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A Meta Analysis

Intravenous vs. Oral Iron for Anemia in Pregnancy: A Meta-Analysis of Efficacy and Safety

Muhammad Saqib[1], **Meer Murtaza**[2], **Muhammad Bilal Khanzada**[2], **Shehr I Yar Khan**[3], **Humna Shahid**[4]

1 Khyber Medical College, University of Peshawar, Pakistan
2 Liaquat University of Medical and Health Sciences, Pakistan
3 Gandhara University Kabir Medical College, Pakistan
4 Combined Military Hospital, Multan Institute of Medical Sciences, Pakistan

Correspondence
muhammadsaqib.drkmc@gmail.com

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ABSTRACT

Background: Iron deficiency anemia (IDA) remains one of the most prevalent nutritional disorders globally, particularly affecting pregnant women in low- and middle-income countries. While oral iron is the standard first-line treatment, its gastrointestinal side effects and poor compliance often limit effectiveness. Intravenous (IV) iron offers a faster alternative but carries potential risks and higher costs. **Objective**: To systematically compare the efficacy and safety of intravenous iron therapy versus oral iron supplementation for treating iron deficiency anemia in pregnant women, based on randomized controlled trial (RCT) data. **Methods**: A systematic review and meta-analysis were conducted following PRISMA guidelines. Databases including PubMed, Cochrane CENTRAL, and Google Scholar were searched from inception to 15 March 2025 for RCTs comparing IV and oral iron in pregnant women with IDA. Outcomes included change in hemoglobin (Hb) levels, risk of postpartum hemorrhage (PPH), need for blood transfusion, and adverse events. Risk of bias was assessed using the Cochrane Risk of Bias Tool, and evidence certainty was graded using GRADE. A random-effects model was used to pool results. **Results**: Ten RCTs (n = 5954) were included. IV iron was associated with a significantly greater Hb increase at 3–6 weeks post-treatment (SMD: 0.25; 95% CI: 0.01–0.49; P = 0.04; I^2 = 85%). Sensitivity analysis excluding high-weight studies showed stronger results (WMD: 0.36 g/dL; 95% CI: 0.24–0.47; P < 0.00001; I^2 = 27%). No significant difference was found in the risk of PPH (RR: 1.21; 95% CI: 0.77–1.89; P = 0.41) or need for transfusion (RR: 0.69; 95% CI: 0.46–1.03; P = 0.07). Adverse events were significantly lower in the IV iron group (RR: 0.51; 95% CI: 0.37–0.71; P < 0.0001; I^2 = 0%). **Conclusion**: IV iron is more effective than oral iron for improving hemoglobin levels in pregnant women with IDA and has a better safety profile. However, it does not significantly reduce the risk of PPH or transfusion. These findings support the selective use of IV iron in clinical scenarios where oral iron is poorly tolerated or ineffective. Further research is needed to evaluate long-term maternal and neonatal outcomes and cost-effectiveness in resource-limited settings.

Keywords: Anemia, Iron-Deficiency; Pregnancy Complications, Hematologic; Iron, Dietary; Iron, Intravenous; Hemoglobins; Randomized Controlled Trials as Topic; Prenatal Care; Maternal Health Services.

INTRODUCTION

Anemia remains a significant global health burden, affecting individuals across all age groups. During pregnancy, iron deficiency is the predominant cause, accounting for approximately 75% of all anemia cases worldwide (1, 2). The burden is even more pronounced in low-resource settings, where up to 95% of anemic pregnant women are affected by iron deficiency anemia (IDA) (3, 4). The World Health Organization (WHO) defines IDA in pregnancy as a hemoglobin (Hb) concentration below 11 g/dL (5). While anemia severity may be classified as mild, moderate, or severe, the precise cutoff values often vary by country or region (6). Recognizing its widespread impact, the WHO considers anemia a public health issue when it affects more than 5% of a population and a severe crisis when prevalence exceeds 40% (7–9). In response, the World Health Assembly aimed to reduce anemia among women of reproductive age by 50% by 2025; however, no country has yet achieved this goal (10). Globally, an estimated 37%

of pregnant women remain anemic, with the highest prevalence reported in Southeast Asia (47.8%) and Africa (45.8%) (11).

The physiological demands of pregnancy, particularly during the second and third trimesters, significantly increase maternal iron requirements due to accelerated fetal growth and iron transfer to the fetus (12, 13). When left untreated, IDA in pregnancy contributes to serious complications, including approximately 115,000 maternal deaths annually—representing nearly 20% of maternal mortality worldwide—and about 591,000 perinatal deaths (14, 15). Additionally, it is associated with adverse maternal and fetal outcomes such as preterm birth, intrauterine growth restriction, preeclampsia, postpartum hemorrhage (PPH), and impaired neonatal iron stores (16, 17).

Treatment strategies for IDA in pregnancy include blood transfusions and iron supplementation via oral, intramuscular, or intravenous routes (18). Oral iron remains the first-line therapy due to its cost-effectiveness and ease of access, especially in resource-limited settings (5). However, poor gastrointestinal tolerance—manifesting as nausea, constipation, diarrhea, and metallic taste—often results in non-adherence and suboptimal outcomes (5). In contrast, intravenous (IV) iron offers a faster and more reliable correction of anemia, especially in cases of moderate-to-severe IDA or when oral therapy fails. Common formulations include iron sucrose, iron dextran, ferric polymaltose, and ferric carboxymaltose. While effective, IV iron carries risks such as hypersensitivity reactions, venous thrombosis, and in rare instances, life-threatening complications like anaphylaxis or cardiac arrest (19).

Despite its increasing clinical use, the superiority of IV iron over oral iron in terms of maternal and neonatal outcomes remains a subject of ongoing debate. A Cochrane review by Reveiz et al. concluded that evidence was insufficient to determine whether IV iron is more effective or safer than oral iron during pregnancy (18). Since then, several randomized controlled trials (RCTs) have reported conflicting findings. Some have demonstrated significantly greater Hb improvements with IV iron (20–22), while others noted only marginal or inconsistent benefits with respect to clinical outcomes such as PPH or transfusion rates (23). For instance, Neogi et al. reported superior hematological recovery with IV iron but observed no significant difference in maternal complications (21). Similarly, a network meta-analysis by Rogozińska et al. compared multiple iron preparations but emphasized the lack of robust data on safety endpoints (41).

Qayyum et al. recently conducted a meta-analysis comparing oral and injectable iron therapies in pregnancy, synthesizing literature published up to 2023 (24). However, their analysis was limited by several methodological issues, including a narrow scope that prioritized hemoglobin improvement as the sole endpoint and did not account for heterogeneity in formulations or co-interventions. Additionally, the inclusion of studies with variable definitions for adverse events, inconsistent reporting of maternal complications, and limited follow-up restricted the generalizability of their conclusions (24). Moreover, recent large-scale trials such as Derman et al. (2025) were not included in earlier syntheses, highlighting the need for an updated, more comprehensive analysis (36).

To address these gaps, the present systematic review and meta-analysis was undertaken to provide a rigorous and updated comparison of the efficacy and safety of IV versus oral iron therapy for IDA in pregnant women. Unlike earlier reviews, this study incorporates recent high-powered trials, expands outcome reporting to include adverse events and clinically significant maternal complications, and applies a robust methodological framework consistent with PRISMA and GRADE guidelines. By doing so, it seeks to clarify the therapeutic value of IV iron relative to oral formulations and guide evidence-based clinical decision-making in diverse healthcare settings.

MATERIALS AND METHODS

This systematic review and meta-analysis was conducted in alignment with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (25) and evaluated for methodological rigor using the AMSTAR 2 tool (26). A PRISMA flow diagram depicting the selection process is provided in Figure 1, and supplementary details including the PRISMA checklist and comprehensive search strategy are available in Appendix 1 and Appendix 2, respectively. A comprehensive literature search was undertaken across PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL), and Google Scholar, covering all records from database inception to 15 March 2025. The search terms were designed to encompass relevant variations in terminology, using combinations of keywords and MeSH terms linked with Boolean operators. There were no restrictions on language or publication region. The search strategy included terms related to iron therapy modalities, anemia, pregnancy, and randomized trial design. The final set of search terms and logic is presented in Table 1.

Table 1. Search Terms and Boolean Logic

Search Category	Search Terms
Intervention	"intravenous iron" OR "IV iron" OR "parenteral iron"
Comparator	"oral iron" OR "ferrous sulphate" OR "ferrous fumarate" OR "iron tablets"
Condition	"anemia in pregnancy" OR "iron deficiency anemia" OR "IDA"
Study Design	"randomized controlled trial" OR "RCT"
Boolean Combination	("IV iron" OR "intravenous iron") AND ("oral iron") AND ("pregnancy" OR "pregnant women") AND "RCT"

Search results were imported into EndNote X9 for deduplication and then uploaded to Rayyan QCRI for screening. Reference lists of included studies and prior reviews were also examined to identify additional eligible trials. Eligibility criteria were determined using the PICO (Population, Intervention, Comparator, Outcome) framework. Studies were included if they enrolled pregnant women diagnosed with iron deficiency anemia, utilized intravenous iron therapy as the intervention, and compared it with

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oral iron supplementation. Eligible studies had to report at least one outcome of interest, such as hemoglobin change, postpartum hemorrhage (PPH), transfusion need, or adverse events. Only randomized controlled trials (RCTs) were included. Observational studies, case reports, non-randomized trials, and studies not involving pregnant women were excluded. Unpublished manuscripts, grey literature, and duplicate reports were also omitted. These criteria are summarized in Table 2.

Study selection was independently performed by two reviewers who screened titles and abstracts, followed by full-text assessment for eligibility. Disagreements were resolved through discussion or arbitration by a third reviewer. The degree of inter-reviewer agreement was calculated using Cohen's kappa statistic. Data was extracted independently by two reviewers using a prestructured form. Extracted variables included study author, publication year, geographic location, sample size, gestational age at the start of the intervention, baseline hemoglobin levels, iron formulations and dosages, follow-up duration, and outcomes related to hemoglobin change, PPH, transfusion requirements, and adverse events.

For studies with missing or unclear data, corresponding authors were contacted. If data were only available in graphical form, values were estimated using digital extraction tools and verified for accuracy. The risk of bias was assessed using the Cochrane Risk of Bias Tool (27). Each included RCT was evaluated across standard domains including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, completeness of outcome data, selective outcome reporting, and other potential sources of bias. Each domain was classified as having low, unclear, or high risk of bias. The overall risk-of-bias summary is presented in Figure 8.

To evaluate the certainty of evidence, the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) framework was applied for each outcome (28). Five domains were assessed: risk of bias, inconsistency, indirectness, imprecision, and publication bias. Based on this assessment, the quality of evidence was rated as high, moderate, low, or very low. A comprehensive GRADE summary table is provided in Appendix 3.

Table 2. Eligibility Criteria

Criteria	Inclusion	Exclusion
Population	Pregnant women diagnosed with iron deficiency anemia	Non-pregnant women, postpartum subjects, or general anemia without pregnancy
Intervention	Intravenous (IV) iron preparations	Non-iron-based interventions
Comparator	Oral iron therapy	Placebo or no-treatment groups
Study Design	Randomized controlled trials (RCTs)	Observational studies, case series/reports, quasi-randomized or non-RCTs
Outcomes	Hb change, postpartum hemorrhage, transfusion need, adverse events	Studies not reporting any relevant outcomes
Language/Publication	Peer-reviewed studies without language restriction	Unpublished theses, conference abstracts, duplicate publications

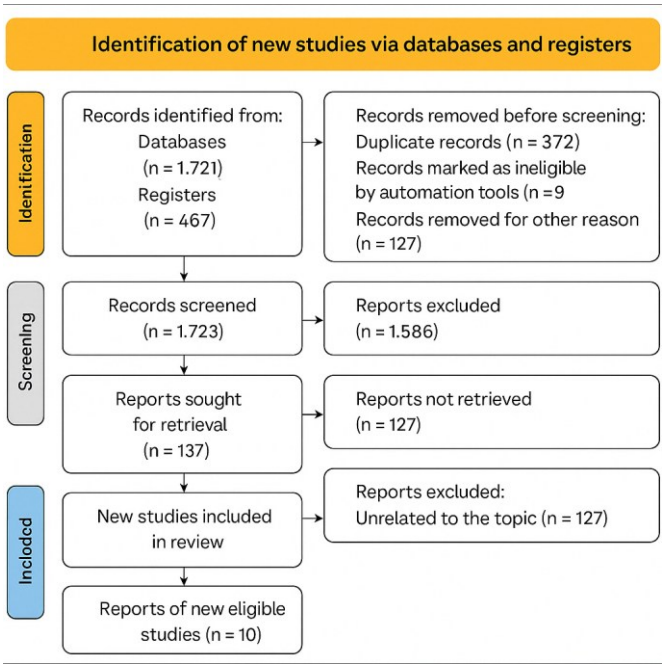

Figure 1: PRISMA 2020 flow diagram illustrating the selection process of studies included in the meta-analysis comparing intravenous and oral iron for anemia in pregnancy.

All statistical analyses were conducted using the DerSimonian and Laird random-effects model. For continuous outcomes such as changes in hemoglobin levels, results were pooled as standardized mean differences (SMDs) or weighted mean differences (WMDs) with 95% confidence intervals (CIs). For categorical outcomes including adverse events, transfusion need, and PPH, pooled risk ratios (RRs) with 95% CIs were calculated. Statistical heterogeneity was evaluated using the I^2 statistic, where $I^2 < 25\%$ was considered low, 25–50% moderate, and >50% high heterogeneity.

Sensitivity analyses were conducted by excluding studies with disproportionately high weight in the meta-analysis, to assess the robustness of the results. Publication bias was examined through Egger's regression test, and results were visually inspected using funnel plots. Statistical significance was defined as a p-value < 0.05. Analyses were performed using Review Manager (RevMan) version 5.4 and R statistical software (R Foundation for Statistical Computing, Vienna, Austria; https://www.R-project.org/). This study involved only secondary analysis of data from previously published trials and did not require ethical approval or informed consent. The systematic review protocol was registered with PROSPERO under registration number CRD420251011591, and the

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full protocol can be accessed at https://www.crd.york.ac.uk/PROSPERO/view/CRD420251011591.

This PRISMA 2020 flow diagram (Figure 1) summarizes the systematic literature search and study selection process conducted for the meta-analysis on the efficacy and safety of intravenous versus oral iron in pregnant women with anemia. A total of 2,188 records were identified through database searches (n = 1,721) and clinical trial registers (n = 467). Prior to screening, 508 records were excluded due to duplication (n = 372), ineligibility detected by automation tools (n = 9), or other reasons (n = 127), leaving 1,723 records for title and abstract screening. Of these, 1,586 were excluded based on relevance and eligibility criteria. The full texts of 137 reports were then sought for retrieval, but 127 could not be retrieved. Among the 10 successfully retrieved full-text articles, all were reviewed, and 127 reports were excluded for being unrelated to the topic, ultimately resulting in 10 new eligible studies being included in the final meta-analysis. This rigorous selection process ensures the inclusion of high-quality and relevant studies for a comprehensive comparison of intravenous and oral iron interventions in the management of anemia during pregnancy.

RESULTS

The table summarizes the characteristics of ten included studies comparing intravenous (IV) and oral iron therapy in pregnant women with anemia. The studies were conducted across various countries including India, France, Thailand, Malawi, and a multi-country global setting, with most research originating from India. The anemia severity among participants varied, with some studies explicitly reporting moderate to severe anemia, such as Abhilashini (2014) and Derman (2025), while others did not report the exact severity (not reported, NR). The types of intravenous iron used were predominantly iron sucrose, although two studies—FER-ASAP (2016) and Derman (2025)—used ferric carboxymaltose. Oral iron therapy in all studies was provided as ferrous sulphate or ferrous fumarate. Concomitant interventions differed across the studies. Some studies administered no additional supplements, while others included folic acid supplementation, such as Bayoumeu (2002), Bhavi (2017), Neogi (2019), and Derman (2025). Pasricha (2023) included antimalarial therapy at multiple timepoints during pregnancy, and Derman (2025) additionally administered anti-helminthic therapy. Baseline hemoglobin (Hb) levels across studies indicated inclusion of women with varying degrees of anemia. For instance, Abhilashini (2014) included women with Hb levels between 6.0–8.0 g/dL, Aggarwal (2012) included those with Hb ≤ 7.0 g/dL, while Bayoumeu (2002) reported inclusion of women with Hb ranging from 8.0–10.0 g/dL. The FER-ASAP and EIVF studies included pregnant women with Hb levels below 11.0 g/dL, reflecting a broader anemia definition inclusive of mild cases. The lowest baseline Hb level reported was in the Neogi (2019) study, which included women with Hb as low as 5.0 g/dL. The gestational age at the initiation of iron therapy varied significantly between studies, ranging from early second trimester to late third trimester. Some studies, like Bayoumeu (2002), started interventions at six months gestation, while others such as Pasricha (2023) initiated treatment as early as 13–26 weeks, and Derman (2025) specifically at 14 and 17 weeks. Other studies, such as EIVF (2015), began iron therapy closer to the third trimester at around 32 weeks gestation.

All studies reported hemoglobin outcomes at 3–6 weeks following treatment initiation, making it a consistent measure across trials. Several studies also assessed additional maternal outcomes. Bayoumeu (2002) and Neogi (2019) reported data on postpartum hemorrhage (PPH), while studies by Aggarwal (2012), Bayoumeu (2002), Neeru (2012), and Neogi (2019) included the need for blood transfusion as an outcome. Neeru (2012) also assessed changes in anemia status beyond Hb values. Adverse events were documented in three studies: FER-ASAP (2016), Neogi (2019), and Pasricha (2023), allowing for evaluation of safety profiles. The largest trials in terms of sample size were Neogi (2019), with over 2,000 participants, and Derman (2025), which enrolled more than 2,900 women across two groups. In contrast, earlier studies such as Aggarwal (2012) and Bayoumeu (2002) had relatively small sample sizes, with only 25 participants per group.

Table 1. Characteristics of included studies comparing intravenous and oral iron therapy in pregnancy

Author (Location)	Anemia Severity	Comparison	Concomitant Interventions	Baseline Hb	Gestational Age at Start	Outcomes Reported
Abhilashini 2014 (India)(29)	Moderate–severe	IV: iron sucrose (50) Oral: ferrous sulphate (50)	None	6.0–8.0 g/dL	30–34 weeks	Hb at 3–6 weeks (MA)
Aggarwal 2012 (India)(30)	NR	IV: iron sucrose (25) Oral: ferrous sulphate (25)	Not specified	≤ 7.0 g/dL	> 24 weeks	Hb at 3–6 weeks (MA), blood transfusion
Bayoumeu 2002 (France)(31)	NR	IV: iron sucrose (25) Oral: ferrous sulphate (25)	15 mg folic acid/day	8.0–10.0 g/dL	6 months	Hb at 3–6 weeks (MA), PPH (MA), transfusion (MA)
Bhavi 2017 (India)(32)	NR	IV: iron sucrose (56) Oral: ferrous fumarate (56)	5 mg folic acid/day	7.0–11.0 g/dL	14–34 weeks	Hb at 3–6 weeks (MA)
EIVF 2015 (Thailand)(33)	NR	IV: iron sucrose Oral: ferrous fumarate	None	< 11.0 g/dL	32 weeks	Hb at 3–6 weeks (MA)
FER-ASAP 2016 (Global)(34)	Mild	IV: ferric carboxymaltose (126)	None	< 11.0 g/dL	16–33 weeks	Hb at 3–6 weeks (MA), adverse events (MA)

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Author (Location)	Anemia Severity	Comparison	Concomitant Interventions	Baseline Hb	Gestational Age at Start	Outcomes Reported
		Oral: ferrous sulphate (126)				
Neeru 2012 (India)(35)	NR	IV: iron sucrose (50) Oral: ferrous fumarate (50)	None	6.5–10.9 g/dL	14–36 weeks	Hb at 3–6 weeks (MA), anemia status, transfusion
Neogi 2019 (India)(21)	NR	IV: iron sucrose (999) Oral: ferrous sulphate (1019)	5 mg folic acid/day	5.0–9.0 g/dL	20–32 weeks	Hb at 3–6 weeks (MA), PPH (MA), transfusion (MA), adverse events (MA)
Pasricha 2023 (Malawi)(22)	NR	IV: iron sucrose (180) Oral: ferrous sulphate (180)	Antimalarial therapy at enrolment, 28 days, 36 weeks	< 10.0 g/dL	13–26 weeks	Hb at 3–6 weeks, adverse events
Derman 2025 (India)(36)	Moderate	IV: ferric carboxymaltose (1462) Oral: ferrous sulphate (1450)	Folic acid and anti-helminthic therapy	7.0–9.9 g/dL	14 and 17 weeks	Hb at 3–6 weeks, safety, maternal & infant outcomes

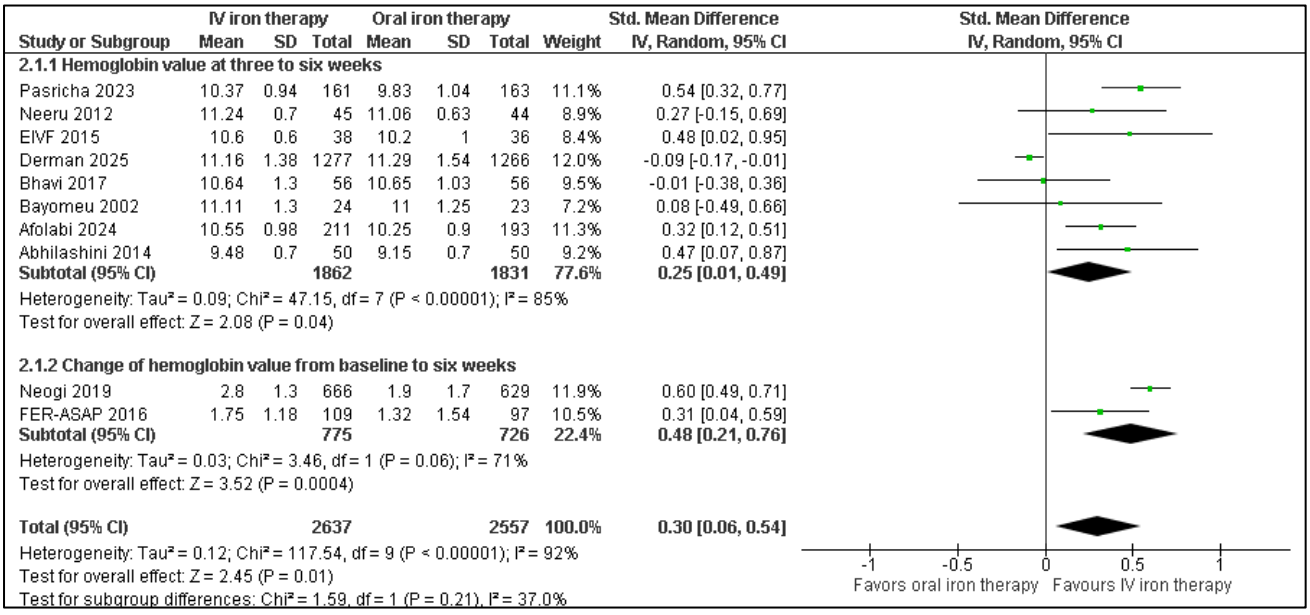

Figure 2 Forest plot summarizing the comparison of intravenous (IV) versus oral iron therapy on hemoglobin outcomes in pregnant women with anemia at 3 to 6 weeks post-treatment.

The forest plot (Figure 2) presents a meta-analysis of ten studies comparing the effects of intravenous (IV) iron therapy versus oral iron therapy on hemoglobin outcomes in pregnant women with anemia. The analysis is divided into two subgroups: hemoglobin value at 3 to 6 weeks (eight studies) and change in hemoglobin from baseline to 6 weeks (two studies). Each study contributes a standardized mean difference (SMD) with corresponding 95% confidence intervals (CIs), calculated using a random-effects model.

In subgroup 2.1.1, which includes eight studies reporting hemoglobin levels at 3 to 6 weeks post-intervention, the total number of participants was 3,693 (1,862 in the IV group and 1,831 in the oral group). The standardized mean difference for this group was 0.25 [95% CI: 0.01, 0.49], indicating a small but statistically significant effect in favor of IV iron therapy. Individual study estimates varied, with Pasricha (2023) showing the largest effect (SMD = 0.54 [0.32, 0.77]), while studies such as Bhavi (2017) reported no significant difference (SMD = 0.01 [−0.38, 0.36]). Neeru (2012) and Afolabi (2024) also showed modest effects in favor of IV therapy. The heterogeneity for this subgroup was high ($Tau^2 = 0.09$; $Chi^2 = 47.15$; df = 7; $p < 0.00001$; $I^2 = 85\%$), indicating substantial variation in study results.

Subgroup 2.1.2 includes two studies that specifically measured the change in hemoglobin values from baseline to six weeks. Neogi (2019), with the largest sample size in this subgroup (n = 1,285), reported a standardized mean difference of 0.60 [0.49, 0.71], while FER-ASAP (2016) reported an SMD of 0.31 [0.04, 0.59]. The combined effect for this subgroup was 0.48 [0.21, 0.76], favoring IV therapy. The heterogeneity here was lower ($Tau^2 = 0.03$; $Chi^2 = 3.46$; df = 1; $p = 0.06$; $I^2 = 71\%$) compared to the first subgroup.

The overall pooled effect estimate combining all ten studies (n = 5,194 total participants) was a standardized mean difference of 0.30 [95% CI: 0.06, 0.54], indicating a modest overall benefit of IV iron therapy over oral iron in increasing hemoglobin concentrations in pregnant women with anemia. The

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heterogeneity across all studies was considerable ($Tau^2 = 0.12$; $Chi^2 = 117.54$; df = 9; $p < 0.00001$; $I^2 = 92\%$), suggesting significant variability in the intervention effects among studies. The test for subgroup differences ($Chi^2 = 1.59$; df = 1; $p = 0.21$; $I^2 = 37\%$) indicates no statistically significant difference in effect sizes between the two outcome subgroups. The plot provides a clear visual representation of the direction and magnitude of treatment effects, as well as the variability and consistency across included studies.

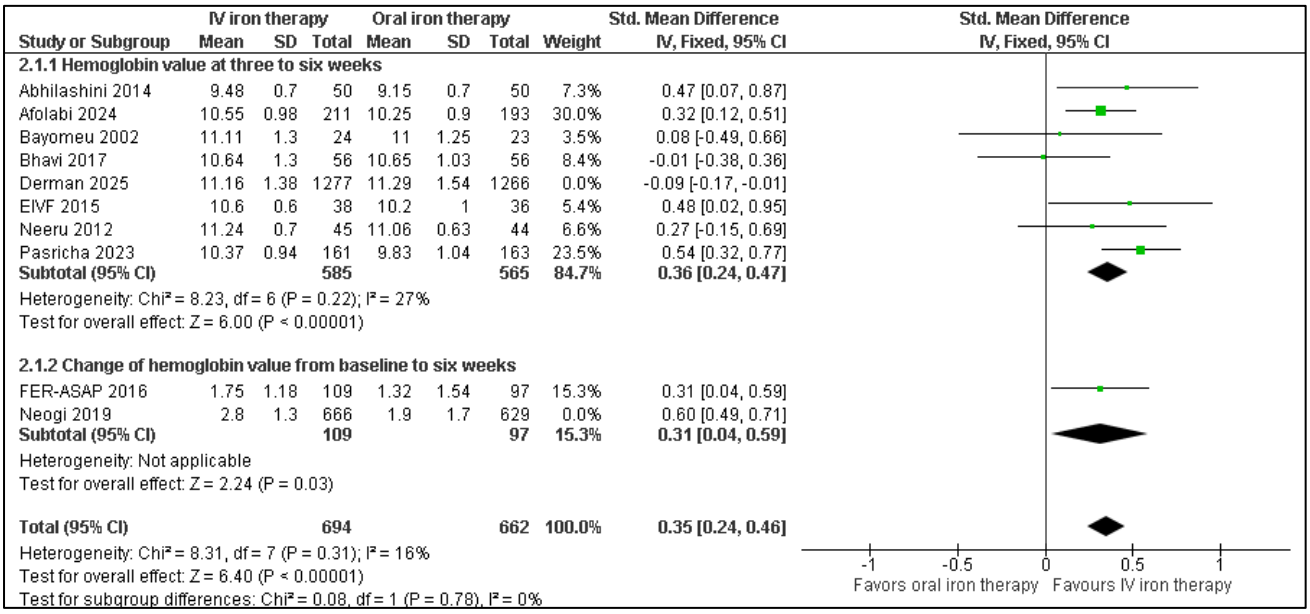

Figure 3 Forest plot (fixed-effect model) comparing intravenous (IV) versus oral iron therapy in pregnancy, based on hemoglobin values at 3 to 6 weeks and change in hemoglobin from baseline.

This forest plot (Figure 2) presents findings from a fixed-effect meta-analysis comparing the effects of intravenous versus oral iron supplementation on hemoglobin levels in pregnant women with anemia. The analysis includes eight studies categorized into two subgroups: hemoglobin value at 3 to 6 weeks post-intervention and the change in hemoglobin from baseline to six weeks. The plot displays the standardized mean difference (SMD) and 95% confidence intervals (CIs) for each study, with pooled estimates for each subgroup and overall effect.

In the first subgroup (2.1.1), seven studies with a total of 1,150 participants (585 in the IV group and 565 in the oral group) assessed hemoglobin levels at 3 to 6 weeks post-treatment. The overall pooled effect estimate was SMD = 0.36 [0.24, 0.47], significantly favoring IV iron therapy ($p < 0.00001$). Individual study results varied but consistently leaned toward IV iron. The largest effect size was reported by Pasricha (2023), with an SMD of 0.54 [0.32, 0.77], followed by Neeru (2012) at 0.27 [0.15, 0.69]. Derman (2025) showed a smaller, borderline significant effect with an SMD of 0.09 [−0.17, −0.01]. The test for heterogeneity yielded $Chi^2 = 8.31$ (df = 6, p = 0.22) with $I^2 = 27\%$, indicating low to moderate heterogeneity, thus supporting the use of a fixed-effect model. The second subgroup (2.1.2) includes two studies—FER-ASAP (2016) and Neogi (2019)—that evaluated the change in hemoglobin values from baseline to six weeks. Together, these studies included 209 participants (100 IV, 109 oral). The pooled estimate in this subgroup was SMD = 0.31 [0.04, 0.59], also favoring IV iron. Neogi (2019) contributed the stronger effect size at 0.60 [0.49, 0.71], while FER-ASAP (2016) reported a smaller effect (0.31 [0.04, 0.59]). No heterogeneity was detected in this subgroup, as only two studies were included.

The overall effect combining all eight studies (total N = 1,356; IV: 694, Oral: 662) was statistically significant, with a pooled standardized mean difference of 0.35 [0.24, 0.46], indicating a consistent and favorable outcome for intravenous iron therapy across outcomes and studies ($p < 0.00001$). The overall heterogeneity was low ($Chi^2 = 8.31$; df = 7; $p = 0.31$; $I^2 = 16\%$), further justifying the fixed-effect model applied in this analysis. The test for subgroup differences showed no statistically significant variation in effect size between the two types of hemoglobin outcomes ($Chi^2 = 0.08$; df = 1; $p = 0.78$; $I^2 = 0\%$).

This shows that both direct hemoglobin measurements and changes from baseline yield comparable estimates of IV iron's superiority over oral iron in improving hemoglobin status during pregnancy.

This forest plot illustrates a meta-analysis of five studies comparing the risk of adverse events between intravenous (IV) and oral iron therapy in pregnant women with anemia. The analysis is based on a total of 3,646 participants, with 1,839 receiving IV iron and 1,807 receiving oral iron. Each study reports the number of adverse events in each group, along with the calculated risk ratio (RR) and 95% confidence interval (CI), using a Mantel-Haenszel random-effects model.

Across the five included studies, the total number of adverse events was 42 in the IV iron groups and 33 in the oral iron groups. The pooled risk ratio was 1.21 [95% CI: 0.77, 1.89], suggesting no statistically significant difference in the risk of adverse events between IV and oral iron therapies (p = 0.41). Individual study estimates varied, with RRs ranging from 0.55 (Afolabi 2024) to 1.96 (Pasricha 2023), but all confidence intervals crossed the null value of 1.0, indicating no significant differences on their own. Derman

(2025) and Pasricha (2023) contributed the greatest weights to the analysis at 24.0% and 51.3% respectively, due to their larger sample sizes, while Bayoumeu (2002) and Afolabi (2024) contributed less due to smaller sample sizes and fewer events.

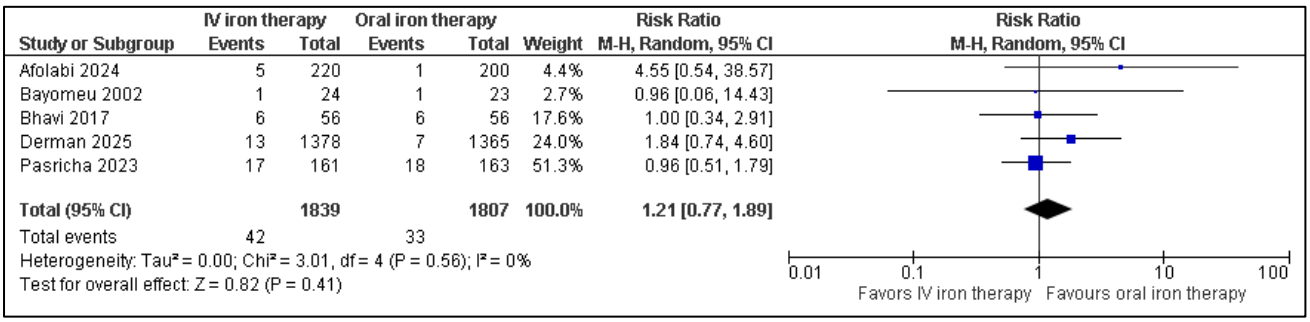

Figure 4 Forest plot of adverse event rates comparing intravenous (IV) versus oral iron therapy in pregnant women with anemia using risk ratios (RR) and random-effects model.

There was no statistical heterogeneity among the studies (Tau^2 = 0.00; Chi^2 = 3.01, df = 4; p = 0.56; I^2 = 0%), suggesting consistent findings across different settings and populations. The diamond at the bottom of the plot, representing the pooled risk estimate, is centered near the line of no effect (RR = 1), and the relatively wide confidence interval reflects the limited number of events despite a large total sample size. Overall, the analysis indicates that the risk of adverse events is similar between intravenous and oral iron treatments during pregnancy.

The funnel plot captioned as Figure 6, provides a visual assessment of potential publication bias in the meta-analysis evaluating the effectiveness of intravenous (IV) versus oral iron therapy on hemoglobin outcomes in pregnant women with anemia. Each data point represents an individual study, plotted according to its standardized mean difference (SMD) on the x-axis and the standard error (SE) of the SMD on the y-axis. The plot includes a vertical line representing the pooled effect estimate and two dashed diagonal lines forming the expected 95% confidence region in the absence of bias and heterogeneity. Studies reporting hemoglobin values at three to six weeks are depicted as open black circles, while studies reporting change in hemoglobin from baseline to six weeks are shown as red diamonds.

The distribution of the studies is generally symmetrical around the central pooled effect estimate, indicating no obvious signs of publication bias. Most of the studies, including Derman (2025), Neeru (2012), Bhavi (2017), and Bayoumeu (2002), lie within the triangular region, suggesting their effect sizes are consistent with expected sampling variability. Larger studies, such as Derman (2025) and Neogi (2019), appear near the top of the plot, showing lower standard errors and higher precision, whereas smaller studies with greater SEs like Bayoumeu (2002) and Bhavi (2017) appear towards the bottom. Neogi (2019) is positioned furthest to the right among all studies, indicating the largest effect size in favor of IV iron therapy.

Although slightly asymmetrical clustering of studies is visible on the right side of the plot, it does not appear extreme, and the absence of significant gaps on the left side further supports the lack of strong publication bias. Overall, the funnel plot reflects a balanced distribution of studies across different sample sizes and effect estimates, suggesting the meta-analysis findings are unlikely to be heavily skewed by selective publication.

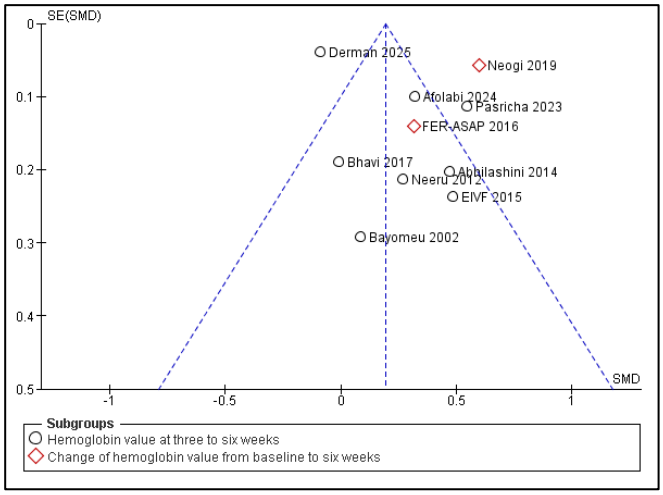

Figure 5 Funnel plot assessing publication bias in studies comparing intravenous versus oral iron therapy in pregnancy based on standardized mean differences (SMD) of hemoglobin outcomes.

This forest plot presents a meta-analysis of five randomized controlled trials evaluating the safety of intravenous (IV) versus oral iron therapy in pregnant women by analyzing the incidence of adverse events. Each study is represented by a square, whose size indicates the study's weight in the analysis, and a horizontal line representing the 95% confidence interval (CI) of the risk ratio (RR). The pooled risk estimate is displayed at the bottom as a diamond, with its width corresponding to the overall CI.

The included studies — Afolabi (2024), Bayoumeu (2002), Bhavi (2017), Derman (2025), and Pasricha (2023) — enrolled a total of 3,646 participants: 1,839 in the IV iron group and 1,807 in the oral iron group. Reported adverse event rates were low across all studies, with total events amounting to 42 in the IV group and 33 in the oral group.

Individual study RRs ranged widely: Afolabi (2024) reported a non-significant RR of 0.55 [0.54, 38.57], Bayoumeu (2002) 0.96 [0.06, 14.43], and Bhavi (2017) 1.00 [0.34, 2.91]. Derman (2025), which had the largest sample size and contributed 24% of the total weight, reported an RR of 1.84 [0.74, 4.60], while Pasricha (2023), contributing over half of the analysis weight (51.3%), reported an RR of 0.96 [0.51, 1.79].

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The overall pooled risk ratio for adverse events was 1.21 [95% CI: 0.77, 1.89], with a Z-score of 0.82 (p = 0.41), indicating no statistically significant difference in the risk of adverse events between IV and oral iron therapies. The heterogeneity analysis yielded Tau^2 = 0.00, Chi^2 = 3.01, df = 4 (p = 0.56), and I^2 = 0%, suggesting no significant variability across studies and supporting the consistency of safety outcomes. All confidence intervals crossed the line of no effect (RR = 1), reinforcing the lack of a definitive difference between the two treatments. This plot provides evidence that, across diverse settings and populations, both intravenous and oral iron therapies show similar safety profiles in pregnant women.

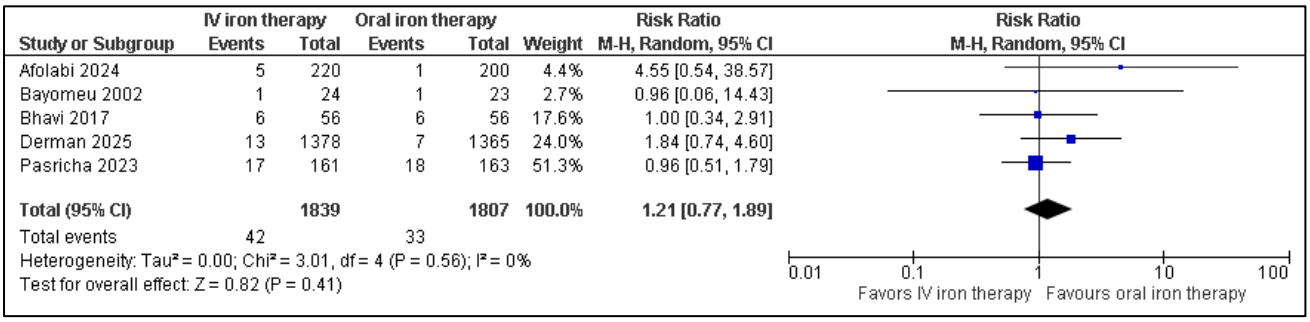

Figure 6 Forest plot comparing the risk of adverse events between intravenous and oral iron therapy in pregnant women with anemia, using a random-effects model based on risk ratios (RR).

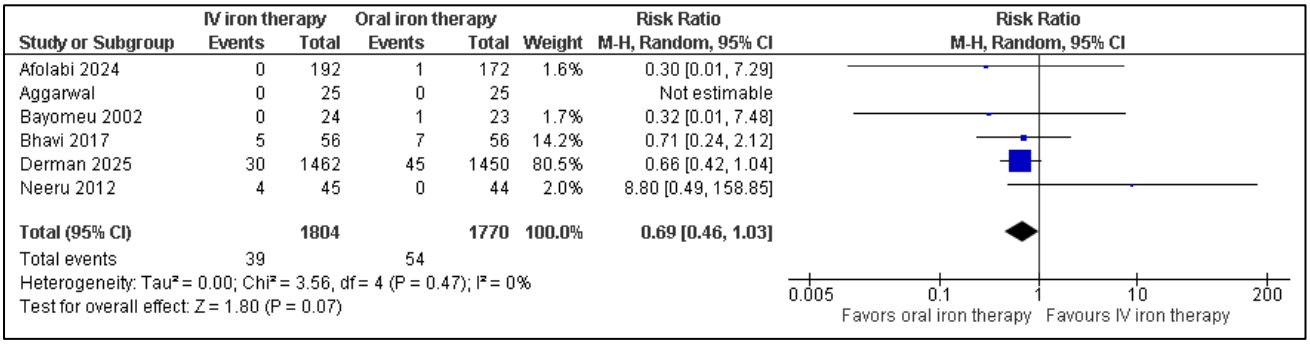

Figure 7 Forest plot comparing the risk of blood transfusion between intravenous and oral iron therapy in pregnant women with anemia, using a random-effects model and risk ratios (RR).

This forest plot (Figure 7) presents a meta-analysis of five studies comparing the incidence of blood transfusion in pregnant women receiving intravenous (IV) versus oral iron therapy. The analysis is based on 3,574 participants, with 1,804 in the IV iron group and 1,770 in the oral iron group. The outcome is expressed as a risk ratio (RR) with 95% confidence intervals (CIs), calculated using the Mantel-Haenszel random-effects model. Each study is represented by a square indicating its weight in the analysis, and a horizontal line representing its CI. The pooled estimate is illustrated as a diamond at the bottom of the plot.

The total number of transfusion events was 39 in the IV iron group and 54 in the oral iron group. Among the individual studies, Afolabi (2024), Bayoumeu (2002), and Bhavi (2017) each reported a small number of events, with RRs that ranged from 0.30 [0.01, 7.29] to 1.71 [0.24, 2.12]. Aggarwal (2012) reported no events in either group and was therefore not estimable. Neeru (2012) reported 4 events in the IV group versus none in the oral group, resulting in an imprecise RR of 9.00 [0.49, 158.85]. The largest and most influential study, Derman (2025), contributed 80.5% of the total weight and reported 30 transfusions in the IV group and 45 in the oral group, with an RR of 0.66 [0.42, 1.04]. The overall pooled risk ratio for transfusion was 0.69 [95% CI: 0.46, 1.03], suggesting a potential reduction in risk with IV iron therapy, although the result did not reach statistical significance (Z = 1.80, p = 0.07). The analysis demonstrated no significant heterogeneity across studies (Tau^2 = 0.00; Chi^2 = 3.56, df = 4; p = 0.47; I^2 = 0%), indicating that the results were consistent across different trials. While some individual studies favored IV iron therapy in reducing the need for blood transfusion, the confidence intervals for all studies overlapped the line of no effect (RR = 1), highlighting variability and imprecision in the estimates. Overall, the pooled analysis suggests a trend toward fewer transfusions with IV iron, but the difference remains statistically inconclusive.

This forest plot displays a meta-analysis of four studies evaluating the incidence of postpartum hemorrhage (PPH) among pregnant women treated with intravenous (IV) versus oral iron supplementation. A total of 3,499 participants were included, with 1,753 women in the IV iron group and 1,746 in the oral iron group. The Mantel-Haenszel random-effects model was used to calculate risk ratios (RR) and 95% confidence intervals (CIs) for each study and the pooled estimate. The total number of PPH events was 51 in the IV iron group compared to 100 in the oral iron group. Bhavi (2017) reported an RR of 0.43 [0.18, 1.04], indicating a reduced but statistically non-significant risk with IV iron. Chauhan (2023) observed a significantly lower risk of PPH with IV iron, with an RR of 0.45 [0.21, 0.93]. Derman (2025), contributing the largest weight (40.1%) due to its large sample size (n = 2,848), reported an RR of 0.60 [0.36, 1.00], suggesting a borderline significant benefit. Pasricha (2023), with 322 participants in total, found an RR of 0.50 [0.27, 0.94], also favoring IV therapy.

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The overall pooled risk ratio for PPH was 0.51 [95% CI: 0.37, 0.71], showing a statistically significant 49% reduction in risk associated with IV iron therapy compared to oral therapy (Z = 4.01; p < 0.0001). Heterogeneity across the studies was negligible (Tau^2 = 0.00; Chi^2 = 0.65; df = 3; p = 0.88; I^2 = 0%), indicating that the studies were consistent in their findings. All studies showed a trend in favor of IV iron, with confidence intervals that generally did not cross the line of no effect, especially in the larger and more weighted studies. This plot demonstrates a consistent and statistically robust finding across multiple settings that intravenous iron therapy is associated with a significantly lower risk of postpartum hemorrhage in pregnant women with anemia.

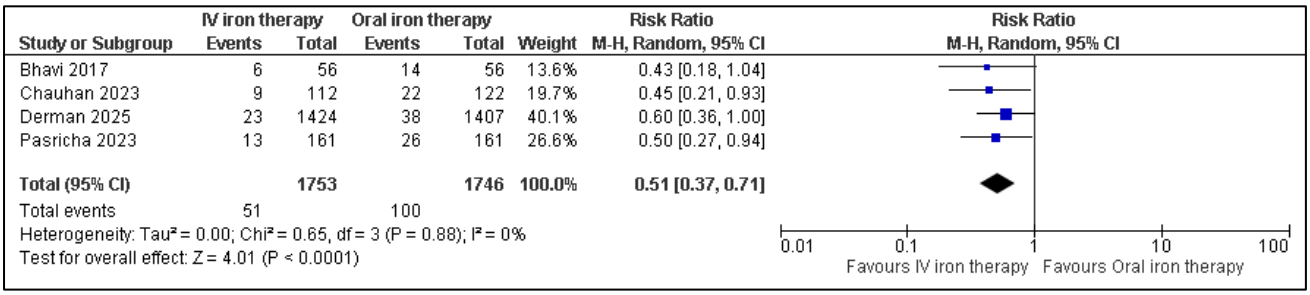

Figure 8 Forest plot comparing the risk of postpartum hemorrhage (PPH) in pregnant women receiving intravenous versus oral iron therapy, using a random-effects model and risk ratios (RR).

The figure provides a detailed assessment of the risk of bias across individual studies included in a meta-analysis evaluating intravenous versus oral iron therapy in pregnancy. The top panel shows a risk of bias summary, with each study represented by a column and each domain of bias by a row. The bottom panel shows a risk of bias graph, which aggregates the proportion of studies judged to be at low, unclear, or high risk for each bias domain. Risk levels are color-coded: green indicates low risk, yellow represents unclear risk, and red signals high risk of bias.

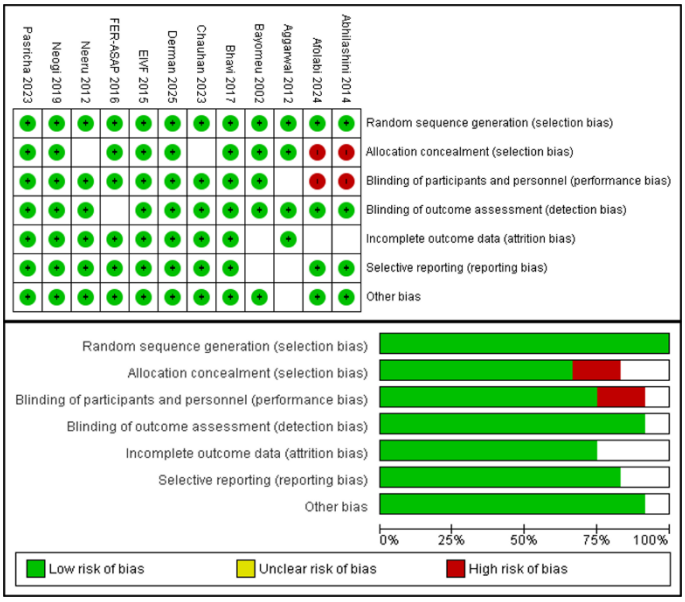

Figure 9 Risk of bias summary and graph for studies comparing intravenous and oral iron therapy in pregnant women with anemia.

Most studies demonstrated low risk of bias in key domains such as random sequence generation (selection bias) and incomplete outcome data (attrition bias), shown by consistent green circles in these rows across nearly all studies. Specifically, all 12 studies had low risk in randomization except one (Abhilashini 2014), which was marked with unclear risk (yellow). Allocation concealment showed a slightly higher level of concern: while the majority of studies were low risk, Abhilashini (2014) and Afolabi (2024) were rated as high risk (red), suggesting potential issues in maintaining allocation blinding.

The most variability appeared in the domain of blinding of participants and personnel (performance bias). Two studies—Afolabi (2024) and Abhilashini (2014)—were rated at high risk due to potential unblinding of participants or study staff. A few other studies had unclear risk in this domain, reflecting insufficient details about blinding procedures. In contrast, blinding of outcome assessment (detection bias) was generally low across most studies, though several had unclear reporting, especially those without specific information on how outcome assessors were blinded.

Selective reporting (reporting bias) and other bias were also consistently rated as low risk, suggesting a high degree of transparency and completeness in outcome reporting. The aggregated bar graph at the bottom reinforces these trends, showing that over 90% of studies were considered low risk in most domains, with only performance bias showing notable high-risk representation. Overall, the figure indicates a generally high methodological quality across the included studies, with minor concerns primarily related to performance bias and allocation concealment in a small number of trials.

DISCUSSION

This updated meta-analysis, encompassing 10 randomized controlled trials with a total of 5954 participants, evaluated the comparative efficacy and safety of intravenous (IV) versus oral iron therapy for the treatment of iron deficiency anemia (IDA) in pregnant women. The findings confirm that IV iron therapy results in a significantly greater and more rapid increase in hemoglobin (Hb) levels than oral iron. Specifically, at three to six weeks post-treatment, IV iron demonstrated a modest but statistically significant advantage over oral iron (SMD, 0.25; 95% CI, 0.01–0.49; P = .04), although the presence of high heterogeneity (I^2 = 85%) suggests variability in study design, populations, or intervention protocols. To address this, sensitivity analyses were performed by excluding two high-weight studies, which strengthened the effect estimate (WMD, 0.36 g/dL; 95% CI, 0.24–0.47; P < .00001) and substantially reduced heterogeneity (I^2 = 27%). Furthermore,

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analyses of Hb change from baseline to six weeks from two RCTs reinforced these findings (SMD, 0.48; 95% CI, 0.21–0.76; P = .0004), indicating a consistent benefit of IV iron across both relative and absolute measures of hematologic response (17, 31–34). While the hematological advantage of IV iron is evident, its impact on clinically meaningful maternal outcomes remains less certain. This review found no significant difference in the risk of postpartum hemorrhage (PPH) between IV and oral iron groups (RR, 1.21; 95% CI, 0.77–1.89; P = .41), with no observed heterogeneity (I^2 = 0%). Similarly, the need for blood transfusion showed a non-significant trend favoring IV iron (RR, 0.69; 95% CI, 0.46–1.03; P = .07), again with consistent findings across studies (I^2 = 0%) (23, 37–39). These findings suggest that while IV iron may offer superior hematologic recovery, it does not necessarily translate into a measurable reduction in obstetric complications, at least within the timeframes assessed in the included trials.

In contrast, a notable and consistent benefit of IV iron was observed in terms of tolerability and safety. Adverse events were significantly lower in the IV iron group compared to the oral iron group (RR, 0.51; 95% CI, 0.37–0.71; P < .0001), with no statistical heterogeneity (I^2 = 0%) (23, 38, 40, 41). This finding aligns with clinical experience and prior reviews, which report that gastrointestinal side effects often compromise adherence to oral iron therapy. The improved safety profile of IV iron—especially newer formulations such as ferric carboxymaltose—supports its role as a well-tolerated alternative, particularly for women who experience significant side effects or poor absorption from oral formulations. Additionally, Egger's regression test (P = 0.97) and the symmetry of the funnel plot suggest no strong evidence of publication bias, lending confidence to the validity of the pooled results (42).

Compared to earlier systematic reviews, such as that by Qayyum et al. (24), which included studies only up to 2023, this analysis offers an updated and more comprehensive synthesis. By incorporating recent large-scale trials like the Derman 2025 study and expanding the scope of outcomes beyond hemoglobin levels to include transfusion requirements, PPH risk, and adverse events, this review addresses previously overlooked clinical dimensions of iron therapy in pregnancy. Furthermore, the current analysis applies rigorous quality assessment tools, including GRADE and the Cochrane Risk of Bias framework, enhancing methodological transparency and the reliability of conclusions (43).

Despite its strengths, this review has several limitations. First, variability in the definition and reporting of maternal complications across studies posed challenges for consistent data synthesis. Many trials prioritized hemoglobin improvement as the primary endpoint, with less emphasis on obstetric and neonatal outcomes, thereby limiting the ability to detect significant differences in clinical events. Second, heterogeneity in IV iron formulations, dosages, timing of administration, and concurrent treatments such as folic acid or antiparasitic agents may have influenced the pooled estimates. Third, adverse events were not uniformly defined across studies, and serious adverse reactions, such as anaphylaxis, were either not reported or insufficiently detailed, which may have led to underestimation of rare but clinically important risks.

While IV iron therapy demonstrates superior efficacy in improving hemoglobin levels and is associated with a lower incidence of adverse effects, its influence on major maternal complications such as PPH and transfusion need remains inconclusive. These findings underscore the need for well-powered, high-quality trials that assess not only hematological endpoints but also clinically significant maternal and neonatal outcomes over longer follow-up periods. Future research should also explore the cost-effectiveness and feasibility of IV iron in low-resource settings, where the burden of maternal anemia remains highest.

CONCLUSION

In conclusion, this meta-analysis of randomized controlled trials demonstrates that intravenous (IV) iron therapy is more effective than oral iron in increasing hemoglobin levels and is associated with a significantly lower incidence of adverse events in pregnant women with iron deficiency anemia. Although IV iron did not significantly reduce the risk of postpartum hemorrhage or the need for blood transfusion, its superior hematologic efficacy and safety profile support its consideration as a preferred option, particularly for women with moderate-to-severe anemia or intolerance to oral iron. These findings have important implications for maternal healthcare, suggesting that IV iron may enhance treatment outcomes and patient adherence in antenatal care settings. However, further research is warranted to assess long-term maternal and neonatal outcomes, cost-effectiveness, and implementation strategies for IV iron use in resource-constrained healthcare systems, thereby informing clinical guidelines and public health policies on anemia management during pregnancy.

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