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Efficacy and Compliance of Oral Iron in Iron Deficiency Anemia in 2nd Trimester Pregnant Females-An Observational Study

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KEYWORDS

Iron deficiency anemia, Pregnancy, Oral iron therapy, Hemoglobin, Compliance, Reticulocyte count

ABSTRACT:

Background: Iron deficiency anemia (IDA) is a major public health problem among pregnant women, especially in developing countries. It is associated with adverse maternal and fetal outcomes, making effective treatment and compliance essential.

Aim: To evaluate the efficacy and compliance of oral iron therapy in second trimester pregnant females with iron deficiency anemia.

Methods: This observational study included 640 second trimester pregnant women diagnosed with IDA. Hemoglobin, serum iron, and reticulocyte count were assessed before and after oral iron therapy. Compliance was evaluated using pill count, and adverse drug reactions (ADRs) were recorded. Statistical analysis was performed using paired t-test and ANOVA.

Results: A statistically significant improvement was observed in all hematological parameters following therapy ($p < 0.000001$). Mean hemoglobin increased from 8.59 ± 1.04 g/dL to 10.12 ± 1.10 g/dL, serum iron from 37.59 ± 6.46 µg/dL to 67.70 ± 10.31 µg/dL, and reticulocyte count from 0.37 ± 0.07% to 1.00 ± 0.27%. Approximately 65–69% of participants showed significant response, while 9–11% showed insignificant response. Compliance was highest in the significant response group (89.88 ± 3.25%), with a strong association between adherence and treatment outcome ($p < 0.000001$). ADRs were mild, with nausea being the most common.

Conclusion: Oral iron therapy is effective, safe, and well tolerated in treating IDA during pregnancy. Compliance plays a crucial role in determining therapeutic success.

INTRODUCTION

Iron deficiency anemia (IDA) remains the most common nutritional deficiency worldwide and continues to be a major public health concern, particularly among pregnant women in developing countries. According to the World Health Organization, anemia affects nearly 40% of pregnant women globally, with a significantly higher prevalence in low- and middle-income countries [1]. In India, the burden is even more alarming, with national surveys reporting anemia prevalence exceeding 50% among pregnant females, thereby contributing substantially to maternal morbidity and adverse fetal outcomes [2].

Pregnancy is a state of increased physiological demand, particularly during the second trimester, when rapid expansion of maternal blood volume and fetal growth significantly increase iron requirements. The total iron requirement during pregnancy is estimated to be approximately 1000 mg, which includes demands for fetal development, placental growth, and expansion of maternal red cell mass [3]. Inadequate dietary intake, poor absorption, and increased physiological needs

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often lead to iron deficiency, making pregnant women highly vulnerable to anemia during this period.

Iron deficiency anemia during pregnancy has been associated with a wide range of complications, including preterm delivery, low birth weight, intrauterine growth restriction, and increased risk of maternal mortality [4]. Additionally, maternal anemia adversely affects neonatal iron stores, thereby predisposing infants to anemia and impaired cognitive development in early life [5]. Therefore, early detection and effective management of IDA during pregnancy are essential components of antenatal care.

Oral iron supplementation remains the cornerstone of treatment for iron deficiency anemia due to its cost-effectiveness, ease of administration, and widespread availability. The World Health Organization recommends routine oral iron and folic acid supplementation for pregnant women as a preventive and therapeutic strategy [1]. Typically, ferrous salts such as ferrous sulfate, ferrous fumarate, and ferrous gluconate are used due to their high bioavailability and efficacy [6]. Clinical studies have demonstrated that oral iron therapy can significantly improve hemoglobin levels and replenish iron stores within a few weeks of treatment initiation [7].

However, despite its effectiveness, oral iron therapy is often limited by poor compliance, primarily due to gastrointestinal adverse effects such as nausea, vomiting, constipation, and epigastric discomfort [8]. These side effects frequently lead to discontinuation or irregular intake of medication, thereby reducing therapeutic efficacy. Furthermore, factors such as socioeconomic status, educational level, and access to healthcare services also play a crucial role in determining adherence to therapy [9].

Recent studies have emphasized the importance of evaluating both efficacy and compliance simultaneously, as treatment success is closely linked to patient adherence. While intravenous iron therapy has emerged as an alternative with faster hematological response and fewer gastrointestinal side effects, its higher cost and need for supervised administration limit its use in resource-constrained settings [10]. Therefore, oral iron continues to be the first-line therapy in most clinical scenarios, particularly in developing countries like India.

In this context, the present study aims to evaluate the efficacy and compliance of oral iron therapy in second trimester pregnant females with iron deficiency anemia. By assessing hematological response along with adherence patterns and adverse effects, this study seeks to provide a comprehensive understanding of treatment outcomes and identify factors influencing therapeutic success.To find out the efficacy, compliance of oral iron therapy in the mild to moderately anemic 2nd-trimester pregnant females.

MATERIALS AND METHODS

1. **STUDY DESIGN AND TYPE:**
   A hospital-based, non-randomized, open-label, observational,
   prospective cohort study
2. **STUDY SETTING:**
   Zydus Medical College and Hospital tertiary care hospital in Dahod.
   DURATION OF STUDY:
   10 Months. (from June 2024 to April 2025)
3. **STUDY POPULATION:**
   Pregnant women attending the ANC clinic in the 2nd trimester
4. **SAMPLE SIZE AND SAMPLING TECHNIQUE:** 383(without attrition) & consecutive sampling

5.1 Sample size calculation:

Therefore, the final sample size target for the present study was set at 425 second-trimester pregnant women with mild-to-moderate anemia.

5.2 Sampling technique:

A non-probability consecutive sampling technique was used. All eligible second-trimester pregnant women with mild-to-moderate anemia who attended the antenatal clinic during the study period and met the inclusion criteria were consecutively recruited until the desired sample size was reached.

5. INCLUSIONAND EXCLUSION CRITERIA:

Table 3.1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
2nd-trimester pregnant females	known case of hemorrhoids or hemorrhoidectomy, sickle cell

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with mild to moderate anemia	anemia, thalassemia
	known case of worm infestation
	known case of bleeding disorder, peptic ulcer, GERD (gastroesophageal reflux disease), bowel resection
	known case of IBD (inflammatory bowel disease)
	known case of megaloblastic anemia, pernicious anemia, celiac disease, tropical sprue, other malabsorption disorders

Table 1: Demographic Profile of Participants (n = 640)

Variable	Category	Number (n)	Percentage (%)
Age (years)	18–25	389	60.78
	26–30	240	37.50
	31–35	11	1.72
	>35	0	0.00
Socioeconomic Class	Class III	64	10.0
	Class IV	128	20.0
	Class V	448	70.0
Total	—	**640**	**100**

Table 2: Hematological Parameters Before and After Oral Iron Therapy (Paired t-test)

Parameter	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Mean Difference	t-value	p-value
Hemoglobin (g/dL)	8.59 ± 1.04	10.12 ± 1.10	+1.54	86.35	<0.0001
Serum Iron (µg/dL)	37.59 ± 6.46	67.70 ± 10.31	+30.11	74.11	<0.0001
Reticulocyte (%)	0.37 ± 0.07	1.00 ± 0.27	+0.63	53.35	<0.0001

***Highly significant (p < 0.001)**

Table 3: Group-wise Distribution and Mean Response Across Parameters

Group	Hb (n)	Serum Iron (n)	Reticulocyte (n)	Hb Rise (g/dL)	Serum Iron Rise (µg/dL)	Reticulocyte Rise (× fold)
A	56	56	56	1.514	29.89	2.690
B	88	96	104	1.524	29.93	2.690
C	128	120	112	1.542	30.07	2.673

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D	128	128	128	1.537	30.38	2.754

Table 4: Response Distribution Across Parameters and Subgroups

A. Hemoglobin Response

Group	≥1.5 g/dL	1.0–1.5 g/dL	<1.0 g/dL
A	38	13	5
B	60	21	7
C	91	27	10
D	88	28	12

B. Serum Iron Response

Group	≥30 µg/dL	20–29 µg/dL	<20 µg/dL
A	34	15	7
B	61	24	11
C	79	28	13
D	87	28	13

C. Reticulocyte Response

Group	≥2.5×	2.0–2.5×	<2.0×
A	35	15	6
B	68	26	10
C	76	25	11
D	89	28	11

Table 5: Overall Response, Compliance, and ADR Distribution

A. Overall Response Across Parameters

Parameter	Significant n (%)	Equivocal n (%)	Insignificant n (%)
Hemoglobin	277 (69.25)	90 (23.0)	33 (9.0)
Serum Iron	261 (65.25)	95 (23.8)	44 (11.0)
Reticulocyte	268 (66.5)	94 (23.8)	38 (9.8)

B. Compliance by Response Category

Category	n	Mean Compliance (%) ± SD	Compliant n (%)
Significant	272	89.88 ± 3.25	272 (100.0)
Equivocal	92	80.21 ± 3.15	55 (59.8)

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Insignificant	36	67.25 ± 4.76	0 (0.0)

p-value (ANOVA): <0.000001*

C. Compliance by Socioeconomic Class

Class	n	Mean Compliance (%) ± SD	Compliant n (%)
III	36	84.9 ± 6.5	28 (77.8)
IV	77	85.4 ± 7.5	63 (81.8)
V	287	85.8 ± 8.1	236 (82.2)

p-value (ANOVA): 0.72 (Not Significant)

D. Adverse Drug Reactions (ADR)

ADR	Frequency (n)	Percentage (%)
Nausea	42	10.5
Epigastric Pain	26	6.5
Constipation	21	5.3
Diarrhea	16	4.0
Mouth Irritation	15	3.8
Bloating/Flatulence	11	2.8
Urticaria/Rash	8	2.0
Metallic Taste	6	1.5

The study included a total of 640 participants, with the majority belonging to the younger age group. Most participants were aged 18–25 years (389, 60.78%), followed by 26–30 years (240, 37.50%), while only 11 participants (1.72%) were in the 31–35 years group, and none were above 35 years. Regarding socioeconomic status, the majority belonged to Class V (448, 70.0%), followed by Class IV (128, 20.0%) and Class III (64, 10.0%). This indicates that the study population predominantly comprised young individuals from lower socioeconomic strata.

A statistically highly significant improvement was observed in all hematological parameters following oral iron therapy. The mean hemoglobin level increased from 8.59 ± 1.04 g/dL before treatment to 10.12 ± 1.10 g/dL after treatment, with a mean rise of 1.54 g/dL ($t = 86.35$, $p < 0.000001$). Similarly, serum iron levels showed a substantial increase from 37.59 ± 6.46 µg/dL to 67.70 ± 10.31 µg/dL, with a mean difference of 30.11 µg/dL ($t = 74.11$, $p < 0.000001$). Reticulocyte count also increased significantly from 0.37 ± 0.07% to 1.00 ± 0.27%, demonstrating a mean rise of 0.63% ($t = 53.35$, $p < 0.000001$). These findings confirm a strong hematological response to oral iron therapy.

Participants were distributed across four groups (A–D) based on baseline severity. Group C and D had the highest number of participants across parameters. The mean hemoglobin rise was relatively uniform across all groups, ranging from 1.514 g/dL in Group A to 1.542 g/dL in Group C. Serum iron levels increased consistently across groups, with values ranging from 29.89 µg/dL (Group A) to 30.38 µg/dL (Group D). Reticulocyte response showed a fold increase between 2.673 and 2.754, with the highest response observed in Group D. These findings suggest that hematological improvement was consistent across all severity groups, with slightly greater response in more severe cases.

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Subgroup analysis demonstrated that the majority of participants across all groups showed a significant response. For hemoglobin, most participants achieved a rise of ≥1.5 g/dL, particularly in Groups C (91 participants) and D (88 participants). Similarly, for serum iron, the majority achieved a rise of ≥30 µg/dL, with the highest response seen in Group D (87 participants). Reticulocyte response also showed a predominant ≥2.5-fold increase, especially in Groups C (76 participants) and D (89 participants). Only a small proportion of participants in each group demonstrated an insignificant response across all parameters. These findings indicate that the therapeutic response was robust and more pronounced in individuals with lower baseline values.

Overall, a significant response was observed in the majority of participants across all parameters: 69.25% for hemoglobin, 65.25% for serum iron, and 66.5% for reticulocyte count. Approximately 23–24% of participants showed an equivocal response, while only 9–11% had an insignificant response. Compliance analysis revealed a strong association between adherence and treatment response. Participants with a significant response had the highest compliance (89.88 ± 3.25%), with 100% meeting compliance criteria, compared to 80.21 ± 3.15% in the equivocal group and 67.25 ± 4.76% in the insignificant group ($p < 0.000001$). In contrast, compliance did not significantly differ across socioeconomic classes ($p = 0.72$). Adverse drug reactions were generally mild, with nausea being the most common (42 cases, 10.5%), followed by epigastric pain (6.5%) and constipation (5.3%). Overall, oral iron therapy was well tolerated with manageable side effects.

DISCUSSION

In the present study, the majority of participants belonged to the younger age group (18–25 years, 60.78%) and predominantly to lower socioeconomic strata (Class V, 70%). This demographic trend is consistent with studies conducted in developing countries where early reproductive age and lower socioeconomic status are strongly associated with higher prevalence of iron deficiency anemia during pregnancy. Similar findings were reported by Finkelstein et al., who observed that maternal anemia is more prevalent among economically disadvantaged populations due to nutritional deficiencies and limited healthcare access [11]. Additionally, Kuitunen et al. highlighted that anemia prevalence in pregnancy ranges between 25–40%, with a higher burden in low-resource settings [12]. The predominance of lower socioeconomic class in our study further supports the established link between poverty, poor dietary intake, and increased risk of anemia, as also emphasized in global maternal health reports [11,12].

The present study demonstrated a highly significant improvement in hemoglobin (increase of 1.54 g/dL), serum iron (increase of 30.11 µg/dL), and reticulocyte count (increase of 0.63%) following oral iron therapy ($p < 0.000001$). These findings are consistent with established literature indicating that oral iron supplementation effectively improves hematological parameters in pregnant women. According to Pantopoulos et al., an optimal response to oral iron therapy is characterized by a hemoglobin rise of approximately 1–2 g/dL within 3–4 weeks, which aligns closely with the results of the present study [13].

Similarly, systematic reviews have shown that daily oral iron supplementation significantly reduces maternal anemia and improves iron stores at term [11]. However, several studies comparing oral and intravenous iron have reported that intravenous iron leads to a faster and greater rise in hemoglobin levels [14–16]. For instance, Afolabi et al. demonstrated that IV iron produced a significantly higher increase in hemoglobin at 4 weeks compared to oral therapy [14]. Despite this, the magnitude of improvement observed in our study confirms that oral iron remains an effective first-line therapy, particularly in resource-limited settings.

In the present study, hematological improvement was observed across all severity groups (A–D), with a relatively uniform rise in hemoglobin (~1.5 g/dL), serum iron (~30 µg/dL), and reticulocyte count (~2.7-fold). Notably, slightly higher responses were observed in groups with more severe baseline anemia (Groups C and D).

This trend is supported by previous studies, which indicate that patients with more severe iron deficiency often exhibit a more pronounced response to therapy due to higher physiological demand and increased iron absorption efficiency. Younis et al. reported that individuals with lower baseline hemoglobin levels

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showed greater improvement following iron therapy [17]. Similarly, meta-analyses comparing oral and IV iron have demonstrated that the magnitude of response is often greater in patients with severe anemia, regardless of the treatment modality [15,17].

These findings suggest that oral iron therapy is effective across varying severity levels and may produce relatively greater benefits in individuals with more pronounced deficiency.

Subgroup analysis in the present study revealed that the majority of participants achieved a significant response across all parameters, particularly in Groups C and D. For hemoglobin, most participants showed a rise ≥1.5 g/dL, while for serum iron and reticulocyte count, the majority achieved ≥30 µg/dL and ≥2.5-fold increases, respectively.

These findings are consistent with clinical expectations of hematological recovery following iron therapy. Reticulocyte response, in particular, is considered an early indicator of bone marrow activity. Studies have shown that reticulocytosis typically occurs within 5–7 days of effective iron therapy, reflecting active erythropoiesis [13].

Furthermore, comparative studies have demonstrated that although intravenous iron may produce a faster response, oral iron therapy still achieves significant hematological improvement in the majority of patients [16,18]. The predominance of significant responders in our study reinforces the efficacy of oral iron therapy, especially when adherence is adequate.

In the present study, approximately two-thirds of participants demonstrated a significant response across all parameters (65–69%), while only 9–11% showed an insignificant response. A strong association between compliance and treatment response was observed, with the highest compliance seen in the significant response group (89.88 ± 3.25%, $p < 0.0001$).

This finding is supported by previous studies indicating that adherence is a critical determinant of therapeutic success in oral iron therapy. Poor compliance, often due to gastrointestinal side effects, has been identified as a major limitation of oral iron supplementation [19]. Kirthan et al. reported that adverse effects such as nausea, constipation, and epigastric discomfort significantly reduce compliance and delay recovery from anemia [19].

In our study, adverse drug reactions were mild and predominantly gastrointestinal, with nausea (10.5%) being the most common. This is consistent with earlier studies, which have documented similar side effect profiles with oral iron therapy [19,20].

Interestingly, compliance did not differ significantly across socioeconomic classes ($p = 0.72$), suggesting that once treatment is initiated and monitored, adherence may not be strongly influenced by socioeconomic status.

Comparative studies have shown that intravenous iron is associated with fewer gastrointestinal side effects and better compliance; however, oral iron remains widely used due to its cost-effectiveness and ease of administration [15,20].

CONCLUSION

The present study demonstrates that oral iron therapy is highly effective in improving hematological parameters among second trimester pregnant women with iron deficiency anemia. A significant rise in hemoglobin, serum iron, and reticulocyte count was observed following treatment, indicating both restoration of iron stores and active erythropoietic response. Approximately two-thirds of participants showed a significant clinical response, confirming the therapeutic efficacy of oral iron as a first-line intervention. Importantly, treatment success was strongly associated with patient compliance, with higher adherence leading to better hematological outcomes. Although mild gastrointestinal adverse effects were reported, they were generally well tolerated and did not significantly impact overall treatment continuation. No significant variation in compliance was noted across socioeconomic classes, suggesting uniform acceptability of therapy. Overall, oral iron supplementation remains a cost-effective, safe, and practical approach for managing iron deficiency anemia in pregnancy, particularly in resource-limited settings where accessibility and affordability are crucial.

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