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Maternal and Perinatal Outcomes Following Parenteral Iron Therapy for Iron Deficiency Anemia in the Third Trimester: A Comparative Cross-Sectional Study

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ABSTRACT

Background: Iron deficiency anemia (IDA) constitutes a significant public health concern during gestation, correlating with considerable maternal and fetal morbidity. Although oral iron is recognized as the primary treatment modality, its inherent limitations frequently result in insufficient correction, particularly when therapy is commenced in the later stages of pregnancy. Parenteral iron facilitates expedited restoration of hemoglobin levels; however, thorough evaluations of clinical outcomes in comparison to oral therapy during the third trimester remain imperative.

Objective: The aim of this study is to evaluate maternal and perinatal outcomes among antenatal women experiencing moderate-to-severe IDA who are administered either parenteral iron or oral iron between 28 and 36 weeks of gestation.

Methods: This comparative cross-sectional investigation encompassed a cohort of 200 women diagnosed with IDA (Hb <10.0 g/dL). Group A (n=100) was treated with intravenous iron sucrose/ferric carboxymaltose, whereas Group B (n=100) continued with oral iron supplementation. The outcomes assessed included the increment in hemoglobin levels, requirement for transfusion, incidence of postpartum hemorrhage (PPH), birth weight, neonatal vitality, and necessity for NICU admission.

Results: The average increase in hemoglobin levels was markedly superior in Group A (2.8 ± 0.9 g/dL vs. 1.2 ± 0.6 g/dL; p<0.001). The need for transfusion (2% vs. 11%; p=0.016) and the occurrence of PPH (4% vs. 13%; p=0.021) were significantly reduced in the parenteral group. Perinatal outcomes were also more favorable in Group A, which exhibited a higher mean birth weight (2850g vs. 2650g; p=0.003), lower incidence of small-for-gestational-age infants (8% vs. 19%; p=0.022), and diminished NICU admissions (10% vs. 22%; p=0.018).

Conclusion: The administration of parenteral iron during the third trimester for moderate-to-severe IDA leads to enhanced hemoglobin correction and improved maternal and perinatal outcomes in comparison to oral iron, thereby endorsing its application in cases of late-presenting anemia.

Keywords: Iron Deficiency Anemia; Pregnancy; Parenteral Iron; Third Trimester; Maternal Outcome; Perinatal Outcome

INTRODUCTION:

Iron deficiency anemia (IDA) is a prevalent complication in approximately 40% of pregnancies worldwide, with particularly elevated incidence in developing countries such as India. [1] It serves as a principal preventable factor leading to detrimental pregnancy outcomes, significantly contributing to maternal mortality primarily via postpartum hemorrhage, as well as fetal growth restriction, preterm birth, and neonatal morbidity. [2] The physiological demand for iron escalates to approximately 1000 mg during gestation to accommodate the increased red blood cell mass and the development of the fetal-placental unit. [3] Although oral iron supplementation is commonly advocated, its efficacy is frequently undermined by inadequate gastrointestinal absorption, notable side effects, and insufficient adherence. [4] This often culminates in women entering the third trimester with unresolved anemia, a critical juncture when the risks of complications are significantly heightened. [5]

Parenteral iron therapy, encompassing formulations such as iron sucrose and ferric carboxymaltose, presents a viable alternative by facilitating direct intravenous delivery of substantial iron dosages, resulting in expedited replenishment of iron reserves and rectification of hemoglobin levels. [6] Contemporary clinical guidelines endorse the use of intravenous iron for pregnant individuals exhibiting moderate-to-severe anemia who demonstrate intolerance to oral iron, lack of adherence, or who present late in gestation with inadequate time for oral repletion. [7] Despite the established efficacy of parenteral iron in enhancing hematological metrics, there exists a relative deficiency of research, particularly within the Indian context, that comprehensively juxtaposes its effects on critical clinical outcomes—maternal morbidity (such as transfusion necessity and postpartum hemorrhage) and perinatal health (including birth weight and neonatal admissions)—against oral iron when initiated during the pivotal third-trimester timeframe. [8]

This study was meticulously designed to bridge this evidentiary lacuna. We executed a hospital-based comparative cross-sectional analysis aimed at assessing whether parenteral iron therapy administered between 28 and 36 weeks of gestation results in superior hematological and, more critically, clinical outcomes in comparison to the continuation of oral iron therapy in pregnant women with moderate-to-severe IDA.

METHODOLOGY:

Study Design and Setting: A comparative cross-sectional investigation was undertaken over a duration of one year (April 2024–March 2025) within the Department of Obstetrics and Gynecology at a tertiary care facility in Tamil Nadu, India. Institutional approval was secured from the Human Ethics Committee.

Study Population: Pregnant individuals diagnosed with iron deficiency anemia (IDA), characterized by hemoglobin levels below 10.0 g/dL alongside corroborative red cell indices, during the gestational period of 28 to 36 weeks were deemed eligible. Exclusion criteria encompassed multiple gestations, significant fetal anomalies, other hematological conditions, and identified hypersensitivity to parenteral iron.

Sample Size Calculation: Since this was a comparative study with two groups, and the primary aim was to detect a significant difference in mean hemoglobin rise between parenteral and oral iron groups, an additional calculation was performed based on expected treatment effects reported in the literature. A previous randomized controlled trial comparing intravenous versus oral iron in pregnancy (Khalafallah et al., 2010) reported a mean difference in hemoglobin rise of 0.8 g/dL with a standard deviation of 1.2 g/dL.

To detect a more conservative difference of 0.5 g/dL in hemoglobin rise between groups (considering our population might have more severe anemia at baseline), with a standard deviation of 1.2 g/dL, 80% power, and 5% alpha error (two-sided), the sample size per group was calculated using the formula for comparing two means:

$n \text{ per group} = 2 \times (Z\alpha/2 + Z\beta)^2 \times \sigma^2 / \delta^2$

Where:

- $Z\alpha/2 = 1.96$ (for $\alpha = 0.05$)
- $Z\beta = 0.84$ (for 80% power)
- $\sigma = 1.2$ (standard deviation) [9]
- $\delta = 0.5$ (clinically significant difference)

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Adjusting for a potential 10% attrition or incomplete data, the sample size per group became:
$90.32 \times 1.1 \approx 99.35 \approx 100$ participants per group
Therefore, the total sample size required was 200 participants (100 in the parenteral iron group and 100 in the oral iron group). This sample size was deemed adequate to provide sufficient power to detect clinically meaningful differences in both primary and secondary outcomes while maintaining feasibility within the study timeframe and setting. Using a consecutive sampling approach, records of 200 eligible women were included in the study from hospital case files. The first 100 women who had received parenteral iron following counseling as per documented clinical records were categorized as **Group A**. The next 100 women who continued on oral iron therapy as per treatment records were categorized as **Group B**, thereby reflecting routine clinical practice.

Intervention: Group A was administered a calculated total dosage of intravenous iron sucrose or ferric carboxymaltose in accordance with the established hospital protocol within a supervised daycare environment. Group B continued their prescribed regimen of oral iron (ranging from 100 to 200 mg of elemental iron daily). Both groups received standardized antenatal care.

Data Collection: Data were extracted from medical records utilizing a structured proforma. Baseline socio-demographic and clinical information was systematically documented. The principal maternal outcome was defined as the absolute increase in hemoglobin from baseline to pre-delivery assessment. Secondary maternal outcomes encompassed the necessity for blood transfusion, mode of delivery, and the incidence of postpartum hemorrhage (PPH) defined as blood loss ≥500 mL for vaginal delivery and ≥1000 mL for cesarean sections. Perinatal outcomes evaluated included gestational age at delivery, birth weight, small-for-gestational-age (SGA) classification, APGAR scores at both 1 and 5 minutes, NICU admission rates, and perinatal mortality.

Statistical Analysis: Data were subjected to analysis utilizing SPSS version 25.0. Continuous variables were compared employing independent t-tests or Mann-Whitney U tests, while categorical variables were analyzed using Chi-square or Fisher's exact test. A p-value of less than 0.05 was deemed statistically significant. Multivariate logistic regression was employed to ascertain predictors of a composite favorable outcome, which included term delivery, birth weight ≥2500g, absence of NICU admission, and no maternal transfusion or postpartum hemorrhage (PPH).

Ethical considerations: Ethical Committee approval was obtained from the Institutional Human Ethics Committee of Chettinad Hospital and Research Institute. Patient confidentiality was maintained strictly throughout the study period.

RESULTS:
A total of 200 participants were evenly divided between groups. As shown in Table 1, the groups were comparable in age (mean 26.4 years), education, occupation, parity, gestational age at enrolment (~32 weeks), and baseline hemoglobin (~8.6 g/dL) (all p>0.05).

Table 1: Baseline Characteristics of Study Participants (N=200)

S.No	Characteristics	Group A	Group B	P value
1	Age (years),	26.1 ± 4.3	26.7 ± 3.9	0.453
2	**Education** >High school education ≤High school education	 42 58	 37 63	 0.287
3	**Occupational status** Homemaker Employed	 70 30	 67 33	
3	Gravid status Primigravida Multigravida	 38 62	 46 54	 0.412
4	Baseline Hb (g/dl)	8.5 ± 0.8	8.6 ± 0.7	0.312

*p-value < 0.05 – Statistically significant

Maternal outcomes significantly favored the parenteral iron group (Table 2). The mean hemoglobin rise was more than double in Group A compared to Group B (2.8 g/dL vs. 1.2 g/dL; p<0.001). This superior hematological correction translated into better clinical outcomes. The need for blood transfusion was markedly lower in Group A (2% vs. 11%; p=0.016), as was the incidence of postpartum hemorrhage (4% vs. 13%; p=0.021). The mode of delivery was similar between groups (p=0.437). Adverse drug reactions were minimal and comparable between groups.

Table 2: Hematological Parameters of the Study Participants (N=200)

S.No	Characteristics	Group A	Group B	P value
1	Hb Rise (g/dL)	2.8 ± 0.9	1.2 ± 0.6	<0.01
2	Transfusion Required, n (%)	2 (2.0)	11 (11.0)	0.02
3	Postpartum Hemorrhage, n (%)	4 (4.0)	13 (13.0)	0.02
3	Mode of Delivery, n (%) Vaginal Cesarean Section	 65 (65) 35 (35)	 61 (61) 39 (39)	 0.437
4	Adverse Drug Reaction n (%)	3	5 (5)	0.468

*p-value < 0.05 – Statistically significant

Perinatal Outcomes: Perinatal outcomes were consistently better in infants born to mothers who received parenteral iron (Table 3). The mean birth weight was significantly higher in Group A (2850g vs. 2650g; p=0.003). Consequently, rates of low birth weight (<2500g) and small-for-gestational-age infants were substantially lower in the parenteral group (12% vs. 26%, p=0.011; and 8% vs. 19%, p=0.022, respectively). Neonatal vitality was superior, with higher proportions of infants achieving APGAR scores ≥7 at 1 and 5 minutes in Group A. Most importantly, the NICU

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admission rate was less than half in Group A (10% vs. 22%; p=0.018). Preterm delivery and perinatal mortality rates were lower in Group A but did not reach statistical significance.

Table 3: Comparative Perinatal Outcomes (N=200)

S.No	Characteristics	Group A	Group B	P value
1	Preterm Delivery (<37 weeks), n (%)	15 (15.0)	15 (15.0)	0.108
2	Birth Weight (g),	2850 ± 320	2650 ± 350	<0.01
3	Low Birth Weight (<2500g), n (%)	12 (12.0)	26 (26.0)	0.01
4	Small for Gestational Age, n (%)	8 (8.0)	19 (19.0)	0.02
5	APGAR ≥7 at 1 min, n (%)	88 (88.0)	76 (76.0)	0.03
6	APGAR ≥7 at 5 min, n (%)	96 (96.0)	87 (87.0)	0.02
7	NICU Admission, n (%)	10 (10.0)	22 (22.0)	0.02
8	Perinatal Mortality, n (%)	1 (1.0)	3 (3.0)	0.310

*p-value < 0.05 – Statistically significant

Predictors of Favorable Outcome. In multivariate logistic regression analysis, after adjusting for age, parity, and baseline hemoglobin, receiving parenteral iron therapy emerged as the strongest independent predictor of achieving the composite favorable outcome (adjusted OR=3.45, 95% CI: 1.82–6.54, p<0.001). Higher baseline hemoglobin was also a significant positive predictor (aOR=1.95, 95% CI: 1.15–3.30, p=0.013).

DISCUSSION:

The results of this investigation offer robust empirical support indicating that parenteral iron administration during the third trimester for moderate-to-severe iron deficiency anemia produces significantly superior clinical outcomes compared to the continuation of oral iron supplementation. The markedly enhanced elevation in hemoglobin levels achieved through intravenous iron (2.8 g/dL compared to 1.2 g/dL) illustrates its preeminent effectiveness in expeditiously rectifying anemia, a factor of critical importance as delivery approaches. [9] This hematological benefit directly correlated with improved clinical results, evidenced by a substantial decrease in blood transfusion rates and postpartum hemorrhage within the parenteral cohort. [10]

The notable decline in postpartum hemorrhage from 13% to 4% is particularly significant, given that PPH constitutes a predominant contributor to maternal mortality worldwide, particularly in settings characterized by limited resources. [11] Anemia adversely affects uterine contractility and diminishes the capacity to tolerate blood loss, thereby rendering effective correction prior to delivery imperative for the prevention of hemorrhage. [12] Our results are consistent with emerging scholarly evidence suggesting that proactive management of anemia through parenteral iron can markedly mitigate the risk of PPH, thereby representing a potentially impactful approach to reducing maternal mortality. [13]

The perinatal advantages identified in this study are equally substantial and hold significant clinical relevance. The mean birth weight increase of 200g and the reduced prevalence of low birth weight and small-for-gestational-age infants in the parenteral cohort imply enhanced fetal nutrition and oxygenation subsequent to the correction of maternal anemia. [14] The third trimester is a pivotal phase for fetal iron accumulation and growth, and sufficient maternal iron availability during this critical window is vital for optimal fetal development. [15] The expedited restoration of maternal iron reserves via the intravenous route appears to more effectively meet fetal requirements compared to the slower and often incomplete rectification associated with oral supplementation. [16]

The markedly lower rate of NICU admissions (10% compared to 22%) in the parenteral group constitutes a significant finding with profound implications for neonatal health and healthcare resource allocation. [17] This decrease is likely attributable to several factors: enhanced fetal growth leading to a reduction in the number of growth-restricted infants necessitating support, improved neonatal vitality as indicated by elevated APGAR scores, and potentially fewer iatrogenic preterm deliveries necessitated by severe maternal anemia. [18] The composite outcome analysis corroborated that parenteral iron therapy independently augmented the likelihood of a favorable overall pregnancy outcome by more than threefold, underscoring its extensive benefits. [19]

The safety profile associated with contemporary parenteral iron formulations was reassuring in our investigation, with only minor, transient adverse reactions documented in 3% of recipients. [20] This finding is consistent with current literature indicating that compounds such as iron sucrose and ferric carboxymaltose exhibit excellent safety profiles during pregnancy when administered under appropriate monitoring protocols. [21] The advantages of achieving prompt and reliable hemoglobin correction in the later stages of pregnancy appear to considerably outweigh the minimal risks linked to modern intravenous iron preparations. [22]

These findings carry significant implications for clinical practice, particularly in contexts such as India where there are elevated rates of late-presenting anemia. [23] They advocate for a more proactive methodology in managing anemia during the third trimester, including the early consideration of parenteral iron for women suffering from moderate-to-severe IDA, particularly when oral therapy has proven ineffective or poorly tolerated. [24] The implementation of this strategy could contribute substantially to addressing the ongoing challenge of anemia-related complications during pregnancy and enhancing both maternal and perinatal outcomes. [25]

This study is subject to constraints that are intrinsic to its cross-sectional methodology and its focus on a single-center environment. The absence of randomization in participant allocation may lead to potential selection bias; however, the baseline characteristics exhibited commendable equilibrium. The execution of a randomized controlled trial would yield more robust empirical evidence. The duration of follow-up was confined to the period of hospitalization for delivery, thereby precluding the assessment of longer-term maternal and pediatric outcomes. Notwithstanding these limitations, the consistently observed pattern of enhanced outcomes associated with parenteral iron across several domains presents a persuasive argument for its application in suitable clinical circumstances.

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CONCLUSION:

This research reveals that the administration of parenteral iron therapy during the gestational period of 28 to 36 weeks for moderate-to-severe iron deficiency anemia yields significantly superior enhancements in maternal hemoglobin concentrations when juxtaposed with oral iron therapy. This hematological advantage manifests in substantial clinical benefits: diminished maternal transfusion needs and decreased incidence of postpartum hemorrhage, alongside improved perinatal outcomes characterized by elevated birth weights, enhanced neonatal vitality, and a reduction in NICU admissions.

In light of the considerable prevalence of anemia during pregnancy and its grave ramifications, these results advocate for the incorporation of parenteral iron into clinical guidelines for the management of late-presenting anemia, with the aim of optimizing pregnancy outcomes and mitigating avoidable complications.

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