checked in terms of hypersensitivity. Iron was given as iron sucrose, which was 200 mg in 200 mL of 0.9% normal saline and infused over 30 minutes, and ferric carboxymaltose was given as a maximum dose of 1000 mg in 250 mL of 0.9% normal saline over 45 minutes. After 12 weeks Hemoglobin levels were again determined, and an operational definition calculated the mean increase in hemoglobin. The laboratory staff in the outcome assessment were not made aware of group assignment in order to reduce measurement bias.

Data Analysis

The Statistical Package of Social Sciences (SPSS) version 24 under Microsoft windows were used to analyze data. The quantitative variables such as age, gestational age, body mass index, baseline hemoglobin, baseline ferritin levels, and hemoglobin levels after 12 weeks were reported in mean plus standard deviation. The two groups were compared using Chi-square test of the efficacy of iron sucrose and ferric carboxymaltose. Stratification was used to adjust the potential modifying factors like age, gestational age and body mass index. Chi-square test was also used to perform post-stratification comparisons. The significance level of 0.05 or below was taken to be significant.

Ethical Considerations

The ethical approval of this study was obtained from the institutional review board of District Headquarters Hospital, Gujranwala. Written informed consent was obtained from all participants prior to enrollment.

RESULTS

Demographic Characteristics

The mean age of the participants in the iron sucrose group (28.6 ± 5.4 years) and ferric carboxymaltose group (29.1 ± 5.1 years) was not found to be significantly different (p=0.48). The study population was also homogeneous with even distribution of gestational age and BMI of both groups. There was no significant difference between distribution of parity and so on implying even-handed obstetric traits.

Table 1: Demographic Characteristics of Study Participants (n = 180)

Variable	Iron Sucrose (n=90) Mean ± SD / n (%)	Ferric Carboxymaltose (n=90) Mean ± SD / n (%)	p-value
Age (years)	28.6 ± 5.4	29.1 ± 5.1	0.48
Gestational age (weeks)	23.1 ± 1.9	22.9 ± 2.0	0.52
BMI (kg/m²)	26.8 ± 3.7	27.2 ± 3.5	0.41
Parity ≤2	54 (60.0%)	57 (63.3%)	0.65
Parity >2	36 (40.0%)	33 (36.7%)	0.65

Baseline Clinical and Laboratory Characteristics

There was no statistically significant difference in the baseline hemoglobin concentration between iron sucrose group (8.2 ± 0.7 g/dL) and the ferric carboxymaltose group (8.3 ± 0.6 g/dL) (p=0.36). Likewise, the baseline serum ferritin levels were low and were almost equal between groups with 12.6 ± 4.1 ng/mL in the iron sucrose group and 12.9 ± 4.3 ng/mL in the ferric carboxymaltose group (p=0.64). The indices of the red blood cells also ensured comparability with the mean corpuscular volume 72.8 ± 6.5fL in the iron sucrose group and 73.4 ± 6.2 fL in the ferric carboxymaltose group (p=0.55). Similar values were also obtained in the mean corpuscular hemoglobin of 23.1 ± 2.8 pg in the iron sucrose group, compared to 23.4 ± 2.6 pg in the ferric carboxymaltose group (p=0.47). The red cell distribution width of both groups was high and it was 16.9 ± 2.1% and 17.2 ± 2.0 respectively, with no significant difference observed (p= 0.38). In the iron SEC group, fatigue occurred in 72 patients (80.0%) and in the ferric carboxymaltose group, fatigue was found in 75 patients (83.3%) (p=0.57). Pallor occurred in 69 patients (76.7%) who took iron sucrose and 71 patients (78.9%) who used ferric carboxymaltose (p=0.71).

Table 2: Baseline Clinical and Laboratory Characteristics of Study Participants

Variable	Iron Sucrose (n=90) Mean ± SD / n (%)	Ferric Carboxymaltose (n=90) Mean ± SD / n (%)	p-value
Baseline Hemoglobin (g/dL)	8.2 ± 0.7	8.3 ± 0.6	0.36
Baseline Serum Ferritin (ng/mL)	12.6 ± 4.1	12.9 ± 4.3	0.64
Mean Corpuscular Volume (fL)	72.8 ± 6.5	73.4 ± 6.2	0.55
Mean Corpuscular Hemoglobin (pg)	23.1 ± 2.8	23.4 ± 2.6	0.47
Red Cell Distribution Width (%)	16.9 ± 2.1	17.2 ± 2.0	0.38
Fatigue present	72 (80.0%)	75 (83.3%)	0.57
Pallor present	69 (76.7%)	71 (78.9%)	0.71

Statistical and Comparative Outcomes

In the stratified comparison of hemoglobin response in the two groups, a much larger percentage of patients in the ferric carboxymaltose group had a minimum hemoglobin increase of 2 g/dL or higher than patients in the iron sucrose group (78.9% vs. 57.8%). This was found to be statistically significant (p=0.003) showing better efficacy of ferric carboxymaltose. The stratification analysis complements the strength of treatment effect adjusting the possible confounders.

Table 3: Pre- and Post-Stratification Analysis of Hemoglobin Improvement (Chi-square Test)

Variable	Hb Rise ≥2 g/dL n (%)	Hb Rise <2 g/dL n (%)	p-value
Iron Sucrose	52 (57.8%)	38 (42.2%)	—
Ferric Carboxymaltose	71 (78.9%)	19 (21.1%)	**0.003**

Hematological outcomes were much more improved in patients who received ferric carboxymaltose. The outcome of 12 weeks revealed that the mean hemoglobin in the ferric carboxymaltose group (11.6 ± 0.8 g/dL) was significantly high than in the iron sucrose group (10.3 ± 0.9 g/dL). Average hemoglobin increase was also higher in ferric carboxymaltose group (3.3 ± 0.9 g/dL and 2.1 ± 0.8 g/dL, respectively). Also, ferritin levels demonstrated a higher replenishment of iron stores in ferric carboxymaltose group. These differences were statistically significant which proved increased efficacy.

Table 4: Comparison of Mean Hemoglobin and Ferritin Levels After 12 Weeks (Independent t-test)

Outcome	Iron Sucrose Mean ± SD	Ferric Carboxymaltose Mean ± SD	p-value
Hb after 12 weeks (g/dL)	10.3 ± 0.9	11.6 ± 0.8	**<0.001**
Mean Hb rise (g/dL)	2.1 ± 0.8	3.3 ± 0.9	**<0.001**
Ferritin after 12 weeks (ng/mL)	48.7 ± 10.2	72.4 ± 12.5	**<0.001**

Fatigue was resolved among 58 patients (64.4%) in iron sucrose group and 76 patients (84.4%) in ferric carboxymaltose group which showed a statistically significant difference in favor of ferric carboxymaltose (p=0.004). Pain at the injection site was also more commonly observed among 14 patients (15.6% of iron sucrose) than was in 6 patients (6.7% of ferric carboxymaltose) (p=0.04). In the iron sucrose group nausea was experienced in 11 patients (12.2%), and in the ferric carboxymaltose group (7.8%), but this was not found to be statistically significant (p=0.31). Headache was also reported in 9 patients who were on the iron sucrose (10.0%) as opposed to 5 patients who were on the ferric carboxymaltose (5.6%) (p = 0.26). Transient hypotension was rare, and it was seen in 6 patients with iron sucrose (6.7%) versus 2 patients with ferric carboxymaltose (2.2%) and there was no statistically significant difference between them (p=0.15). The percentage of patients with no adverse effects was greater in the ferric carboxymaltose group 84 patients (93.3%) than the iron sucrose group 78 patients (86.7%), although not significantly different (p=0.14). The iron sucrose group was found to have a significantly greater requirement of repeat infusion, with 36 patients (40.0%) affected compared to 9 patients (10.0%) in the ferric carboxymaltose group (p<0.001).

Table 5: Comparison of Clinical Outcomes and Adverse Effects Between Groups (Chi-square Test)

Outcome / Adverse Effect	Iron Sucrose n (%)	Ferric Carboxymaltose n (%)	p-value
Resolution of fatigue	58 (64.4%)	76 (84.4%)	**0.004**
Injection site pain	14 (15.6%)	6 (6.7%)	**0.04**
Nausea	11 (12.2%)	7 (7.8%)	0.31
Headache	9 (10.0%)	5 (5.6%)	0.26
Transient hypotension	6 (6.7%)	2 (2.2%)	0.15
No adverse effects	78 (86.7%)	84 (93.3%)	0.14
Need for repeat infusion	36 (40.0%)	9 (10.0%)	**<0.001**

Hemoglobin increase had a significant correlation with important treatment-related and clinical variables. Of the patients with iron-deficiency anaemia, a rise in hemoglobin of 3g/dl or more was significantly more prominent among those who took ferric carboxymaltose than among those who took iron sucrose ($p<0.001$). Both lower baseline hemoglobin and earlier gestational age were also significantly correlated with more hemoglobin improvement. Such correlations indicate that ferric carboxymaltose is more effective in patients who have a more severe anaemia and when given sooner in the pregnancy.

Table 6: Correlation Between Hemoglobin Rise and Selected Variables (Chi-square Test)

Variable	Hb Rise ≥3 g/dL n (%)	Hb Rise <3 g/dL n (%)	p-value
Ferric carboxymaltose	63 (70.0%)	27 (30.0%)	**<0.001**
Iron sucrose	34 (37.8%)	56 (62.2%)	—
Baseline Hb ≤8 g/dL	58 (64.4%)	32 (35.6%)	**0.02**
Gestational age ≤24 weeks	61 (67.8%)	29 (32.2%)	**0.01**

DISCUSSION

This study was conducted to determine the clinical and hematological efficacy and effectiveness of intravenous iron sucrose and ferric carboxymaltose in the management of iron deficiency anaemia in pregnancy. In the current research, the two groups were similar at baseline, so the average hemoglobin levels were 8.2 ± 0.7 g/dl in the iron sucrose group and 8.3 ± 0.6 g/dl in the ferric carboxymaltose group ($p=0.36$), which made the comparisons of the outcomes internally valid. The baseline levels of serum ferritin were also significantly depleted in both groups of 12.6 ± 4.1 ng/mL and 12.9 ± 4.3 ng/mL respectively, thus confirming real iron deficiency in the whole study group. These results are consistent with the world statistics that reported the mean baseline hemoglobin between 7.8 and 8.5 g/dL in pregnant women with moderate iron deficiency anaemia in the low- and middle-income nations (Jose et al., 2019; Shahzadi et al., 2025). Similar severity of the disease at entry was also supported by the similarity of red cell indices, such as the mean corpuscular volume, which is about 73 fL in both groups. Similar baseline fatigue prevalence of 80.0% versus 83.3% also implied similar clinical burden during study entry (Sattar et al., 2023). This type of homogeneity enhances causal inference of effects of treatment observed later in the study.

A greater response of ferric carboxymaltose over iron sucrose was observed in the hematological response with mean hemoglobin levels at 12 weeks at 11.6 ± 0.8 g/dL and at 10.3 ± 0.9 g/dL respectively ($p<0.001$). The average increment in hemoglobin in ferric carboxymaltose group was 3.3 ± 0.9 g/dL versus 2.1 ± 0.8 g/dL in the iron sucrose group, which indicates a clinically significant difference ($p<0.001$). These results are in line with the randomized trials in the Indian pregnant cohorts, in which ferric carboxymaltose causes an increase in hemoglobin of 3.0-3.6 g/dL within 8 to 12 weeks (Agrawal and Masand, 2019; Singh et al., 2025). The enhanced effect of ferric carboxymaltose is explained by the stability of its iron-carbohydrate complex that enables the release of iron to regulate iron processing and its uptake by reticuloendothelial cells in a short time (Patel et al., 2020). This capability to administer increased doses of iron was probably what led to quicker iron replacement and maintained erythropoiesis in this group. The same superiority of ferric carboxymaltose has been previously observed in large observational studies with over 1,000 pregnant women, and a few centers (Hansen et al., 2023).

Iron stores measured by serum ferritin levels also were significantly restored in the ferric carboxymaltose group with post-treatment ferritin of 72.4 ± 12.5 ng/mL compared to 48.7 ± 10.2 ng/mL in the iron sucrose group ($p<0.001$). The difference also suggests better replenishment of lost iron stores, which is critical to maintaining hematological benefit after pregnancy (Milman, 2011). A previous study by Khatun and Biswas (2022) involving pregnant women also showed a post treatment ferritin ranging between 60-90 ng/mL using ferric carboxymaltose, which is in close relation with the current results. The observed elevated ferritin concentrations in the ferric carboxymaltose group and not the isolated elevation of transient hemoglobin may indicate that it is more effective in iron deficit correction than temporary

elevation of transient hemoglobin. This difference is especially applicable in the case of pregnancy where the iron requirements are high during the pregnancy and lactation (Khatun and Biswas, 2022). As such, ferric carboxymaltose seems to provide a more holistic treatment of iron deficiency anaemia in expectant women.

Clinical outcomes also indicated the greater effectiveness of ferric carboxymaltose since fatigue resolution was found in 84.4% of the patients compared to 64.4% in the iron sucrose group (p=0.004). Similar trial in pregnant population by Gupte et al., (2024) has suggested fatigue reduction rates of about 80-88% after ferric carboxymaltose intake, which are comparable to the current results. Conversely, iron sucrose has been found to have lower levels of symptom resolution, especially in a protracted or intermittent treatment. Repeat infusion was also warranted in the iron sucrose group at 40.0% than in the ferric carboxymaltose group at 10.0% only (p<0.001), thereby echoing the limitations of logistics and therapy (Gupte et al., 2024). Multicenter trials on pregnant women in resource-constrained environments have also reported similar decreases in requirements of repeat dosing (Shin et al., 2021).

In this trial, the pain at the site of injection was more prevalent in the iron sucrose group of 15.6% in comparison to the ferric carboxymaltose group of 6.7% (p=0.04), which probably was the result of recurrent venous access. The incidence of transient hypotension was infrequent in both groups; 6.7% versus 2.2% of patients respectively (p=0.15) which is in line with existing safety historians. Similar findings are supported by previous large-scale study which found adverse event rates lower than 10% during ferric carboxymaltose pregnancy (Bharadwaj et al., 2023). Notably, the improved tolerability is indicated by the greater percentage of patients who reported to have no adverse effects in the ferric carboxymaltose group (93.3% vs. 86.7%) and the decreased percentage in the iron carboxymaltose group (62.8% vs. 86.7%). The specified safety outcomes are especially applicable to pregnancy wherein maternal and fetal safety is of utmost importance (Farooq et al., 2025). In general, the safety data informs the use of ferric carboxymaltose as a therapeutic well-tolerated agent in antenatal care.

Irrespective of the strengths, this study has some limitations which ought to be noted. The research was carried out in one tertiary care facility, which can restrain the overall applicability of the results to the other healthcare facilities, especially to primary or rural care. The study used non-probability consecutive sampling, thus subject to selection bias even in the cases of randomization to treatment groups. Follow-up was restricted to 12 weeks, which would not allow measuring long-term maternal and neonatal outcomes, such as postpartum anaemia and neonatal iron status. The cost-effectiveness analysis was not done properly, yet economic considerations are relevant in the context of resources limitation to a considerable extent. Also, the biochemical markers (transferrin saturation, hepcidin concentrations, etc.) were not analyzed, which might have given more mechanism information on iron metabolism.

Conclusion

This research has shown that intravenous ferric carboxymaltose was much more effective than iron sucrose in enhancing the hematological, as well as clinical outcomes in expecting women with iron deficiency anaemia. Ferric carboxymaltose was found to have a higher mean hemoglobin increase (3.3 ± 0.9 g/dl) than iron sucrose (2.1 ± 0.8 g/dl) and the difference was statistically significant at 12 weeks (p<0.001). Ferric carboxymaltose also demonstrated better iron stores restoration than ferritin (higher post-treatment serum ferritin levels of 72.4 ± 12.5 ng/mL versus 48.7 ± 10.2 ng/mL; p<0.001). In clinical terms, a much greater proportion of patients who were treated with ferric carboxymaltose showed fatigue resolution (84.4% vs. 64.4%; p=0.004), and a much lower recurrence of infusions (10.0% vs. 40.0%; p<0.001). The findings substantiate the preferential application of ferric carboxymaltose in successful anaemia management in the antenatal period especially where quick remedies and minimal visits to health facilities are fundamental.

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