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RESEARCH ARTICLE

NOVEL COMPOUNDS FOR IRON DEFICIENCY ANEMIA IN PREGNANCY.

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Abstract

Background: Iron deficiency anemia(IDA) remains a significant health challenge during pregnancy, adversely affecting both maternal and fetal outcomes. Despite the common use of oral iron supplements, their efficacy is often hindered by gastrointestinal side effects, leading to poor compliance. Intravenous iron therapies, such as ferric carboxymaltose (FCM) and iron (III) isomaltoside, have emerged as superior alternatives due to their ability to rapidly replenish iron stores and normalize hemoglobin levels

Objectives: This study aimed to evaluate the hemoglobin rise and improvement in iron profile in antenatal patients with iron deficiency anemia on treatment with these newer iron formulations respectively.

Method :This open-label, two-arm randomized clinical trial was conducted from June 2022 to June 2024 at GSVM Medical College, Kanpur. Pregnant women with IDA were randomly assigned to receive either FCM or iron(III) isomaltoside. Hemoglobin levels and iron profiles were measured at baseline and at 3, 6, and 12 weeks post-treatment. Data were analysed using paired t-tests within groups and independent t-tests between groups.

Results: The study found that haemoglobin levels increased progressively in both groups, with the iron isomaltoside group achieving a higher mean haemoglobin level at 12 weeks (10.08644 g/dL) compared to the FCM group (9.47695 g/dL). Additionally, the iron isomaltoside group had higher mean levels of iron and ferritin and demonstrated more favorable total iron-binding capacity and transferrin saturation.

Conclusion: The findings indicated that iron isomaltoside was more effective than FCM in increasing hemoglobin levels and improving iron-related parameters in pregnant women with IDA.

Introduction:-

Iron deficiency anemia (IDA) still remains a prevalent and critical health issue during the pregnancy, significantly impacting both maternal and foetal outcomes. The condition is associated with a spectrum of adverse effects, including increased susceptibility to infections, hemorrhage, and cardiac failure especially during periods of high output in the mother. [1] For the foetus, the implications are equally severe, with IDA contributing to low birth weight, preterm delivery, birth asphyxia, and impaired neurodevelopmental outcomes. [2] Despite the widespread

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use of oral iron supplementation as a first-line treatment, its efficacy is often compromised by gastrointestinal side effects such as nausea, constipation, and diarrhoea, leading to poor compliance and inadequate management, particularly in cases of moderate to severe anemia. [3]

Given these challenges, intravenous (IV) iron therapies have emerged as a superior alternative for the rapid and effective treatment of IDA in pregnancy. [4] Among the IV formulations, ferric carboxymaltose (FCM) and iron isomaltoside are at the forefront due to their ability to deliver high doses of iron in a single administration without the need for a test dose. [5] These agents were designed to facilitate swift replenishment of iron stores and normalization of hemoglobin levels, thereby reducing the necessity for blood transfusions during the antenatal and postpartum periods. Ferric carboxymaltose is a polynuclear iron(III)-hydroxide carbohydrate complex engineered to mimic the physiological properties of ferritin, ensuring efficient iron delivery with a favourable safety profile. Conversely, iron isomaltoside is characterized by a unique matrix structure that allows for a controlled release of iron, potentially minimizing the risk of labile iron toxicity. [6]

Despite their clinical utility, there is a paucity of direct comparative studies evaluating the efficacy and safety of these two IV iron formulations in pregnant women with IDA. [7] This gap in the literature underscores the necessity for a rigorous comparative analysis to determine the relative effectiveness of FCM and iron isomaltoside in increasing hemoglobin concentration and hematocrit levels, as well as their respective side effect profiles. [8]

This study aimed to address this critical need by conducting a comprehensive evaluation of these two IV iron therapies in a cohort of pregnant patients with IDA. By comparing hemoglobin response and adverse events associated with FCM and iron isomaltoside , the findings from this study provided an evidence-based guidance for optimizing antenatal care and improving maternal and neonatal health outcomes in populations at risk of IDA.

Materials and Methods.

This open-label, two-arm randomized clinical trial was conducted from June 2022 to June 2024 at theDepartment of Obstetrics and Gynaecology, Upper India Sugar Exchange Maternity Hospital, GSVM Medical College, Kanpur, and its associated hospitals. Ethical clearance was obtained from the Ethical Committee of GSVM Medical College, Kanpur.

The study included 590 antenatal patients with period of gestation between 14 and 34 weeks and with haemoglobin levels between 7gm/dl to 9gm/dl , diagnosed with iron deficiency anemia based upon the iron study panel. Patients with a documented allergy to intravenous iron compounds, a history of chronic liver disease or chronic kidney disease, and those diagnosed with thalassemia were excluded. Furthermore, participants exhibiting signs and symptoms of cardiac failure, or those not willing to give informed consent as well as patients with hemoglobin levels below 4 gm/dL at any stage of gestation, were not included in the research.

Participants were randomly assigned to one of two groups, each comprising of 295 patients: Group I received iron(III) isomaltoside , and Group II received ferric carboxymaltose . The total iron dose was calculated using the Ganzoni formula. Bo
th the compounds were administered intravenously at a maximum dose of 500 mg per session, diluted in 100 ml of 0.9% saline with FCM being administered over 30 minutes and iron isomaltoside being administered as a slow IV infusion over 45 minutes. Vital signs were monitored before ,during and after the infusion to detect any adverse effects. None of the patients were administered a dose >1000mg during the treatment.

Follow-up visits occurred at 3, 6, and 12 weeks post-treatment to measure hemoglobin levels and assess the iron profile at 12 weeks. Data were analyzed using paired t-tests within groups and independent t-tests between groups,with a significance level set at $p < 0.05$. Statistical software was used to analyze the data and determine the comparative efficacy and safety of the two treatments.

Statistical Analysis

A pilot study was conducted on 10 patients. They were randomly assigned into 2 groups and given two types of iron. The group 1 was given iron isomaltoside and the mean improvement in Hb at 3 weeks was 2.35 g/dl. The group 2 was given FCM and the mean improvement was 2.32 g/dl. Standard deviation was 0.13 Using the formula for comparing means the sample size was calculated.

$$\frac{2\left(Z_{\alpha/2} + Z_{\beta}\right)^2 \cdot s^2}{\Delta^2} * s^2$$

A total of 295 pregnant women between 14 -34 weeks of period of gestation suffering from iron deficiency anemia were randomly selected for each group based on the calculated sample size.

Result

Assessment of 590 antenatal patients with iron deficiency anemia through hemoglobin levels and iron profiles showed a mean increase of 2.10 g/dl in hemoglobin levels 12 weeks after treatment with iron (III) isomaltoside and a significant improvement in iron indicies.

Table 1 represents summarizes the hemoglobin levels at baseline and at 3, 6, and 12 weeks after treatment with iron(III) isomaltoside. Figure 1 illustrates the mean hemoglobin levels showing a progressive increase over time, starting from 7.99 g/dL at baseline to 10.09 g/dL at 12 weeks post treatment. The standard deviation remained consistent across the time points, indicating a similar degree of variation in hemoglobin levels among the participants.

Descriptive Statistics

	Mean	Standard Deviation	Skewness	Minimum	Median	Maximum
Baseline Hb	7.99051	0.65883	0.22921	7	8	9.5
Haemoglobin at 3 weeks	8.47153	0.65875	0.29079	7.2	8.5	10.5
Haemoglobin at 6 weeks	9.15254	0.71632	0.3719	8	9.2	11
Haemoglobin at 12 weeks	10.08644	0.68115	-0.04842	8.5	10.2	12

Table 1: Descriptive analysis of mean haemoglobin levels seen at 3, 6 and 12 weeks post treatment with iron(III) isomaltoside.

Figure 1 : Mean haemoglobin levels rise at 3, 6 and 12 weeks post treatment with iron(III) isomaltoside.

In Table 2 and Figure 3, a comprehensive descriptive analysis was performed alongside a student's t-test to evaluate the differences in hemoglobin (Hb) levels at various time points between two distinct groups. The analysis revealed statistically significant differences across all measured time points, with a p-value of less than 0.0001, indicating a high level of confidence in the results.

Descriptive Statistics

	N total	Mean	Standard Deviation	Sum	Minimum	Median	Maximum
Haemoglobin at 12 weeks (Ferric carboxymaltose)	295	9.47695	0.6942	2795.7	8.2	9.5	11
Haemoglobin at 12 weeks (Iron(iii) isomaltoside)	295	10.08644	0.68115	2975.5	8.5	10.2	12

Table 2: Descriptive analysis showing mean haemoglobin levels at 12 weeks post treatment with iron(III) isomaltoside and ferric carboxymaltose respectively.

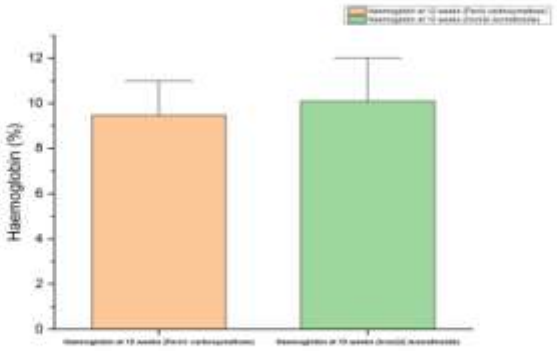

Figure 2 : Histogram showing haemoglobin levels at 12 weeks post treatment of iron(III) isomaltoside and ferric carboxymaltose respectively.

The findings demonstrated that the administration of Iron (III) isomaltoside resulted in a more pronounced increase in hemoglobin levels compared to ferric carboxymaltose (FCM) after a treatment period of 12 weeks. This suggests that Iron (III) isomaltoside may be a more effective therapeutic option for enhancing hemoglobin levels in patients requiring iron supplementation. The consistent statistical significance across all time points further underscores the robustness of these results, highlighting the potential clinical implications of choosing Iron (III) isomaltoside over FCM for improving iron status and overall hematological health in patients .

Table 3 represents the comparative analysis at 12 weeks post-treatment showing that the Iron(iii) Isomaltoside group had higher mean levels of iron and ferritin, indicating better iron replenishment and storage compared to the Ferric Carboxymaltoside group. Additionally, the Iron(iii) Isomaltoside group exhibited lower TIBC and slightly higher transferrin saturation, suggesting more efficient iron utilization. These findings suggest that Iron(iii) Isomaltoside may be more effective in managing iron deficiency anemia.A descriptive analysis shown in Table 3 and Figure 3, accompanied by a student's "t" test, was conducted to compare the study variables—iron, ferritin, total iron-binding capacity (TIBC), and transferrin—at the 12-week mark. The analysis revealed statistically significant differences across all variables when comparing group 1 to group 2 ($p<0.0001$). The findings indicate that Iron (III) isomaltoside effectively enhances the levels of iron, ferritin, and transferrin among the study participants in contrast to those receiving ferric carboxymaltose (FCM). Additionally, it was observed that TIBC significantly decreased in participants administered Iron (III) isomaltoside compared to those treated with FCM.

Descriptive Statistics

	N total	Mean	Standard Deviation	Skewness	Kurtosis	Minimum	Median	Maximum
Iron 12 week(Ferric carboxymaltose)	295	65.79322	25.55442	0.96836	1.74569	17	59	196
Iron 12 week (Iron(iii) isomaltoside)	295	88.47119	37.55112	1.19063	2.49287	32	86	265
Ferritin 12 weeks (Ferric carboxymaltose)	295	79.97966	27.28808	0.13283	4.2017	14	85	247
Ferritin 12 weeks (Iron(iii) isomaltoside)	295	101.8610 2	70.44372	1.35623	1.96437	11	94	368
TIBC 12 week(Ferric carboxymaltose)	295	412.6044 1	63.65874	-0.82549	3.4115	35	411	535
TIBC 12 week (Iron(iii) isomaltoside)	295	337.6847 5	76.71951	-0.69597	0.73086	33	354	498
Transferrin saturation at 12 weeks (Ferric carboxymaltose)	295	23.20678	23.27944	14.66002	237.834 2	10	21	401
Transferrin saturation at 12 weeks (Iron(iii) isomaltoside)	294	28.45646	29.56361	12.16632	183.421 6	10	24	478

Table 3 : Descriptive analysis showing comparative analysis of study variables in both groups

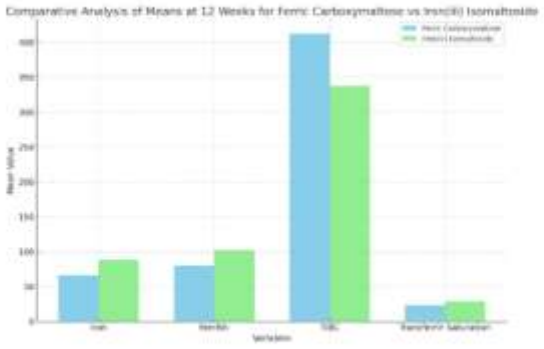

Figure3: **Histogram showing comparative analysis of study variables in both groups**

Discussion

Anemia remains a critical health issue during pregnancy, posing a substantial challenge due to its negative impact on both maternal and perinatal mortality rates worldwide. The primary contributor to anemia in pregnant females is nutritional deficiency, with iron being the predominant micronutrient responsible for this condition. Treatment options include both oral and parenteral methods. This study seeks to assess the efficacy of two such parenteral formulations, specifically iron(III) isomaltoside and ferric carboxymaltose, in the management of anemia during pregnancy. Our study findings demonstrated that the administration of Iron (III) isomaltoside resulted in a more pronounced increase in hemoglobin levels compared to ferric carboxymaltose (FCM) after a treatment period of 12

weeks. This suggests that iron (III) isomaltoside may be a more effective therapeutic option for enhancing hemoglobin levels in patients requiring iron supplementation. The consistent statistical significance across all time points further underscores the robustness of these results, highlighting the potential clinical implications of choosing Iron (III) isomaltoside over FCM for improving iron status and overall hematological health in patients. This study found that hemoglobin levels showed a significant and progressive increase from baseline through 3, 6, and 12 weeks post-treatment. Initially, the mean hemoglobin level was 7.99 g/dL at baseline, which steadily rose to 10.09 g/dL at 12 weeks. The standard deviation remained relatively consistent, indicating a similar degree of variability in hemoglobin levels among the study participants

In comparing the two treatment groups at 12 weeks post-treatment, the study found that the Iron(iii) Isomaltoside group had a higher mean hemoglobin level (10.08644 g/dL) compared to the Ferric Carboxymaltoside group (9.47695 g/dL). The standard deviations for both groups were similar, indicating that the variability in hemoglobin levels was consistent within each group. This suggests that Iron(iii) Isomaltoside may be slightly more effective in increasing hemoglobin levels in patients with iron deficiency anemia.

Furthermore, the study's comparative analysis of iron-related parameters at 12 weeks post-treatment revealed that the Iron(iii) Isomaltoside group had higher mean levels of iron (88.47119 µg/dL) and ferritin (101.86102 µg/L) compared to the Ferric Carboxymaltoside group, which had mean iron and ferritin levels of 65.79322 µg/dL and 79.97966 µg/L, respectively. Additionally, the Iron(iii) Isomaltoside group demonstrated a lower total iron-binding capacity (TIBC) (337.68475 µg/dL) and slightly higher transferrin saturation (28.45646%) than the Ferric Carboxymaltoside group, which had TIBC and transferrin saturation values of 412.66441 µg/dL and 23.20678%, respectively. These findings suggest that Iron(iii) Isomaltoside may be more effective in replenishing and utilizing iron stores compared to Ferric Carboxymaltoside.

This study is an open-label design of the study which may introduce bias in assessing patient outcomes and side effects, as blinding is absent. Due to the specific gestational age bracket of 14 to 34 weeks, results may not be generalizable to all pregnant women with iron deficiency anemia. Additionally, exclusion of patients with severe comorbidities such as chronic liver or kidney disease may limit the applicability of the findings to a broader population.The study relies on the assumption that the calculation of total iron deficit using the Ganzoni formula is accurate for all individuals, which may not account for individual variations in iron metabolism.

In their study, Verma et al. [10] (2015) compared the efficacy and safety of single-dose intravenous ferric carboxymaltose (FCM) versus multidose iron sucrose in postpartum cases of severe iron deficiency anemia. The study included 100 postpartum women, with 50 in each treatment group. The findings revealed that the mean increase in hemoglobin levels was significantly higher in the FCM group, with an increase of 2.9 g/dL compared to 2.1 g/dL in the iron sucrose group. The study also reported fewer side effects in the FCM group, making it a more favorable option for treating severe postpartum anemia .

Hol et al. [11] (2015) conducted a comparative study of intravenous iron sucrose versus ferric carboxymaltose in treating iron deficiency anemia among postpartum patients. Their study included 120 postpartum women, divided equally between the two treatment groups. The results demonstrated that the FCM group achieved a higher mean hemoglobin increase (3.2 g/dL) compared to the iron sucrose group (2.5 g/dL). Additionally, the FCM group required fewer infusions, which reduced the overall treatment burden. This study highlighted FCM as a more effective and convenient treatment option for postpartum anemia .

Metgud et al. [12] conducted a randomized controlled trial to compare the efficacy and safety of ferric carboxymaltose versus iron sucrose in treating antepartum iron deficiency anemia. The study involved 150 pregnant women, with 75 in each group. The results showed that the FCM group had a significantly higher mean hemoglobin increase of 3.5 g/dL compared to 2.8 g/dL in the iron sucrose group. The safety profile was also better in the FCM group, with fewer reported adverse events.

study concluded that FCM is more efficacious and safer than iron sucrose for treating antepartum anemia .

Singh et al. [13] (2016) compared the safety and efficacy of intravenous iron sucrose and ferric carboxymaltose in treating postpartum anemia in a study involving 200 women. The FCM group showed a greater mean increase in hemoglobin levels of 3.1 g/dL compared to 2.3 g/dL in the iron sucrose group. The study also found that FCM was associated with a faster recovery of iron stores and fewer gastrointestinal side effects, making it a preferable choice for postpartum women with anemia .

Arulmozhi et al [14] (2014) conducted a comparative study of intravenous ferric carboxymaltose and iron sucrose in the management of postnatal iron deficiency anemia. The study included 90 women, with 45 in each group. The results showed that the FCM group achieved a higher mean hemoglobin increase of 2.8 g/dL, compared to 2.0 g/dL in the iron sucrose group. The study also noted that the FCM group required fewer doses to achieve the desired hemoglobin levels, making it a more efficient treatment option .

Mahajan et al. [15] (2018) compared the efficacy and safety of ferric carboxymaltose versus iron sucrose in the treatment of iron deficiency anemia during pregnancy in a tertiary care hospital. The study involved 100 pregnant women, with 50 in each group. The FCM group had a mean hemoglobin increase of 3.0 g/dL, while the iron sucrose group had a mean increase of 2.4 g/dL. The study also reported fewer side effects in the FCM group, supporting the use of FCM as a superior treatment option for pregnant women with iron deficiency anemia .

Jose et al. [16] (2019) conducted a randomized controlled trial comparing ferric carboxymaltose and iron sucrose for treating iron deficiency anemia in pregnancy. Their study involved 200 pregnant women, with equal distribution between the two groups. The results showed that the FCM group achieved a higher mean hemoglobin increase of 3.2 g/dL compared to 2.5 g/dL in the iron sucrose group. The study also found that FCM required fewer infusions and was associated with fewer adverse reactions, making it a more effective and safer option for treating anemia in pregnancy .

Agrawal and Masand et al [17] (2019) conducted a study on the efficacy and safety of ferric carboxymaltose versus iron sucrose in treating iron deficiency anemia among pregnant women in a tertiary care hospital. The study included 150 pregnant women, with 75 in each treatment group. The FCM group showed a mean hemoglobin increase of 3.4 g/dL, while the iron sucrose group had an increase of 2.7 g/dL. The study concluded that FCM is more effective and has a better safety profile compared to iron sucrose .

Patel et al. [18] (2020) conducted a comparative study of ferric carboxymaltose and iron sucrose as parenteral iron treatments for iron deficiency anemia during pregnancy. The study involved 180 pregnant women, with 90 in each group. The FCM group achieved a mean hemoglobin increase of 3.3 g/dL compared to 2.6 g/dL in the iron sucrose group. The study also noted that FCM was associated with fewer infusions and a lower incidence of adverse events, supporting its use as a preferred treatment option for iron deficiency anemia during pregnancy .

Despite the widespread availability of free oral iron supplements through various national health initiatives aimed at addressing anemia, we still face significant challenges in overcoming this health obstacle. Our research endeavours to evaluate and compare these two novel intravenous iron preparations for use during pregnancy, with the potential to effectively combat this condition

Conclusion

The study's findings indicated that Iron(iii) Isomaltoside demonstrated superior efficacy in increasing hemoglobin levels and improving iron-related parameters compared to Ferric Carboxymaltoside in patients with iron deficiency anemia. Over the course of 12 weeks, patients treated with Iron(iii) Isomaltoside exhibited higher mean hemoglobin levels and better iron and ferritin storage, while also maintaining more favorable total iron-binding capacity and transferrin saturation levels. The consistent variability in standard deviation between the two treatment groups suggested reliable outcomes across the patient population, with Iron(iii) Isomaltoside proving to be slightly more effective in managing anemia. These results highlighted the potential of Iron(III) Isomaltoside as a preferred treatment option for enhancing hemoglobin levels and iron storage in this patient cohort.

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