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Effectiveness and safety of oral versus intravenous iron therapy in iron deficiency anemia during pregnancy: A pharmacological review

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Abstract

Background: Iron deficiency anemia is a global health problem commonly occurring during pregnancy. The World Health Organization reported a prevalence of 35.5% in 2023, which may lead to serious consequences for both mother and fetus. Management of this condition is generally carried out through oral or intravenous iron therapy, each having its own advantages and limitations.

Purpose: to evaluate the effectiveness and safety of oral versus intravenous iron therapy in pregnant women with iron deficiency anemia.

Method: A limited systematic review was conducted based on PRISMA guidelines. Literature searching was performed using the PubMed database for studies published between 2015 and 2025. A total of 75 articles were identified, of which 5 studies met the inclusion criteria and were analyzed descriptively.

Results: The findings showed that intravenous iron therapy, particularly ferric carboxymaltose, was more effective in increasing hemoglobin and ferritin levels compared to oral therapy. In terms of safety, oral iron was more frequently associated with gastrointestinal side effects, whereas intravenous iron was generally well tolerated with mild adverse effects.

Conclusion: Intravenous iron therapy demonstrates superior effectiveness in improving hematological parameters; however, oral iron remains the first-line therapy due to its accessibility and lower cost. Therefore, treatment selection should be individualized based on the patient's clinical condition.

Keywords: Intravenous Iron; Iron Deficiency Anemia; Oral Iron; Pregnancy; Therapeutic Effectiveness.

INTRODUCTION

According to the Global Anemia Estimates 2025 published by the World Health Organization, the prevalence of anemia among pregnant women aged 15-49 years reached 35.5% in 2023. This figure is higher than the prevalence reported among all women of reproductive age (30.7%) and among non-pregnant women (30.5%). These findings highlight that anemia remains a major global public health problem, with a disproportionately greater burden among pregnant women compared with the general female population (World Health Organization, 2025).

In Indonesia, based on the 2023 Indonesian Health Survey, the prevalence of anemia among pregnant

women was 27.7%, representing a decline from the 48.9% reported in the 2018 Basic Health Research. Nevertheless, anemia during pregnancy remains an important health concern and continues to require serious attention because of its implications for both maternal and neonatal health (Ministry of Health of the Republic of Indonesia, 2023).

Anemia in pregnancy is defined as a hemoglobin (Hb) concentration below the normal threshold according to World Health Organization criteria. During pregnancy, plasma volume expands more markedly than erythrocyte production, resulting in physiological hemodilution and a consequent decline in Hb

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concentration. This condition may be exacerbated by preeclampsia, certain medical comorbidities, and other contributing factors such as vitamin B12 deficiency, folate deficiency, thalassemia, hemolysis, and blood loss, with iron deficiency remaining the most common cause (Pavord, Daru, Prasannan, Robinson, Stanworth, & Girling, 2020; American College of Obstetricians and Gynecologists, 2021). Iron-deficiency anemia during pregnancy not only affects maternal hematologic status but is also associated with an increased risk of adverse maternal and perinatal outcomes, including fatigue, reduced functional capacity, preterm birth, and impaired fetal growth. In addition, iron requirements progressively increase throughout pregnancy to support maternal erythrocyte mass expansion, placental growth, and fetal development. Therefore, early detection and appropriate management are essential to prevent further complications (Georgieff, 2020; Benson, Shah, Frise, & Frise, 2021).

Iron therapy for iron-deficiency anemia can be administered either orally or parenterally. Oral iron preparations remain the first-line treatment in clinical practice because of their ease of administration, relatively low cost, and widespread availability. During pregnancy, oral iron supplementation is commonly used both for prophylaxis and as initial treatment for iron-deficiency anemia. However, the effectiveness of oral therapy is often limited in more severe cases, as the hemoglobin response tends to be slower and treatment is frequently accompanied by gastrointestinal adverse effects that may reduce patient adherence. Consequently, intravenous iron therapy is increasingly considered, particularly in pregnant women with severe iron-deficiency anemia, intolerance to oral preparations, inadequate response to oral treatment, or when rapid hemoglobin correction is required (Pels & Ganzevoort, 2015). Compared with oral therapy, intravenous iron is able to increase hemoglobin levels and replenish iron stores more

rapidly and effectively, especially in moderate-to-severe anemia. Nevertheless, this treatment requires healthcare facilities, medical supervision, and still carries the potential for certain adverse effects (Nicholson, Axon, Daru, & Rogozińska, 1996).

RESEARCH METHOD

This study was conducted as a limited systematic review aimed at evaluating the effectiveness and safety of oral iron therapy compared with intravenous iron therapy for iron-deficiency anemia during pregnancy. The review was conducted following a simplified approach based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

A literature search was performed in April 2026 using one electronic database, PubMed. The search strategy employed a combination of keywords and Medical Subject Headings (MeSH), including "iron-deficiency anemia," "pregnancy," "oral iron," "intravenous iron," and "adverse events," combined with Boolean operators (AND, OR). The inclusion criteria were as follows: pregnant women with iron-deficiency anemia; studies comparing oral and intravenous iron therapy; randomized controlled trials (RCTs) and meta-analyses; publications from 2015 to 2025; and full-text articles available. Of the 75 articles initially identified, 5 studies met the inclusion criteria and were included in the descriptive analysis.

The literature search and selection process identified several studies that met the inclusion criteria and were relevant to the objective of this review. The studies included randomized controlled trials (RCTs) and meta-analyses comparing the effectiveness and safety of oral and intravenous iron therapy for iron-deficiency anemia during pregnancy. The main characteristics of each study, including study design, population size, type of intervention, and key findings, are systematically summarized in the following table.

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RESEARCH RESULT

Table Characteristics of Included Studies and Comparison of the Effectiveness and Safety of Oral and Intravenous Iron Therapy for Iron-Deficiency Anemia During Pregnancy

(Author & Year)	Method	Population	Intervention	Main Findings
(Bhavi & Jaju, 2017).	A randomized controlled trial was performed involving 112 patients attending the antenatal clinic at Shri B.M.Patil Medical college Hospital, Bijapur from October 2011 to August 2012, with hemoglobin levels between 70-110 g/L and serum ferritin of < 15 ng/ml. In the intravenous group, 200 mg of iron sucrose was administered in 100 ml 0.9% sodium chloride per day. Participants in the oral group were given 200 mg of ferrous fumarate per day. The primary outcome measures for the trial, haemoglobin and serum ferritin levels were measured after 4 weeks. Statistical significance was assessed using Student's t-test.	112 pregnant women aged 18–45 years with Hb 70–110 g/L and serum ferritin <15 ng/mL	Participants were randomly assigned into two groups: oral iron (Group A) and intravenous iron (Group B), with 56 women in each group	After 4 weeks, the increase in Hb was significantly greater in the intravenous group than in the oral group (22 ± 11.5 g/L vs 12 ± 9 g/L; $p < 0.0001$). Serum ferritin increased significantly more in the intravenous group (112.17 ± 98.15 ng/mL vs 22.71 ± 11.32 ng/mL; $p < 0.0001$). Hb increase >20 g/L was achieved by 55% of women in the intravenous group compared with 11% in the oral group. Adverse effects were reported in 30% of patients receiving oral iron, whereas only mild adverse effects were noted in the intravenous group.
(Breyman et al., 2016)	Pregnant women (n= 252; gestational weeks 16–33) with IDA were randomized 1: 1 to FCM (1000–1500 mg iron) or FS (200 mg iron/day) for 12 weeks. The	252 pregnant women aged ≥ 18 years in the second or third trimester with iron-deficiency anemia and serum	Participants were randomized 1:1 to receive intravenous ferric carboxymaltose (FCM) or oral ferrous sulfate (FS) for 12 weeks	FCM resulted in a significantly higher anemia correction rate than FS, with 84% of women achieving Hb ≥ 11.0 g/dL compared with 70% in the FS group (OR

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	primary objective was to compare efficacy; ferritin ≤ 20 ng/mL secondary objectives included safety and quality of life.			2.06; $p = 0.031$). Hb increased at a comparable rate in both groups. FCM significantly improved vitality and social functioning before delivery. Treatment-related adverse events occurred in 11% of the FCM group and 15% of the FS group; gastrointestinal adverse effects were more frequent with FS. (e) No unexpected safety concerns were reported with FCM.
(Jose et al., 2019)	A randomized clinical trial was conducted from (January 2016-August 2017). at a tertiary hospital. Pregnant women diagnosed with moderate to severe iron deficiency anaemia were screened for the study. One hundred patients were randomized to receive either intravenous FCM or ISC. Primary outcome was rise in hemoglobin (Hb) from baseline after 12 weeks. Secondary outcomes were change in RBC indices, serum iron studies, improvement in fatigue scores, number of visits and perinatal outcome.	100 pregnant women with moderate-to-severe iron-deficiency anemia	Participants were randomized into two groups of 50 women each to receive intravenous ferric carboxymaltose (FCM) or intravenous iron sucrose complex (ISC)	Mean Hb increase at 12 weeks was significantly greater with FCM than with ISC (29 g/L vs 22 g/L; $p < 0.001$). Fewer doses were required in the FCM group than in the ISC group (2.0 ± 0 vs 6.04 ± 0.45 ; $p < 0.001$). Serum ferritin was significantly higher in the FCM group at 3 weeks, although the difference disappeared by 12 weeks. No serious adverse events were observed in either group. Total treatment cost was significantly higher in the FCM group.
(Francés & Martinez-Bujanda, 2020).	Electronic databases PubMed and the Cochrane Library were searched for studies published up to March 2019. Clinical or observational studies reporting	8,454 subjects from 54 studies; 8,142 included in efficacy analysis and 8,005 in tolerability analysis	Among participants included in the efficacy analysis, 6,450 received iron protein succinylate and 1,692 received other iron formulations as	Iron protein succinylate was evaluated in 54 studies. Mean Hb increased by 19.65% among patients treated with iron protein

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	data on the tolerability of oral iron protein succinylate were included. Results were statistically described to evaluate and compare the efficacy and safety of iron protein succinylate with the comparators under study.	comparators	succinylate while receiving H2 antagonists. A mean Hb increase of $\geq 25\%$ was observed in patients with gastroenteric disorders. Mean ferritin increased by 52.8% in 3,071 treated patients. Iron protein succinylate showed a lower rate of adverse effects than other oral iron preparations, confirming good tolerability.
(Gupte et al., 2024).	Meta-analysis of randomized controlled trials. Selection of studies: Studies related to ferric carboxymaltose in pregnancy were scanned. Observational studies, review articles, and case reports were excluded. Randomized studies in pregnant women involving ferric carboxymaltose and other intravenous iron formulations were shortlisted	Nine randomized controlled trials identified through systematic searches of EMBASE, PubMed, and Web of Science (2005–2021) involving pregnant women receiving ferric carboxymaltose	Comparison of ferric carboxymaltose (FCM) with iron sucrose or iron polymaltose FCM significantly improved Hb compared with iron sucrose/polymaltose (standardized mean difference 0.89 g/dL; 95% CI 0.27–1.51). Ferritin increase after FCM treatment was also greater. No serious adverse effects were reported with FCM or other intravenous iron formulations. The effect of FCM on Hb was sustained up to 12 weeks. No statistically significant differences were found in neonatal outcomes between FCM and iron sucrose groups.

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Based on the studies analyzed, iron therapy administered either orally or intravenously, using various formulations such as Ferric carboxymaltose and iron sucrose, showed variable effects on clinical outcomes in iron-deficiency anemia during pregnancy. Most studies reported that intravenous therapy produced a faster and greater increase in hemoglobin and ferritin levels compared with oral therapy, although not all studies demonstrated consistent differences across all outcomes, including safety and neonatal outcomes. These differences in findings may be explained by variations in study design, participant characteristics, the type and dosage of iron preparations, duration of treatment, and the outcome measures used. Therefore, the evaluation of the effectiveness and safety of iron therapy during pregnancy should be interpreted in the context of the specific characteristics of each study.

DISCUSSION

Based on the findings of this review, intravenous iron therapy consistently demonstrated superior efficacy in improving hemoglobin (Hb) levels and body iron stores, as reflected by increased ferritin concentrations, compared with oral therapy in pregnant women with iron-deficiency anemia. This advantage can be explained by its pharmacological mechanism, as intravenous administration allows iron to enter the systemic circulation directly without passing through the often limited absorptive processes of the gastrointestinal tract. This is particularly relevant during pregnancy, when iron requirements increase substantially to support maternal blood volume expansion and fetal development. In contrast, the effectiveness of oral therapy depends largely on intestinal absorptive capacity, which may be influenced by gastrointestinal mucosal conditions, food interactions, and patient adherence, resulting in a slower Hb response (Bhavi et al., 2017; Breyman et al., 2016; World Health Organization, 2016).

These findings are further supported by a clinical trial showing that intravenous iron was superior to oral therapy in preventing anemia and in increasing hemoglobin and ferritin levels in pregnant women with persistent iron deficiency. Improvements in hematologic parameters were also accompanied by reduced fatigue, improved psychological well-being

within the first six weeks, and better physical well-being within the first three weeks after treatment. In terms of safety, no unexpected safety concerns were identified; hypersensitivity reactions were transient, resolved rapidly without the need for adrenaline, and no increased risk of hypophosphatemia was observed. However, the study was not sufficiently powered to assess obstetric and perinatal outcomes conclusively. Therefore, the main benefit of intravenous therapy lies not only in faster hemoglobin correction but also in the improvement of patient-reported clinical symptoms, although its impact on long-term pregnancy outcomes still requires further investigation (Hansen, Sommer, Pinborg, Krebs, Thomsen, Moos, & Holm, 2023). Consistent with these findings, reported that ferric carboxymaltose administered during late pregnancy produced a faster and greater increase in hemoglobin levels than oral therapy. This further supports the role of intravenous iron as an effective option, particularly in pregnant women who require rapid anemia correction before delivery (Pasricha, Moya, Ataíde, Mzembe, Harding, Mwangi, & Phiri, 2025).

From a safety perspective, oral iron therapy is more frequently associated with adverse effects, particularly gastrointestinal symptoms such as nausea, vomiting, epigastric pain, and constipation, which may reduce adherence to long-term treatment. In contrast, intravenous iron therapy generally shows a more favorable tolerability profile, with fewer adverse events, most of which are mild in severity. One study demonstrated that ferric carboxymaltose significantly increased hemoglobin levels within three to six weeks after treatment in pregnant women with mild, moderate, and severe iron-deficiency anemia. In women with iron deficiency without anemia, this therapy did not cause hemoconcentration. Moreover, no serious adverse events were reported; the adverse effects observed were generally mild and transient, including local irritation, nausea, and headache, and were not associated with adverse fetal or neonatal outcomes (Froessler, Gajic, Dekker, & Hodyl, 2018). Nevertheless, intravenous iron administration still requires caution because of the potential for hypersensitivity reactions, although these events are rarely reported. Thus, intravenous therapy not only offers greater hematologic improvement but may also serve as a safe alternative, especially in patients who

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are intolerant to oral therapy or who require rapid correction of anemia (Breyman et al., 2016; Jose et al., 2019; Gupte et al., 2023).

However, not all studies showed entirely consistent findings regarding the superiority of intravenous over oral therapy. Some studies reported no significant difference in Hb improvement between the two treatment modalities at certain evaluation time points. This inconsistency is likely attributable to heterogeneity across studies, including differences in study design, participant characteristics (such as anemia severity and gestational age), the type and dose of iron preparations used, and the duration of intervention. In addition, differences in the outcome measures assessed, such as timing of Hb measurement or other clinical indicators, may also have influenced the overall interpretation of results (Bhavi et al., 2017; Gupte et al., 2023).

With regard to maternal and neonatal clinical outcomes, the available evidence remains limited and heterogeneous. Although intravenous iron therapy has consistently been shown to improve hematologic parameters more effectively, several meta-analyses have not demonstrated significant differences between oral and intravenous therapy in neonatal outcomes, such as birth weight or neonatal intensive care unit admission. Overall, randomized controlled trials suggest that intravenous iron tends to produce faster ferritin recovery and, in many studies, more rapid hemoglobin improvement than oral therapy, while also being associated with fewer gastrointestinal adverse effects. This advantage appears consistent across different intravenous formulations, including iron sucrose, ferric carboxymaltose, and ferric derisomaltose, and across different patient populations, particularly pregnant women with moderate-to-severe anemia, persistent iron deficiency, or late pregnancy requiring correction within a limited timeframe. Nevertheless, several large pragmatic clinical trials have not demonstrated clear improvements in major composite maternal outcomes, anemia prevalence at 36 weeks of gestation, birth weight, or preterm birth. These findings suggest that the primary benefit of intravenous therapy lies in faster hematologic recovery and better tolerability, whereas its effect on long-term maternal and neonatal outcomes remains uncertain and requires further study (Toro, Jaramillo, Pazmino, & Caceres, 2026).

These findings are consistent with the systematic review and meta-analysis which included 34 studies involving 8,061 women. Their analysis showed that intravenous iron therapy increased hemoglobin levels more rapidly during pregnancy and the postpartum period and was associated with an approximately 21% reduction in maternal complications, as well as fewer adverse events, compared with oral therapy. However, these advantages were not consistently observed for neonatal outcomes or for individual maternal complications (Pandey, Gautam, Tolani, & Neogi, 2024). Therefore, the principal benefit of intravenous therapy appears to lie mainly in faster hematologic improvement and a possible overall reduction in maternal complications, but not necessarily in improved long-term clinical outcomes for mothers or infants.

On the other hand, some oral iron formulations, such as iron protein succinylate, have also demonstrated good effectiveness in improving hemoglobin and ferritin levels, with better tolerability than conventional oral iron preparations (Frances et al., 2020; Gupte et al., 2023).

Overall, the findings of this review suggest that intravenous iron therapy, particularly formulations such as ferric carboxymaltose, offers advantages in both the speed and magnitude of hemoglobin improvement and iron store replenishment compared with oral therapy, while maintaining a relatively favorable safety profile. Nevertheless, oral iron remains the recommended first-line treatment in routine clinical practice because of its ease of administration, lower cost, and broader accessibility, especially in primary healthcare settings. Therefore, treatment selection should be individualized according to the patient's clinical condition, including anemia severity, response to previous therapy, drug tolerability, and the availability of healthcare resources, in order to ensure a rational and evidence-based therapeutic approach (World Health Organization, 2016).

This review has several limitations that should be acknowledged. First, the number of included studies was relatively limited, which may affect the generalizability of the findings. Second, the literature search was conducted using only one database, namely PubMed, which may have resulted in omission of relevant studies. Third, substantial heterogeneity existed across studies in terms of design, participant

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characteristics, and the type and dose of interventions used. Therefore, the findings of this review should be interpreted with caution.

CONCLUSION

Intravenous iron therapy has been shown to be more effective than oral therapy in achieving a faster increase in hemoglobin levels and replenishment of iron stores in pregnant women with iron-deficiency anemia, while maintaining a relatively favorable safety profile. Nevertheless, oral iron therapy remains the first-line treatment because of its ease of administration, lower cost, and wider accessibility. Therefore, treatment selection should be individualized according to the patient's clinical condition, the severity of anemia, tolerance to therapy, and the availability of healthcare facilities in order to achieve optimal outcomes for both mother and fetus.

SUGGESTION

Further studies using more standardized methodologies are needed to strengthen the evidence regarding the effectiveness and safety of oral and intravenous iron therapy during pregnancy. In clinical practice, treatment choice should be tailored to the patient's condition, anemia severity, and treatment tolerability, with intravenous therapy considered in selected cases. In addition, improving patient education and access to appropriate treatment is essential to optimize the management of anemia during pregnancy.

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