ISSN: 3066-9855
Research Article

Journal of Gynecology Obstetrics and Mother Health

A Comprehensive Evaluation of Iron Therapy in Pregnant Women: Efficacy and Adverse Drug Reaction in the Department of Obstetrics and Gynecology at Integral Institute of Medical Science and Research

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Submitted: 26 May 2025 **Accepted:** 02 June 2025 **Published:** 09 June 2025

https://doi.org/10.63620/MKJGOMH.2025.1031

Citation: *Khushtar, M., Nusaiba, A., Khan, M. S., Anshu, A. K., Khushtar, M., & Gupta, B. (2025). A Comprehensive Evaluation of Iron Therapy in Pregnant Women: Efficacy and Adverse Drug Reaction in the Department of Obstetrics and Gynecology at Integral Institute of Medical Science and Research. J of Gyne Obste & Mother Health, 3(3), 01-06.*

Abstract

Background: *Iron deficiency anemia poses a significant medical challenge during pregnancy, being the most prevalent issue.*

Objective: *The study aimed to evaluate iron therapy's uses and potential adverse reactions in pregnant women.*

Material and Method: *This was the prospective observational study, hundred pregnant anemic women (age above 18 years) with varying degrees of moderate and severe anemia participated, following institutional ethical approval. All patients were monitored for laboratory response and adverse effects. In this study, Statistical Package for the Social Sciences software was utilized.*

Results: *The study included patients aged 18-45 years (100%). Among the most number of patients were from age group of 25-31 (52%). Among hundred cases fifty patients were moderate and the remaining fifty were severely anemic. Iron was administered parenterally (17.6%) and orally (82.4%). While hemoglobin levels increased in both groups, the parenteral group exhibited a significantly (p-value <0.001) higher percentage increase of 55% after treatment, while in the oral group 20% increase was found after treatment.*

Conclusion: *Parenteral iron therapy proves more efficacious than oral iron therapy for managing iron deficiency anemia during pregnancy.*

Keywords: Anemia, Hemoglobin, Pregnancy, Moderate Anemia, Severe Anemia

Introduction

Anemia, characterized by reduced red blood cell count or hemoglobin concentration, is a considerable concern in obstetrics and perinatal care. As per the World Health Organization (WHO), anemia is known as a hemoglobin level below 12 g/dL in women. Three to five percent of women suffer from a common subtype of anemia that is caused by inadequate iron. Insufficient iron without anemia is even more widespread, impacting 12-16% of women before menopause [1, 2]. Pregnant women face a heightened risk of iron deficiency and iron-deficiency anemia

(IDA) due to heightened iron demands during pregnancy. Iron deficiency anemia is thought to affect between 35% and 75% of pregnant women in impoverished nations while in industrialized countries, the average prevalence is 18% [3]. In obstetrics and perinatal care, anemia is a prevalent issue. Depleted iron reserves, iron deficient erythropoiesis without anemia, and iron deficiency anemia, the most severe type of iron shortage, are the three phases of iron insufficiency. Anemia can be aggravated during pregnancy by several factors, including uterine or placental hemorrhage, gastrointestinal bleeding, and peripartum blood loss. The primary reason for anemia in both males and females is iron deficiency, with females being more frequently impacted [4]. Anemia develops because of a disproportion in erythrocyte loss relative to production; this can be due to ineffective or deficient erythropoiesis (e.g., from nutritional deficiencies, inflammation, or genetic Hb disorders) and/or excessive loss of erythrocytes (due to hemolysis, blood loss, or both). As a result, the causes of anemia might be classified as nutritional or non-nutritional, emphasizing the etiological significance of dietary inadequacy as the main causative component. Any disease that causes anemia increases the likelihood of an abnormal pregnancy and increases mother and newborn morbidity and death. Anemia is associated with 40% of maternal fatalities globally, according to WHO data. Constipation, heartburn, and nausea are among the gastrointestinal side effects that might restrict the dosage of oral iron preparations and can affect up to 50% of patients. The intestines have a limited capacity to absorb iron. The maximal rate of absorption of 100 mg of orally administered iron is 20% to 25%, which is only achieved in the late stages of iron insufficiency. Nonetheless, because oral iron is easily accessible, affordable, and easy, it's a potential therapeutic choice [5]. An equally vital alternative to oral preparations is parenteral iron. Insufficient or no response to oral iron, severe anemia, and intolerance to oral iron are all reasons for parenteral iron therapy [6, 7]. Intravenous iron is especially helpful in treating iron-deficient anemia when oral iron intake is insufficient [8]. According to the study conducted the prevalence of mild, moderate, and severe anemia was 43.6%, 47.6%, and 8.8% in pregnant women without any significant difference between urban and rural women between Hindu and Muslim women and no significant prevalence was found between rural and urban but literacy significantly decreases anemia [9]. A similar study found an increase in hemoglobin level is directly proportional to blood pressure and a decrease in hemoglobin is directly proportional to blood pressure. Low maternal hemoglobin also affects the hemoglobin level of the delivered baby [10-16]. Severely anemic mothers are more prone to delivering babies with low hemoglobin levels and low birth weight [17-24].

Materials and Methodology

The institutional ethics council approved this prospective observational study, which was carried out at the Integral Institute of Medical Sciences and Research's Department of Obstetrics and Gynaecology in Lucknow, India. A cohort of one hundred pregnant women, aged above 18 years and diagnosed with moderate and severe anemia based on World Health Organization guidelines (moderate anemia is defined as hemoglobin levels between 7.0 and 8.9 grams per deciliter, and severe anemia as hemoglobin levels below 7.0 grams per deciliter), were enrolled. Inclusion criteria comprised women with iron deficiency anemia, both severe and moderate cases, and the before and after hemoglobin levels were assessed during treatment. Exclusion criteria encompassed individuals unwilling to participate or with certain co-morbidities like hypertension and diabetes mellitus. Written approval was acquired from all eligible participants meeting the inclusion criteria. Comprehensive physical, systemic, and obstetric examinations were conducted, with hemoglobin levels assessed as portion of the inclusion process. Participants were then categorized into two groups based on their method of iron administration: parenteral and oral. Adverse reactions, such as itching and rashes, were monitored. Statistical analysis involved examining the dataset for significant hemoglobin level changes before and after iron therapy using Statistical Package for the Social Science software, with data entry facilitated through Microsoft Excel 2019.

Results

In our study among all hundred patients; they were classified as given below. Among these, it was discovered that 52 patients among individuals aged 25–31 have the highest number of patients. However, with just 2 patients, the age range is 39–45 (Table 1).

Table 1: Age Range of Patients

S.NO.	Age range	No. of patient
1	18-24	34
2	25-31	52
3	32-38	12
4	39-45	2

Iron was administered in two forms of administration; Parenteral and Oral. Medications administered parenteral were 17.6%, whereas medications administered orally were 82.4% (Figure 1). Among a hundred cases, fifty patients were moderate and the remaining patients were severely anemic. The average hemoglobin concentration in moderate and severe anemic patients before starting iron therapy in parenteral was observed to be 8.41 ± 0.19, 6.43 ± 1.45, and in oral observed to be 8.14 ± 0.63, and 6.28 ± 0.40 (Table 2). A significant rise in hemoglobin was found in post-parenteral therapy with a average hemoglobin concentration of 11.71 ± 1.02 in moderate anemic patients while in severe anemic patients, it was observed to be 11.22 ± 0.94, and in post-oral therapy with a mean hemoglobin level in moderate anemic patients was 9.67 ± 0.93, and in severely anemic was 7.62 ± 0.43(Table 2). A 39% increase in average hemoglobin concentration was observed in moderate anemic treated with intravenous whereas in severe anemic dramatic percentage increase was recorded which was 74% (Table 2). Oral administration of iron increases the hemoglobin level by 18% in moderate anemia and 21% in severe anemia (Table 2).

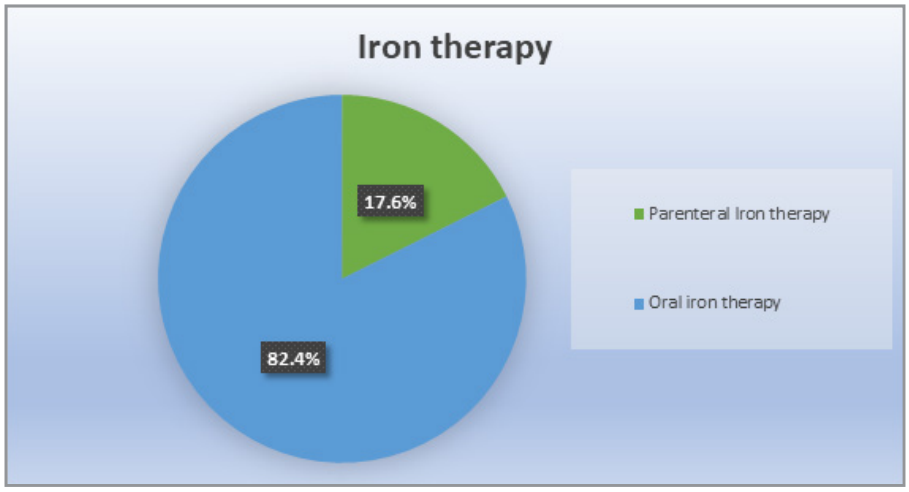

Figure 1: Administration form of Iron Therapy

Table 2: Effect of Parenteral and Oral Iron Therapy on Hemoglobin (Hb) Level

Effect of parenteral iron therapy on Hb level							
Moderate					Severe		
S.No		Before	After	Change in Percentage	Before	After	Change in Percentage
1	Sample size	7	7		8	8	
2	Mean	8.41	11.71	39%	6.43	11.22	74%
3	Standard deviation	0.19	1.02		1.45	0.94	
Effect of oral therapy on Hb level							
Moderate					Severe		
S.No		Before	After	Change in Percentage	Before	After	Change in Percentage
1	Sample size	43	43		42	42	
2	Mean	8.14	9.67	18%	6.28	7.62	21%
3	Standard deviation	0.63	0.93		0.4	0.43	

A dramatic increase was recorded in the hemoglobin level by 55% on parenteral administration of iron therapy whereas on oral administration the percentage increase was only 20% (Table 3). By using the Naranjo scale, the adverse drug reactions were reported in oral iron therapy which include rashes while itching in parenteral iron therapy these adverse drug reactions were categorized as given below (Table 4)

Table 3: Comparison of Parenteral and Oral Iron Therapy on Hemoglobin (Hb) Level

Comparison of parenteral and oral iron therapy on Hb level									
Parenteral						Oral			
S.No		Before	After	Change in Percentage	Significance	Before	After	Change in Percentage	Significance
1	Sample size	15	15			85	85		
2	Mean	7.36	11.45	55%	P < 0.001	7.2	8.64	20%	P < 0.001
3	Standard deviation	1.45	0.97			1.07	1.26		

Table 4: Naranjo Scale

Question	Yes	No	Do Not Know	Score
1. Are there previous conclusive reports on this reaction?	1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	2	-1	0	
3. Did the adverse event improve when the drug was discontinued or a specific antagonist was administered?	1	0	0	

4. Did the adverse event reappear when the drug was readministered?	2	-1	0	
5. Are there alternative causes that could on their own have caused the reaction?	-1	2	0	
6. Did the reaction reappear when a placebo was given?	-1	1	0	
7. Was the drug detected in blood or other fluids in concentrations known to be toxic?	1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	1	0	0	
10. Was the adverse event confirmed by any objective evidence?	1	0	0	

Table 5: Interpretation of Scores

Score	Interpretation of Scores
Total Score ≥9	Definite. The reaction (1) followed a reasonable temporal sequence after a drug or in which a toxic drug level had been established in body fluids or tissues, (2) followed a recognized response to the suspected drug, and (3) was confirmed by improvement on withdrawing the drug and reappeared on reexposure.
Total Score 5 to 8	Probable. The reaction (1) followed a reasonable temporal sequence after a drug, (2) followed a recognized response to the suspected drug, (3) was confirmed by withdrawal but not by exposure to the drug, and (4) could not be reasonably explained by the known characteristics of the patient's clinical state.
Total Score 1 to 4	Possible. The reaction (1) followed a temporal sequence after a drug, (2) possibly followed a recognized pattern to the suspected drug, and (3) could be explained by characteristics of the patient's disease.
Total Score ≤0	Doubtful. The reaction was likely related to factors other than a drug.

The following patients in our research had adverse medication responses reported to us (Table 6)

Table 6: Naranjo Score and ADR Possibility Based on the Naranjo Algorithm

S.NO	Naranjo score	ADR Probability	Type of Therapy
1.	5	Probable	Oral
2.	5	Probable	Parenteral
3.	6	Probable	Parenteral
4.	5	Probable	Parenteral
5.	5	Probable	Parenteral

Discussion

The uses and suspected adverse drug reactions of iron sucrose therapy in pregnant women were conducted based on the prospective observational study in the OPD and IPD department of gynecology and obstetrics for consecutive 6 months at Integral University Hospital, Lucknow. A total of a hundred volunteers were included according to inclusion and exclusion criteria [25]. Among the hundred cases, the patients were reserved among individuals aged of 18- 45, and the range between (25-31) has the highest number of patients. A comparable study by Robalo et al., shows the age range of most participants (24- 30)[26]. The study involved hundred pregnant women who were analyzed, parenteral iron was administered to 17.6%, and oral iron therapy was administered at 82.6% which is similar to a study carried out which asserted that iron sucrose was commonly utilized and beneficial in managing iron deficient anemia in the individual who does not respond well to oral therapy [27, 28]. In this study iron was administered in two ways that are oral and parenteral, oral iron was prescribed in 82.6% of cases, iron sucrose was prescribed in 17.6% of cases and the hemoglobin level was significantly increased in intravenous iron (55%) than oral iron (20%) which is similar to an article which showed the rise in hemoglobin levels was much larger in intravenous than in oral iron, and concluded that parenteral iron raises iron reserves quicker than oral iron [29]. Within this study, the average hemoglobin concentration in patients before starting parenteral iron therapy in moderate and severe was observed to be 8.41 and 6.43. A significant outcome in hemoglobin was found in post-parenteral iron therapy with a mean hemoglobin level of 11.71 and 11.22 respectively among moderate and severe cases. The individuals administered parenteral iron therapy yielded a substantial average increase of 39% in hemoglobin levels with moderate anemia. However, in the parenteral group, those with severe anemia experienced a more pronounced percentage increase of 74%, indicating a dramatic improvement in their hemoglobin levels. The administration of oral iron increases the hemoglobin level by 18% in moderate anemia whereas the increase in hemoglobin level is 21% in severe anemia. A study conducted found that the parenteral group had substantially higher hemoglobin levels (p-value < 0.001) along with hemoglobin levels differing between the groups receiving oral and parenteral treatment [30]. In our research, a comparison analysis revealed that the parenteral group achieved a significant level of difference (p-value < 0.001) in comparison to the oral group, indicating strong statistical significance, along with a study conducted found hemoglobin levels differed between the groups receiving oral and parenteral treat-

ment [31]. Among the hundred enrolled patients, five patients reported potential adverse drug reactions. As per the Naranjo scale, rashes and itching were among the recorded adverse drug responses. A similar study was performed by Neogi et al., who observed that adverse effects of intravenous iron sucrose were hypotension, hypertension, syncope, rash, anaphylactic reaction, the sensation of chest compression, metallic taste, nausea, and vomiting and observed the adverse effects of intravenous iron sucrose were nausea, bradycardia, vomiting, diarrhea, chest pain, headache, pruritis, and allergic reactions [32, 33].

Conclusion

In conclusion, our study demonstrates that both parenteral and oral administration of iron effectively increases hemoglobin levels in patients with anemia. However, parenteral administration shows a significantly greater increase in hemoglobin levels compared to oral administration, with a higher percentage increase in severe anemic patients. While oral iron therapy remains a valuable option it may result in a lower percentage increase in hemoglobin level. Additionally, adverse drug reactions such as rashes, and itching were reported, highlighting the importance of monitoring and managing side effects in clinical practice. Overall, these findings emphasize the need for individualized treatment approaches considering the severity of anemia and potential adverse effects when selecting the route of iron administration.

Compliance with Ethical Standards and Conflict of Interest

The author asserts that they have no conflict of interest with the contents of this manuscript. The study was conducted with the principles that have their origin in the Declaration of Helsinki. The present study is a prospective observational study with informed consent of using data and it was approved by the institutional ethics committee (Registration No. IEC/IIMS&R/2023/50).

References

1. Looker, A. C., Cogswell, M. E., & Gunter, E. W. (2002). Iron deficiency-United States, 1999-2000.
2. Looker, A. C., Dallman, P. R., Carroll, M. D., Gunter, E. W., & Johnson, C. L. (1997). Prevalence of iron deficiency in the United States. Jama, 277(12), 973-976.
3. Gupta, A., Manaktala, U., & Rathore, A. M. (2014). A randomised controlled trial to compare intravenous iron sucrose and oral iron in treatment of iron deficiency anemia in pregnancy. Indian Journal of Hematology and Blood Transfusion, 30, 120-125.
4. De Benoist, B., Cogswell, M., Egli, I., & McLean, E. (2008). Worldwide prevalence of anaemia 1993-2005; WHO Global Database of anaemia.
5. Cancelo-Hidalgo, M. J., Castelo-Branco, C., Palacios, S., Haya-Palazuelos, J., Ciria-Recasens, M., Manasanch, J., & Pérez-Edo, L. (2013). Tolerability of different oral iron supplements: a systematic review. Current medical research and opinion, 29(4), 291-303.
6. Werner, E., Kaltwasser, J. P., & Ihm, P. (1976). Intestinal absorption from therapeutic iron doses (author's transl). Arzneimittel-forschung, 26(11), 2093-2100.
7. Breymann, C. (2002). Iron supplementation during pregnancy. Fetal and maternal medicine review, 13(1), 1-29.
8. Khalafallah, A. A., & Dennis, A. E. (2012). Iron deficiency anaemia in pregnancy and postpartum: pathophysiology and effect of oral versus intravenous iron therapy. Journal of pregnancy, 2012(1), 630519.
9. Koutroubakis, I. E., Oustamanolakis, P., Karakoidas, C., Mantzaris, G. J., & Kouroumalis, E. A. (2010). Safety and efficacy of total-dose infusion of low molecular weight iron dextran for iron deficiency anemia in patients with inflammatory bowel disease. Digestive diseases and sciences, 55, 2327-2331.
10. Mishra, S., Gupta, P., Bhardwaj, P., Sachan, B., Srivastav, J. P., & Mishra, A. N. (2016). Effect of antenatal services during pregnancy on prevalence of anemia amongst pregnant women in Lucknow. Indian Journal of Medical Sciences, 68(1), 17-20.
11. Khan, A., & Agarwal, D. (2018). Effect of Maternal Anaemia on Cord Blood Haemoglobin. International Journal of Clinical Obstetrics and Gynaecology, 2, 15-17.
12. Anzar Bashir Alvi, S. M., Waseem, A., & Raj, P. (2019). Study of BMI, haemoglobin and blood pressure in subjects visiting OPD's of a medical college in Lucknow, Uttar Pradesh. Indian Journal of Clinical Anatomy and Physiology, 6(1), 113-117.
13. Fisher, A. L., & Nemeth, E. (2017). Iron homeostasis during pregnancy. The American journal of clinical nutrition, 106, 1567S-1574S.
14. Hyder, S. Z., Persson, L. Å., Chowdhury, A. M. R., & Ekström, E. C. (2002). Do side-effects reduce compliance to iron supplementation? A study of daily-and weekly-dose regimens in pregnancy. Journal of Health, Population and Nutrition, 175-179.
15. Rastogi, S., Waseem, S. M. A., & Bano, R. (2018). Study of anaemia amongst OPD patients visiting a private medical college in Lucknow, Uttar Pradesh. Indian J Clin Anat Physiol, 5(4), 546-552.
16. Bayoumeu, F., Subiran-Buisset, C., Baka, N. E., Legagneur, H., Monnier-Barbarino, P., & Laxenaire, M. C. (2005). Iron therapy in iron deficiency anemia in pregnancy: intravenous route versus oral route. European Journal of Obstetrics & Gynecology and Reproductive Biology, 123, S15-S19.
17. Cook, J. D., Finch, C. A., & Smith, N. J. (1976). Evaluation of the iron status of a population.
18. CRITCHLEY, J., & DUNDAR, Y. (2007). Adverse events associated with intravenous iron infusion (low-molecular-weight iron dextran and iron sucrose): a systematic review. Transfusion Alternatives in Transfusion Medicine, 9(1), 8-36.
19. Dewey, K. G., & Oaks, B. M. (2017). U-shaped curve for risk associated with maternal hemoglobin, iron status, or iron supplementation. The American journal of clinical nutrition, 106, 1694S-1702S.
20. Breymann, C., Bian, X. M., Blanco-Capito, L. R., Chong, C., Mahmud, G., & Rehman, R. (2011). Expert recommendations for the diagnosis and treatment of iron-deficiency anemia during pregnancy and the postpartum period in the Asia-Pacific region.
21. Kochhar, P. K., Kaundal, A., & Ghosh, P. (2013). Intravenous iron sucrose versus oral iron in treatment of iron deficiency anemia in pregnancy: a randomized clinical trial. Journal of Obstetrics and Gynaecology Research, 39(2), 504-510.

22. Neeru, S., Nair, N. S., & Rai, L. (2012). Iron sucrose versus oral iron therapy in pregnancy anemia. Indian Journal of Community Medicine, 37(4), 214-218.
23. Smith-Wade, S., Kidson-Gerber, G., Shand, A., Grzeskowiak, L., & Henry, A. (2020). The use of intravenous iron in pregnancy: for whom and when? A survey of Australian and New Zealand obstetricians. BMC Pregnancy and Childbirth, 20, 1-11.
24. Auerbach, M., & Macdougall, I. C. (2014). Safety of intravenous iron formulations: facts and folklore. Blood transfusion, 12(3), 296.
25. Perewusnyk, G., Huch, R., Huch, A., & Breymann, C. (2002). Parenteral iron therapy in obstetrics: 8 years experience with iron–sucrose complex. British journal of nutrition, 88(1), 3-10.
26. Robalo Nunes, A., Mairos, J., Brilhante, D., Marques, F., Belo, A., Cortez, J., & Fonseca, C. (2020). Screening for anemia and iron deficiency in the adult Portuguese population. Anemia, 2020(1), 1048283.
27. Cançado, R. D., Figueiredo, P. O. N. D., Olivato, M. C. A., & Chiattone, C. S. (2011). Efficacy and safety of intravenous iron sucrose in treating adults with iron deficiency anemia. Revista brasileira de hematologia e hemoterapia, 33, 439-443.
28. Shukla, S. K., Shukla, S., Verma, R. K., Singh, L. V., Khan, B. J., Gupta, V., ... & Sharma, N. (2018). Study of Anaemia in children and current update. Indian Journal of Biotechnology and Pharmaceutical Research, 6(3).
29. Shafi, D., Purandare, S. V., & Sathe, A. V. (2012). Iron deficiency anemia in pregnancy: intravenous versus oral route. The Journal of Obstetrics and Gynecology of India, 62, 317-321.
30. Al-Momen, A. K., Al-Meshari, A., Al-Nuaim, L., Saddique, A., Abotalib, Z., Khashogji, T., & Abbas, M. (1996). Intravenous iron sucrose complex in the treatment of iron deficiency anemia during pregnancy. European Journal of Obstetrics & Gynecology and Reproductive Biology, 69(2), 121-124.
31. Al, R. A., Unlubilgin, E., Kandemir, O., Yalvac, S., Cakir, L., & Haberal, A. (2005). Intravenous versus oral iron for treatment of anemia in pregnancy: a randomized trial. Obstetrics & Gynecology, 106(6), 1335-1340.
32. Neogi, S. B., Devasenapathy, N., Singh, R., Bhushan, H., Shah, D., Divakar, H., ... & Baswal, D. (2019). Safety and effectiveness of intravenous iron sucrose versus standard oral iron therapy in pregnant women with moderate-to-severe anaemia in India: a multicentre, open-label, phase 3, randomised, controlled trial. The Lancet Global Health, 7(12), e1706-e1716.
33. Silverstein, S. B., & Rodgers, G. M. (2004). Parenteral iron therapy options. American journal of hematology, 76(1), 74-78.