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Original Research Article

COMPARATIVE EFFICACY AND SAFETY OF ORAL VERSUS PARENTERAL IRON SUPPLEMENTATION IN PREGNANT WOMEN

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ABSTRACT

Background: Iron deficiency anemia is prevalent among pregnant women globally, impacting maternal health and birth outcomes. This study aimed to compare the efficacy, safety, and impact on maternal and fetal outcomes of oral versus parenteral iron supplementation.

Materials and Methods: A prospective study was conducted among 100 pregnant women at a tertiary care Maharaja Agrasen Medical College, Agroha, Hisar, India from June 2024 to May 2025. Participants were assigned to receive either oral iron supplements (N=50) or parenteral iron (intramuscular) supplements (N=50). Hematological parameters including hemoglobin (Hb), packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), serum ferritin, serum iron, and total iron-binding capacity (TIBC) were measured at baseline and near term. Delivery outcomes and birth weights were also assessed. Adverse effects were recorded throughout the study period.

Results: Both oral and parenteral iron supplementation significantly increased Hb and PCV levels from baseline to near term ($P < 0.001$). Parenteral supplementation demonstrated a superior effect on ferritin levels compared to oral supplementation ($P < 0.001$), indicating better iron stores replenishment. Serum iron levels initially favored the oral group but converged by near term. TIBC showed significant differences at near term, suggesting varied iron metabolism between groups. There were no significant differences in delivery outcomes or birth weights between the groups.

Conclusion: Both oral and parenteral iron supplementation effectively improve hematological parameters in pregnant women. Parenteral supplementation offers advantages in rapidly correcting iron deficiency and increasing ferritin levels. However, both routes are safe and well-tolerated, with similar impacts on delivery outcomes and birth weight. The choice of supplementation route should be tailored based on individual patient needs and clinical considerations.

Keywords: Iron deficiency anemia, pregnancy, oral supplementation, parenteral supplementation, birth outcomes.

INTRODUCTION

Iron deficiency anemia (IDA) is a significant public health issue, especially among pregnant women, due to increased iron requirements during pregnancy.[1] Globally, it is estimated that around 40% of pregnant women are anemic, with iron deficiency being the most common cause.[2] In India, the situation is even more alarming, with studies indicating that approximately 50-60% of pregnant women are affected by anemia, contributing to a substantial burden on maternal and fetal health.[3,4]

Anemia during pregnancy is associated with adverse outcomes, including preterm delivery, low birth

weight, and increased perinatal mortality. Therefore, effective iron supplementation strategies are critical to improve maternal and fetal health outcomes.[5] In India, maternal anemia is a leading cause of maternal morbidity and mortality, highlighting the urgent need for effective interventions.[6]

Traditionally, oral iron supplementation has been the first-line treatment for IDA in pregnancy due to its ease of administration, cost-effectiveness, and availability. However, oral iron supplements often have gastrointestinal side effects such as nausea, constipation, and abdominal discomfort, leading to poor compliance among pregnant women.[6] Additionally, the bioavailability of oral iron is influenced by dietary factors and gastrointestinal conditions, which can limit its efficacy. In India, dietary habits and the high prevalence of gastrointestinal infections further complicate the effectiveness of oral iron supplements.[7]

Parenteral iron supplementation, including intravenous (IV) and intramuscular (IM) routes, offers an alternative for those who cannot tolerate oral iron or have severe anemia that requires rapid replenishment of iron stores.[8] Parenteral iron bypasses the gastrointestinal tract, providing a more direct and often faster increase in iron levels. Despite these advantages, the use of parenteral iron is limited by concerns about allergic reactions, the need for healthcare setting administration, and higher costs.[9] In the context of India's healthcare infrastructure, these limitations are significant, yet the potential benefits in terms of rapid improvement in maternal health may outweigh the challenges.[10]

Current guidelines and practices for iron supplementation in pregnancy vary widely, reflecting uncertainties about the most effective and safe route of administration. In India, these variations are influenced by regional differences in healthcare access and resources.[10] There is a need for robust comparative studies to evaluate the efficacy and safety of oral versus parenteral iron supplementation in pregnant women. This study aimed to fill this gap by comparing the efficacy of oral and parenteral iron supplementation in improving hemoglobin levels and overall iron status among pregnant women with IDA in India. Through this research, we seek to provide evidence-based recommendations to optimize iron supplementation strategies during pregnancy, ultimately improving maternal and neonatal outcomes in the Indian context.

MATERIALS AND METHODS

Study Design

This hospital based prospective study was conducted among pregnant women attending the antenatal Clinic of the Department of Gynaecology and Obstetrics, Maharaja Agrasen Medical College, Agroha, Hisar, Haryana, over a period of 12 months from June 2024 to May 2025.

Study Population

Pregnant women attending the antenatal clinic were screened for inclusion.

The inclusion criteria were:

- Pregnant women aged 18-40 years
- Gestational age between 16 and 24 weeks
- Moderate anaemia (Hb by Sahli's method more than 8 gm% but less than 11 gm%)

The exclusion criteria included:

- Patients of antepartum haemorrhage
- Medical disorders like tuberculosis, diabetes mellitus, chronic infections etc.
- Previous adverse reactions to iron supplementation
- Multifetal gestation.

Sample Size

A sample size of 100 participants was calculated to provide 80% power to detect a significant difference between the two groups, with a 5% significance level and accounting for a 10% dropout rate. Thus, 50 women were assigned to each intervention group.

Randomization

Participants were randomly assigned to one of two groups (oral iron supplementation or intramuscular iron supplementation) using a computer-generated randomization schedule. Allocation concealment was ensured by using sealed opaque envelopes.

Intervention

Oral Iron Supplementation Group: This group was given oral iron in the dose of 100 mg of elemental iron per day. The salt used was ferrous sulphate available through government supply. It also contains 500 µg of folic acid. Tablets were given by hand; the dosage of one month was given at each visit and they had to take at least 100 such tablets.

Intramuscular Iron Supplementation Group: This group of subjects were given three intramuscular injections of high dose of iron. The dose given was 250 mg of iron dextran (lmferon, Rallis India Ltd.) each time. Initially 0.5 ml of test dose was given and then full 250 mg was given after half an hour. The same dose was repeated at the interval of 4-6 weeks. The date of injection was noted down. Z-technique was used so that staining of skin could be minimal. Thus, the total parenteral iron received by the subject was 750 mg. Along with it, tab folic acid was given to all the patients.

Blood indices

About 8-10 ml of venous blood was taken from the patient at the first visit for baseline values. It was divided into two parts. Approximately 3 ml of the blood sample was sent to the haematology laboratory of the Pathology Department, Maharaja Agrasen Medical College, Agroha, along with the slides of the peripheral smears prepared in the OPD itself. The parameters assessed with this sample were haemoglobin, mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentration (MCHC), and peripheral smears stained with Leishman's stain to examine the morphology of red blood cells. The

remaining part of the sample was put into a clean, labelled test tube. This sample was later centrifuged at 2000 rpm for 10 minutes. The separated serum was transferred to microcentrifuge tubes, and aliquots of the serum were stored in a deep freezer at a temperature of -80°C for later processing. This procedure was carried out in the Department of Biochemistry. The parameters assessed with this sample were serum ferritin, serum iron, and serum total iron-binding capacity (TIBC). Blood samples were taken initially for baseline evaluation of blood indices and then again near term to assess the effect of iron supplementation in the two groups.

Data Collection

Baseline data were collected at the time of enrolment, including demographic information, obstetric history, dietary habits, and baseline blood indices. An initial deworming was done in all the patients with tablet albendazole (400 mg) 1 tablet stat per oral. Also, the patients were informed about the possible side effect with the iron therapy, both oral and parenteral. They were observed for initial reactions to parenteral iron and were asked to report immediately in case any problems occurred like any skin redness and itching, joint aches, breathlessness etc. On subsequent visits, patients were asked regarding compliance and side effects to oral iron therapy; also, about their tolerance and complaints related to parenteral therapy.

Statistical Analysis

Data were analyzed using SPSS version 26.0. Descriptive statistics were used to summarize baseline characteristics. Independent t-tests and chi-square tests were used to compare continuous and categorical variables, respectively, between the two groups. Paired t-tests were used to compare changes within groups. A p-value of <0.05 was considered statistically significant.

Ethical Considerations

The study protocol was approved by the Institutional Ethics Committee of Maharaja Agrasen Medical College, Agroha. Written informed consent was obtained from all participants prior to enrollment. Participants were assured of confidentiality and the right to withdraw from the study at any time without any impact on their medical care.

RESULTS

The study included 100 pregnant women, with 50 participants in each group receiving either oral or parenteral iron supplementation. The mean age was similar between the groups (Oral group: 23.88 ± 3.24 years vs. Parenteral group: 23.88 ± 2.72 years, P = 1.000). Most participants were literate, with secondary education being predominant in both groups (Oral group: 68.0% vs. Parenteral group: 70.0%, P = 0.618). There were no significant differences observed in literacy levels between the groups. The mean gestational age at enrolment was also comparable (Oral group: 19.66 ± 2.34 weeks vs. Parenteral group: 20.38 ± 3.12 weeks, P = 0.196). Regarding parity, the distribution of primiparous and multiparous women was similar between the groups (Primiparous: Oral group 44.0% vs. Parenteral group 48.0%, P = 0.684; Multiparous: Oral group 56.0% vs. Parenteral group 52.0%). [Table 1]

Table 1: Baseline characteristics of the study participants

Variables	Oral group (N=50)	Parenteral group (N=50)	P value
	Frequency (%)/ Mean±SD		
Age (years)	23.88±3.24	23.88±2.72	1.000
Literacy			
Illiterate	8 (16.0)	6 (12.0)	0.618
Primary	4 (8.0)	2 (4.0)	
Secondary	34 (68.0)	35 (70.0)	
Graduate	4 (8.0)	7 (14.0)	
Gestational age (weeks)	19.66±2.34	20.38±3.12	0.196
Parity			
Primiparous	22 (44.0)	24 (48.0)	0.684
Multiparous	28 (56.0)	26 (52.0)	

At baseline, both groups had similar haemoglobin (Hb), packed cell volume (PCV), mean corpuscular haemoglobin concentration (MCHC), mean corpuscular haemoglobin (MCH), mean corpuscular volume (MCV), ferritin, serum iron, and total iron-binding capacity (TIBC) levels (all P > 0.05). Following intervention, significant increases in Hb and PCV were observed in both groups (P < 0.001). At near term, parenteral supplementation showed higher ferritin levels compared to oral supplementation (P < 0.001). Serum iron levels were significantly higher in the oral group compared to the parenteral group at baseline (P = 0.017) and near term (P = 0.005). MCV increased significantly in both groups at near term (P < 0.001). In the oral group, 32% achieved Hb > 11gm%. In the parenteral group, 38% achieved Hb > 11gm%. [Table 2]

Table 2: Comparison of blood indices among two groups pre and post intervention

Variables	Oral group (N=50)	Parenteral group (N=50)	P value
	Frequency (%)/ Mean±SD		
Hb (gm%)			
Baseline	9.70±0.87	9.62±0.91	0.639
Near term	10.70±0.73	10.76±0.68	0.653
P value	<0.001	<0.001	
Hb at near term			
<11 gm%	34 (64.0)	31 (62.0)	0.569
>11 gm%	16 (32.0)	19 (38.0)	
PCV (%)			
Baseline	31.20±3.65	30.96±2.75	0.707
Near term	37.69±4.15	37.24±3.94	0.585
P value	<0.001	<0.001	
MCHC (gm%)			
Baseline	31.11±3.46	31.03±3.42	0.903
Near term	28.44±2.86	28.91±2.75	0.408
P value	<0.001	<0.001	
MCH (gm%)			
Baseline	27.54±3.09	27.56±3.79	0.977
Near term	29.13±2.11	28.71±3.37	0.460
P value	0.004	0.027	
MCV (fl)			
Baseline	84.66±7.41	83.26±6.98	0.334
Near term	102.22±8.67	98.58±15.76	0.156
P value	<0.001	<0.001	
Ferritin (ug/l)			
Baseline	8.60±7.51	8.87±8.21	0.864
Near term	15.75±9.51	34.07±24.92	<0.001
P value	<0.001	<0.001	
Serum Iron (umol/l)			
Baseline	37.39±8.98	31.11±15.92	0.017
Near term	40.83±10.70	33.18±15.67	0.005
P value	<0.001	0.115	
TIBC (umol/l)			
Baseline	118.18±34.94	125.13±63.87	0.502
Near term	126.14±58.58	110.36±51.43	0.155
P value	0.413	0.036	

This study assessed delivery outcomes and birth weight in pregnant women receiving oral (N=50) and parenteral (N=50) iron supplementation. The proportion of term deliveries was similar between the oral (86.0%) and parenteral (88.0%) groups (P = 0.766). Likewise, there were no significant differences in mean birth weight between the oral group (2773.64 ± 484.00 g) and the parenteral group (2782.14 ± 467.90 g, P = 0.930). [Table 3]

Table 3: Comparison of foetal outcomes among two groups

Variables	Oral group (N=50)	Parenteral group (N=50)	P value
	Frequency (%)/ Mean±SD		
Delivery			
Term	43 (86.0)	44 (88.0)	0.766
Preterm	7 (14.0)	6 (12.0)	
Birth weight (gms)	2773.64±484.00	2782.14±467.90	0.930

Among the participants receiving oral iron supplementation, side effects were reported as follows: dyspepsia was noted in 20.0% (10 participants), constipation in 10.0% (5 participants), diarrhea in 6.0% (3 participants), vomiting in 4.0% (2 participants), and generalized rash with itching in 2.0% (1 participant). [Table 4]

Table 4: Side effects among oral group participants

Side Effect	Frequency (%)
Dyspepsia	10 (20.0)
Constipation	5 (10.0)
Diarrhoea	3 (6.0)
Vomiting	2 (4.0)
Generalized Rash & Itching	1 (2.0)

Table 5. summarizes the side effects experienced by participants receiving parenteral iron supplementation via intramuscular injection (I.M.). Local pain was predominantly mild across all doses (Dose I: 24 participants, 48.0%; Dose II: 13 participants, 26.0%; Dose III: 14 participants,

28.0%), with a minimal incidence of severe pain (Dose II: 1 participant, 2.0%). Staining at the injection site varied, with mild staining reported in Dose I (18.0%) and Dose III (18.0%), and more frequently in Dose II (38.0%). Fever occurred in 8.0% (Dose I), 18.0% (Dose II), and 6.0% (Dose III) of participants. Other side effects such as systemic ache, arthralgia, itching, rash, and headache were generally mild and varied across doses. No participants experienced abscess formation, and only a few required hospital admissions due to severe reactions. One patient required admission due to systemic anaphylaxis and was managed accordingly. The other three patients required hospitalization due to severe arthralgia, body ache, and fever; they were treated with anti-inflammatory drugs like diclofenac sodium and were discharged the next day. Parenteral therapy was discontinued in the patient who had developed systemic anaphylaxis; she was shifted to oral iron supplementation. No case of gluteal abscess or death was reported. [Table 5]

Table 5: Side effects among parenteral group participants

Side Effect	Frequency (%)		
	Dose I	Dose II	Dose III
Local pain			
Mild	24 (48.0)	13 (26.0)	14 (28.0)
Severe	0 (0.0)	1 (2.0)	0 (0.0)
Staining			
Mild	9 (18.0)	19 (38.0)	9 (18.0)
Moderate	1 (2.0)	0 (0.0)	0 (0.0)
Fever	4 (8.0)	9 (18.0)	3 (6.0)
Systemic ache	4 (8.0)	5 (10.0)	1 (2.0)
Arthralgia	3 (6.0)	2 (4.0)	2 (4.0)
Itching & rashes	3 (6.0)	4 (8.0)	0 (0.0)
Immediate headache & giddiness	1 (2.0)	1 (2.0)	0 (0.0)
Malaise	1 (2.0)	1 (2.0)	0 (0.0)
Vasovagal due to apprehension	1 (2.0)	0 (0.0)	0 (0.0)
Systemic reaction	1 (2.0)	0 (0.0)	0 (0.0)
Abscess	0 (0.0)	0 (0.0)	0 (0.0)
Admission	3 (6.0)	1 (2.0)	0 (0.0)

DISCUSSION

Iron deficiency anemia remains a significant public health concern during pregnancy, impacting maternal and fetal health outcomes worldwide. This study aimed to compare the efficacy, safety, and impact on maternal and fetal outcomes of oral versus parenteral iron supplementation in pregnant women.

Hematological and Iron Status Outcomes

Our findings underscore the efficacy of both oral and intramuscular routes in improving hematological parameters, particularly hemoglobin (Hb) levels and packed cell volume (PCV). The observed increase in Hb levels from baseline to near term was significant in both groups ($P < 0.001$), aligning with previous literature demonstrating the effectiveness of iron supplementation in correcting maternal anemia.[11,12] Notably, intramuscular iron supplementation showed a more pronounced effect on serum ferritin levels compared to oral supplementation. Serum Ferritin, an indicator of iron stores, increased significantly in the intramuscular group ($P < 0.001$), suggesting more effective replenishment of iron stores with this route. This finding is consistent with studies highlighting the superior bioavailability and direct delivery of iron to tissues with intramuscular administration.[13,14]

Serum iron levels initially favored the oral supplementation group but converged with the intramuscular group by near term. This divergence and subsequent convergence can be attributed to differences in absorption kinetics and compliance with oral supplements, as well as the sustained release and direct delivery of iron into circulation with intramuscular administration.[15] Total iron-binding capacity (TIBC), reflecting iron transport capacity, did not differ significantly at baseline but showed significant differences at near term, indicating varied rates of iron utilization and metabolism between the two routes.[16]

Delivery Outcomes and Birth Weight

The study found no significant differences in the rates of term deliveries or mean birth weights between the oral and intramuscular supplementation groups. These findings are consistent with recent meta-analyses that reported no significant impact of iron supplementation route on birth outcomes, suggesting that while iron status is crucial, the supplementation route may not significantly influence these delivery parameters.[17,18]

Side Effects and Safety

Side effects associated with iron supplementation were generally mild and comparable between the oral and intramuscular groups. Local pain at the injection site was the most commonly reported side effect in the intramuscular group, with the majority being mild and transient. Other reported side effects such as fever, systemic ache, and gastrointestinal symptoms did not differ significantly between the groups. These findings are consistent with previous studies indicating that while intramuscular iron may be associated with more immediate discomfort at the injection site, both routes are generally well-tolerated and safe during pregnancy.[19,20]

Clinical Implications

The results of this study have significant clinical implications for the management of iron deficiency anemia in pregnancy. Parenteral iron supplementation appears advantageous in rapidly correcting iron deficiency and replenishing iron stores, particularly indicated in cases where oral supplementation is inadequate or poorly tolerated. However, oral supplementation remains a viable and widely accessible option, especially in resource-limited settings where parenteral administration may pose logistical challenges.

Study Strengths and Limitations

Strengths of this study include rigorous methodology, including randomized allocation and comprehensive assessment of hematological parameters and maternal-fetal outcomes. Limitations include the relatively small sample size, which may have limited the detection of small but potentially clinically significant differences between the groups. Furthermore, variations in individual adherence to supplementation protocols and dietary intake could have influenced outcomes, despite efforts to standardize these factors.

CONCLUSION

In conclusion, both oral and intramuscular iron supplementation effectively improve hematological parameters and iron status in pregnant women. Intramuscular supplementation demonstrates advantages in rapidly correcting iron deficiency and increasing ferritin levels compared to oral supplementation. However, both routes are generally safe and well-tolerated, with similar impacts on delivery outcomes and birth weight. The choice between oral and intramuscular supplementation should be individualized based on patient preferences, clinical indications, and resource availability. Further research with larger cohorts and longer follow-up periods is warranted to confirm these findings and optimize strategies for iron supplementation during pregnancy.

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