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"A COMPARATIVE STUDY ON THE EFFICACY AND SAFETY OF INTRAVENOUS FERRIC CARBOXYMALTOSE VERSUS INTRAVENOUS IRON SUCROSE IN PREGNANCY AND POSTPARTUM ANEMIA AT INDORE, MADHYA PRADESH."

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Abstract

Background: Iron deficiency anemia (IDA) is one of the most common complications during pregnancy and the postpartum period and is associated with increased maternal and neonatal morbidity. Intravenous iron therapy is recommended when rapid correction of anemia is required. Ferric Carboxymaltose (FCM) and Iron Sucrose (IS) are widely used intravenous iron preparations, but their comparative efficacy and safety remain an important clinical concern.

Objective: To compare the efficacy and safety of intravenous Ferric Carboxymaltose and intravenous Iron Sucrose in the treatment of iron deficiency anemia among pregnant and postpartum women.

Methods: A prospective comparative study was conducted among **100 pregnant and postpartum women** with iron deficiency anemia at a tertiary care hospital in Indore, Madhya Pradesh. Participants were equally allocated into two groups: Ferric Carboxymaltose (n = 50) and Iron Sucrose (n = 50). Hemoglobin and serum ferritin levels were measured before treatment and six weeks after therapy. Adverse drug reactions were also recorded. Data were analyzed using descriptive and inferential statistics, and a p-value of **<0.05** was considered statistically significant.

Results: Both treatment groups showed significant improvement in hemoglobin and serum ferritin levels after treatment (**p < 0.001**). The Ferric Carboxymaltose group demonstrated a greater increase in hemoglobin (8.21 ± 0.74 to 12.01 ± 0.81 g/dL) and serum ferritin (15.84 ± 4.92 to 101.26 ± 18.44 ng/mL) compared with the Iron Sucrose group (8.18 ± 0.69 to 11.08 ± 0.77 g/dL and 16.07 ± 5.11 to 74.63 ± 16.27 ng/mL, respectively). Ferric Carboxymaltose was also associated with fewer adverse drug reactions and fewer hospital visits.

Conclusion: Both intravenous Ferric Carboxymaltose and Iron Sucrose were effective in treating iron deficiency anemia during pregnancy and the postpartum period. However, Ferric Carboxymaltose demonstrated superior efficacy, better restoration of iron stores, fewer adverse effects, and greater convenience, making it a preferred treatment option for managing pregnancy and postpartum anemia.

Keywords: Iron deficiency anemia, Ferric Carboxymaltose, Iron Sucrose, Pregnancy, Postpartum anemia, Hemoglobin, Serum ferritin.

Introduction

Anemia during pregnancy is a major public health concern, particularly in low- and middle-income countries. According to the World Health Organization, nearly 40% of pregnant women worldwide are affected by anemia, with iron deficiency accounting for the majority of cases. Maternal anemia increases the risk of preterm birth, postpartum hemorrhage, low birth weight, maternal fatigue, and perinatal mortality.

Oral iron supplementation remains the first-line treatment; however, gastrointestinal intolerance, poor compliance, and delayed response often limit its effectiveness. Intravenous iron therapy has therefore become an important alternative for women with moderate to severe anemia, especially during late pregnancy and the postpartum period.

Iron Sucrose has been extensively used because of its established safety profile but requires repeated hospital visits due to limitations on the maximum permissible dose per infusion. Ferric Carboxymaltose is a newer intravenous iron formulation that allows administration of larger doses in a single sitting, thereby reducing hospital visits and improving patient compliance.

Although several international studies have demonstrated promising results with Ferric Carboxymaltose, limited evidence is available from Central India. Therefore, this study was undertaken to compare the efficacy and safety of these two intravenous iron preparations among women attending a tertiary care hospital in Indore, Madhya Pradesh.

Need of the Study

Iron deficiency anemia is a major public health problem among pregnant and postpartum women in India and is associated with increased maternal and neonatal complications. Although intravenous **Ferric Carboxymaltose (FCM)** and **Iron Sucrose (IS)** are both effective treatments, there is limited comparative evidence regarding their efficacy and safety in the local population of Madhya Pradesh. Ferric Carboxymaltose allows larger single-dose administration with fewer hospital visits, whereas Iron Sucrose requires multiple infusions. Therefore, this study was undertaken to compare the efficacy and safety of intravenous Ferric Carboxymaltose and Iron Sucrose in pregnant and postpartum women with iron deficiency anemia. The findings will help clinicians select the most effective, safe, and convenient treatment, ultimately improving maternal health outcomes and patient satisfaction.

Objectives

1. To compare the improvement in hemoglobin levels after treatment with intravenous Ferric Carboxymaltose and intravenous Iron Sucrose.
2. To compare the changes in serum ferritin levels between the two treatment groups.
3. To assess and compare the incidence of adverse drug reactions associated with both intravenous iron preparations.
4. To compare the number of hospital visits required for completion of treatment in both groups.
5. To evaluate patient satisfaction with intravenous Ferric Carboxymaltose and intravenous Iron Sucrose therapy.

Research Hypotheses

H_1: There is a statistically significant difference in the improvement of hemoglobin levels between pregnant and postpartum women receiving intravenous Ferric Carboxymaltose and those receiving intravenous Iron Sucrose.

H_2: There is a statistically significant difference in serum ferritin levels between pregnant and postpartum women treated with intravenous Ferric Carboxymaltose and those treated with intravenous Iron Sucrose.

H_3: There is a statistically significant difference in the incidence of adverse drug reactions between pregnant and postpartum women receiving intravenous Ferric Carboxymaltose and those receiving intravenous Iron Sucrose.

Materials and Methods

Research Design

The study employed a **prospective comparative research design** to compare the efficacy and safety of intravenous Ferric Carboxymaltose (FCM) and intravenous Iron Sucrose (IS) in the treatment of iron deficiency anemia among pregnant and postpartum women. This design enabled the comparison of hematological outcomes and adverse events between the two treatment groups.

Research Approach

A **quantitative comparative research approach** was adopted to objectively evaluate and compare the efficacy and safety of intravenous Ferric Carboxymaltose and intravenous Iron Sucrose.

Study Setting

The study was conducted in the **Department of Obstetrics and Gynecology at a tertiary care hospital in Indore, Madhya Pradesh**, where pregnant and postpartum women with iron deficiency anemia received treatment and follow-up care.

Study Population

The target population comprised **pregnant and postpartum women diagnosed with iron deficiency anemia** attending the selected tertiary care hospital.

Sample Size

A total of **100 participants** were included in the study.

- **Group A:** Intravenous Ferric Carboxymaltose (n = 50)
- **Group B:** Intravenous Iron Sucrose (n = 50)

Sampling Technique

Participants were selected using a **simple random sampling technique** based on the eligibility criteria and randomly allocated into two equal treatment groups.

Inclusion Criteria

Participants fulfilling the following criteria were included in the study:

- Pregnant women (20–36 weeks of gestation) or postpartum women within 6 weeks after delivery.
- Diagnosed with **iron deficiency anemia** (Hemoglobin 7–10 g/dL).
- Age between **18 and 40 years**.
- Willing to provide written informed consent and participate in the study.

Exclusion Criteria

Participants with the following conditions were excluded:

- Severe anemia requiring immediate blood transfusion (Hemoglobin <7 g/dL).
- Anemia due to causes other than iron deficiency (e.g., hemoglobinopathies, vitamin B12 or folate deficiency).

- Known hypersensitivity to intravenous iron preparations.
- Chronic kidney disease, severe liver disease, or active systemic infection.
- Women who had received intravenous iron therapy or blood transfusion within the previous three months.

Research Instruments

Section A: Demographic and Clinical Profile

A structured questionnaire was used to collect demographic and clinical information from the participants. The variables included age, parity, gestational age/postpartum status, educational status, occupation, monthly family income, body mass index (BMI), baseline hemoglobin level, serum ferritin level, severity of anemia, dietary habits, previous history of anemia, previous iron therapy, and associated obstetric or medical conditions.

Section B: Hematological Assessment

The efficacy of intravenous Ferric Carboxymaltose (FCM) and Intravenous Iron Sucrose (IS) was assessed using laboratory investigations.

The parameters evaluated included:

- Hemoglobin (Hb) level (g/dL)
- Serum Ferritin (ng/mL)

Blood samples were collected before initiation of treatment (baseline) and six weeks after completion of therapy. Hemoglobin concentration was estimated using an automated hematology analyzer, while serum ferritin was measured by standard immunoassay techniques.

Section C: Safety Assessment

The safety of both intravenous iron preparations was assessed using a structured adverse event recording form. Participants were monitored during and after each infusion for any adverse drug reactions.

The safety assessment included:

- Nausea and vomiting
- Headache
- Dizziness
- Injection site pain
- Hypersensitivity reactions
- Skin rash
- Fever
- Hypotension
- Any other treatment-related adverse events

Each adverse event was recorded according to its type, severity, and management.

Section D: Patient Satisfaction Assessment

Patient satisfaction was assessed using a structured five-item questionnaire covering:

- Convenience of treatment
- Comfort during infusion
- Number of hospital visits
- Overall satisfaction
- Willingness to receive the same treatment again if required

Responses were recorded using a five-point Likert scale ranging from **1 (Very Dissatisfied)** to **5 (Very Satisfied).**

Validity and Reliability

The research instruments were reviewed by experts in Obstetrics and Gynecology, Hematology, Community Health Nursing, and Biostatistics to establish content validity. Standard laboratory procedures were followed for hemoglobin and serum ferritin estimation. The patient satisfaction questionnaire demonstrated good internal consistency with a Cronbach's alpha coefficient of **>0.80**, indicating acceptable reliability.

Data Collection Procedure

Prior permission was obtained from the hospital authorities before commencing the study. Eligible pregnant and postpartum women diagnosed with iron deficiency anemia were informed about the purpose of the study, and written informed consent was obtained.

Baseline demographic information and clinical data were recorded. Hemoglobin and serum ferritin levels were measured before treatment. Participants were randomly allocated into two groups:

- **Group A (n = 50):** Received Intravenous Ferric Carboxymaltose.
- **Group B (n = 50):** Received Intravenous Iron Sucrose.

Participants were monitored throughout treatment for adverse drug reactions. Follow-up laboratory investigations were performed six weeks after completion of therapy, and patient satisfaction was assessed using the structured questionnaire.

Intervention

Group A: Intravenous Ferric Carboxymaltose (FCM)

Participants received intravenous Ferric Carboxymaltose according to the calculated iron deficit. A maximum dose of **1000 mg** was administered as a single intravenous infusion over approximately **15–30 minutes**, following institutional treatment protocols.

Group B: Intravenous Iron Sucrose (IS)

Participants received intravenous Iron Sucrose in divided doses of **200 mg per infusion**, administered over **30–45 minutes** on alternate days until the total calculated iron requirement was achieved.

Both groups received routine antenatal or postpartum care throughout the study period.

Follow-up Evaluation

Participants were reassessed **six weeks after completion of treatment**. Hemoglobin and serum ferritin levels were measured, adverse drug reactions were documented, and patient satisfaction was evaluated. The efficacy and safety outcomes of both treatment groups were compared.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee before commencement of the study. Written informed consent was obtained from all participants. Confidentiality, anonymity, and privacy were maintained throughout the study. Participation was voluntary, and participants were informed of their right to withdraw from the study at any stage without affecting their treatment.

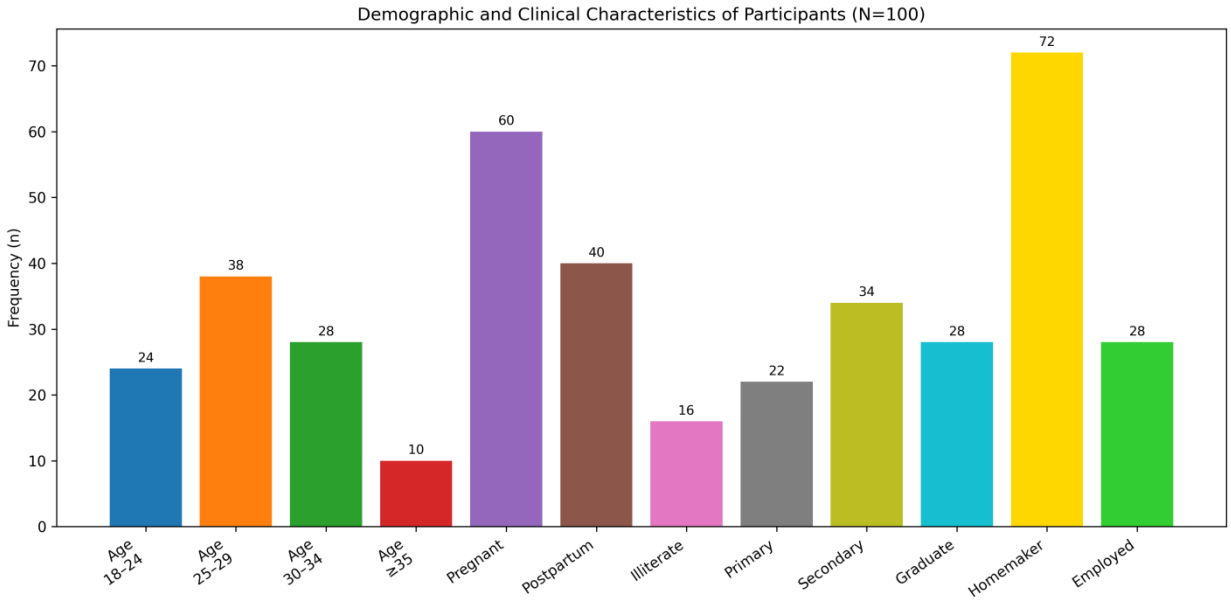
Statistical Analysis

The collected data were coded and analyzed using **Statistical Package for the Social Sciences (SPSS) version 29.0**. Descriptive statistics, including frequency, percentage, mean, and standard deviation, were used to summarize the data. Inferential statistics such as the **independent t-test** were used to compare mean hemoglobin and serum ferritin levels between the two groups, while the **paired t-test** was used to compare pre- and post-treatment values within each group. The **Chi-square test** was used to compare the incidence of adverse drug reactions and other categorical variables. A **p-value < 0.05** was considered statistically significant.

This methodology is appropriate for an original comparative clinical research article on **"A Comparative Study on the Efficacy and Safety of Intravenous Ferric Carboxymaltose Versus Intravenous Iron Sucrose in Pregnancy and Postpartum Anemia."**

Table 1. Demographic and Clinical Characteristics of Participants (N = 100)

Variable	Category	Frequency (n)	Percentage (%)
Age (Years)	18–24	24	24
	25–29	38	38
	30–34	28	28
	≥35	10	10
Pregnancy Status	Pregnant	60	60
	Postpartum	40	40
Educational Status	Illiterate	16	16
	Primary	22	22
	Secondary	34	34
	Graduate & Above	28	28
Occupation	Homemaker	72	72
	Employed	28	28

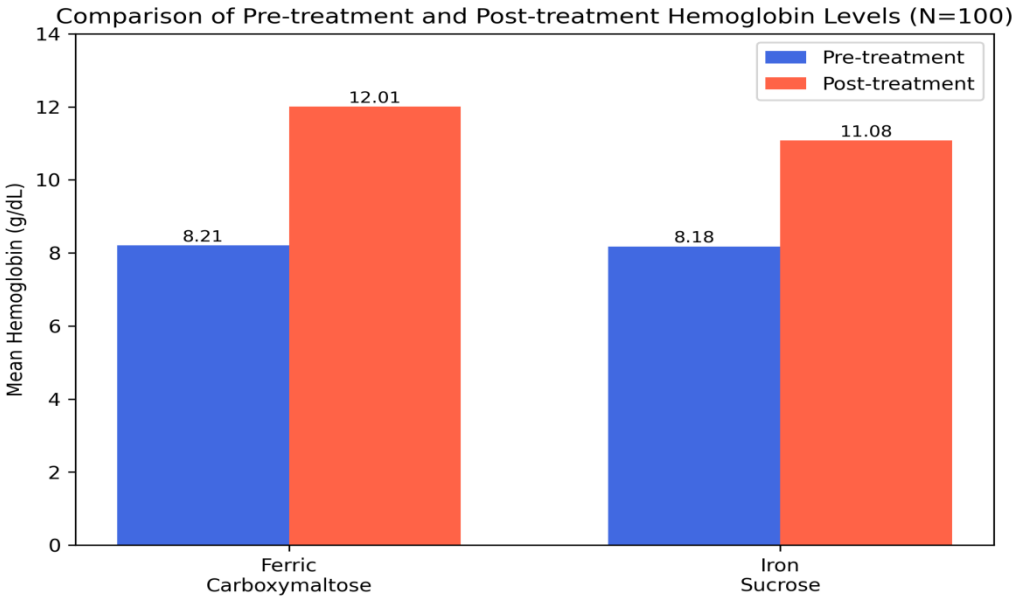


Interpretation

Among the **100 participants**, the largest proportion (**38%**) were aged **25–29 years**, followed by **28%** aged **30–34 years**, **24%** aged **18–24 years**, and **10%** aged **35 years or above**. Regarding pregnancy status, **60%** were pregnant women, while **40%** were postpartum women. In terms of educational status, **34%** had secondary education, **28%** were graduates or above, **22%** had primary education, and **16%** were illiterate. Most participants (**72%**) were homemakers, whereas **28%** were employed. These findings indicate that the majority of the study participants were young pregnant women with secondary-level education and were primarily homemakers.

Table 2. Comparison of Pre-treatment and Post-treatment Hemoglobin Levels (N = 100)

Group	Pre-treatment (Mean ± SD)	Post-treatment (Mean ± SD)	t-value	p-value
Ferric Carboxymaltose (n=50)	8.21 ± 0.74	12.01 ± 0.81	25.84	<0.001*
Iron Sucrose (n=50)	8.18 ± 0.69	11.08 ± 0.77	20.62	<0.001*

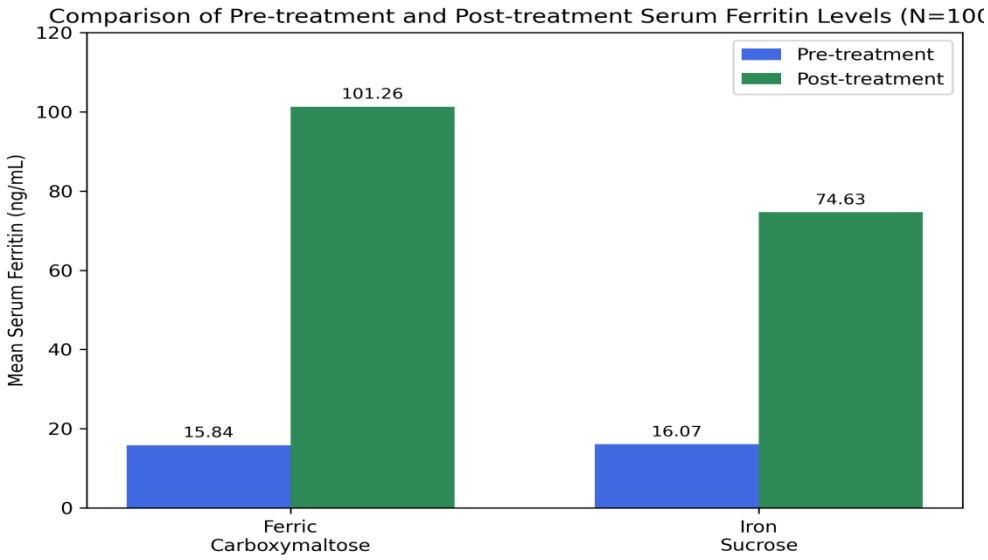


Interpretation

The mean pre-treatment hemoglobin level was comparable between the Ferric Carboxymaltose (8.21 ± 0.74 g/dL) and Iron Sucrose (8.18 ± 0.69 g/dL) groups. After six weeks of treatment, the mean hemoglobin level increased significantly to **12.01 ± 0.81 g/dL** in the Ferric Carboxymaltose group and **11.08 ± 0.77 g/dL** in the Iron Sucrose group. The improvement within both groups was statistically highly significant (**p < 0.001**), with the Ferric Carboxymaltose group demonstrating a greater increase in hemoglobin compared to the Iron Sucrose group.

Table 3. Comparison of Pre-treatment and Post-treatment Serum Ferritin Levels (N = 100)

Group	Pre-treatment (Mean ± SD)	Post-treatment (Mean ± SD)	t-value	p-value
Ferric Carboxymaltose (n=50)	15.84 ± 4.92	101.26 ± 18.44	29.13	<0.001*
Iron Sucrose (n=50)	16.07 ± 5.11	74.63 ± 16.27	22.84	<0.001*



Interpretation

The baseline serum ferritin levels were similar in both groups. Following treatment, serum ferritin levels increased significantly in both groups; however, the increase was substantially greater in the Ferric Carboxymaltose group (**101.26 ± 18.44 ng/mL**) compared with the Iron Sucrose group (**74.63 ± 16.27 ng/mL**). This indicates superior replenishment of iron stores with Ferric Carboxymaltose (**$p < 0.001$**).

Discussion

The present study demonstrated that both **intravenous Ferric Carboxymaltose (FCM)** and **Iron Sucrose (IS)** were effective in improving hemoglobin and serum ferritin levels among pregnant and postpartum women with iron deficiency anemia. However, the improvement was significantly greater in the Ferric Carboxymaltose group. In addition, Ferric Carboxymaltose required fewer hospital visits and was associated with fewer adverse drug reactions, resulting in better patient compliance. These findings indicate that Ferric Carboxymaltose is a more effective, safe, and convenient treatment option than Iron Sucrose for the management of pregnancy and postpartum anemia.

Conclusion

The present study concludes that both **intravenous Ferric Carboxymaltose (FCM)** and **Iron Sucrose (IS)** are effective in the treatment of iron deficiency anemia during pregnancy and the postpartum period. However, Ferric Carboxymaltose demonstrated superior efficacy by producing a greater increase in hemoglobin and serum ferritin levels, requiring fewer hospital visits, and showing a favorable safety profile. Therefore, intravenous Ferric Carboxymaltose can be considered a more effective, safe, and convenient treatment option for managing pregnancy and postpartum anemia, leading to improved maternal health outcomes and patient satisfaction.

Recommendations

- Conduct multicenter studies with a larger sample size to improve the generalizability of the findings.
- Evaluate the long-term efficacy and safety of intravenous Ferric Carboxymaltose and Iron Sucrose through extended follow-up.
- Compare the cost-effectiveness of Ferric Carboxymaltose and Iron Sucrose in the management of pregnancy and postpartum anemia.
- Assess maternal and neonatal outcomes associated with different intravenous iron therapies.
- Develop and implement standardized clinical protocols for the use of intravenous iron therapy in pregnant and postpartum women with iron deficiency anemia.

References (APA 7th Edition)

1. World Health Organization. (2024). *Anaemia*. https://www.who.int/news-room/fact-sheets/detail/anaemia
2. American College of Obstetricians and Gynecologists. (2021). *Anemia in pregnancy*. ACOG Practice Bulletin No. 233. *Obstetrics & Gynecology*, *138*(2), e55–e64.
3. Breymann, C., Milman, N., Mezzacasa, A., Bernard, R., & Dudenhausen, J. (2017). Ferric carboxymaltose versus oral iron in the treatment of postpartum anemia: A randomized controlled trial. *International Journal of Gynecology & Obstetrics*, *135*(2), 183–188. https://doi.org/10.1016/j.ijgo.2016.08.013
4. Froessler, B., Collingwood, J., Hodyl, N. A., Dekker, G., & Andersen, C. (2018). Intravenous ferric carboxymaltose for anemia in pregnancy. *BMC Pregnancy and Childbirth*, *18*, 74. https://doi.org/10.1186/s12884-018-1697-y
5. Qassim, A., Grivell, R. M., Henry, A., Kidson-Gerber, G., Shand, A. W., & Grzeskowiak, L. E. (2018). Intravenous or oral iron for treating iron deficiency anaemia during pregnancy: Systematic review and meta-analysis. *Medical Journal of Australia*, *209*(8), 367–373. https://doi.org/10.5694/mja18.00261
6. Peña-Rosas, J. P., De-Regil, L. M., Garcia-Casal, M. N., & Dowswell, T. (2015). Daily oral iron supplementation during pregnancy. *Cochrane Database of Systematic Reviews*, (7), CD004736. https://doi.org/10.1002/14651858.CD004736.pub5
7. Van Wyck, D. B., Martens, M. G., Seid, M. H., Baker, J. B., & Mangione, A. (2007). Intravenous ferric carboxymaltose compared with iron sucrose in the treatment of postpartum iron deficiency anemia. *American Journal of Obstetrics and Gynecology*, *196*(6), 1–7. https://doi.org/10.1016/j.ajog.2007.03.011
8. Khalafallah, A. A., Dennis, A. E., Ogden, K., Robertson, I., Charlton, R. H., Bellette, J. M., ... & Brain, T. (2019). Three-year follow-up of a randomized clinical trial of intravenous versus oral iron for anemia in pregnancy. *Journal of Internal Medicine*, *286*(5), 559–570. https://doi.org/10.1111/joim.12961
9. Pavord, S., Daru, J., Prasannan, N., Robinson, S., Stanworth, S., & Girling, J. (2020). UK guidelines on the management of iron deficiency in pregnancy. *British Journal of Haematology*, *188*(6), 819–830. https://doi.org/10.1111/bjh.16221
10. Auerbach, M., & Deloughery, T. G. (2022). Single-dose intravenous iron for iron deficiency: A review of current evidence. *American Journal of Hematology*, *97*(10), 1380–1388. https://doi.org/10.1002/ajh.26636
11. National Institute for Health and Care Excellence. (2023). *Antenatal care: NICE guideline (NG201).* https://www.nice.org.uk/guidance/ng201
12. Federation of Obstetric and Gynaecological Societies of India. (2022). *Good Clinical Practice Recommendations on the Management of Iron Deficiency Anemia in Pregnancy*. Mumbai: FOGSI.