

Efficacy of heme iron polypeptide in managing iron deficiency anemia in pregnancy: A case series

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ABSTRACT

Iron deficiency anemia (IDA) is a major global health concern, especially affecting pregnant women and posing significant risks to both maternal and fetal health. Conventional iron therapies are often limited by gastrointestinal intolerance and poor adherence. Heme iron polypeptide (HIP), a new-generation oral iron supplement, offers improved bioavailability and tolerability. This case series reports outcomes in four women with IDA treated with HIP (12 mg/day). All patients showed significant hematological improvements with HIP; hemoglobin levels rose from 8.0 to 9.0 g/dL at baseline to 11.0–11.8 g/dL within 3 months. Serum ferritin levels were increased from 10 to 20 µg/L to 29–50 µg/L. Patients experienced better energy and well-being, with no gastrointestinal side effects or compliance issues. One patient initially treated with ferrous fumarate switched to HIP due to intolerable side effects, achieving similar hematological correction without adverse events. Overall, HIP demonstrated effective anemia correction with excellent tolerability and compliance, supporting its role as a safe alternative to conventional iron therapies during pregnancy.

Key words: Compliance, Ferritin, Heme iron polypeptide, Iron deficiency anemia, Pregnancy

Iron deficiency and iron-deficiency anemia (IDA) remain major global health issues, especially among pregnant women and women of reproductive age [1]. According to data from the World Health Organization, about 35.5% of pregnant women aged 15–49 years were anemic in 2023, demonstrating the scale of the problem [1]. During pregnancy, the mother's iron requirement increases substantially to support the expansion of maternal blood volume, placental growth, and fetal development. IDA in pregnancy is associated with adverse outcomes, including low birth weight, prematurity, and intrauterine growth restriction [2]. Standard oral non-heme iron (NHI) salts are widely prescribed; however, their efficacy is often limited due to gastrointestinal side-effects, poor absorption, and suboptimal compliance [3]. Conventional NHI salts are commonly associated with gastric discomfort

and constipation, leading to reduced treatment adherence [4]. Certain medications, such as antacids, H2 receptor blockers, and anti-cholesterol drugs, can interfere with iron absorption. Nutritional supplements, particularly those containing calcium or manganese, further impair NHI uptake due to shared absorptive pathways and similar physicochemical properties [4]. Heme-iron supplements hold biological promise because they use an absorption pathway less affected by dietary inhibitors. It offers a 2–7 fold higher bioavailability than NHI, making it a superior option for treating IDA [3].

In India, where maternal anemia remains highly prevalent, and evidence on heme iron (HI) use in pregnancy is limited, real-world data on newer oral iron formulations are urgently needed. Given this gap, reporting the present case series offers valuable clinical insight into the therapeutic role, safety, and acceptability of HI polypeptide (HIP) during pregnancy. This case series describes four pre-pregnant or pregnant

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Table 1: Patient presentations (n=4)

Case	Age	Gestational age	Past medical history	Symptoms	General examination	Laboratory findings
1	30 years	Pre-pregnancy	No significant history, family history, or mother diabetic	Palpitations, fatigue, shortness of breath, no icterus, cyanosis, clubbing, or lymphadenopathy	BP: 120/80 mm/Hg, HR: 78 bpm; RR: 16/min, Temp: 98.6°F	Hb: 8.1 g/dL; baseline serum ferritin: 20.01 ug/L; CBC revealed microcytic hypochromic anemia, OGTT, and TSH were normal. HPLC and iron studies confirmed moderate iron deficiency anemia. Transvaginal pelvic images demonstrate a normal uterus that was anteverted, with no significant abnormality
2	26 years	16 weeks	Gravida 2 para 1. Mother with hypertension	Fatigue, leg cramps, abnormal paleness of skin from the past 2 months, no icterus, cyanosis, clubbing, or lymphadenopathy	BP: 128/70 mmHg HR: 80 bpm, RR: 18 beats/min Temp: 98.6°F	Hb: 8 g/dL Serum iron: 60 ug/dL CBC revealed microcytic hypochromic anemia TSH normal, HPLC and iron studies confirmed moderate iron deficiency anemia
3	28 years	Second trimester	Primigravida	Severe Nausea, mild fatigue, and occasional dizziness. Sudden rise in GI symptoms due to hormonal changes.	BP: 115/75 mmHg HR: 82 bpm RR: 16 bpm No hepatosplenomegaly, CV, or respiratory examination was unremarkable	Hb: 9 g/dL; Hematocrit: 29% MCV: 74 fL, MCH: 25 pg, MCHC: 31g/dL Serum iron: 40 ug/dL TIBC: 400 ug/dL Serum ferritin: 15 ng/L
4	35.5 years	13 weeks	Mild IDA during the first pregnancy, poorly controlled due to non-compliance with treatment. Intolerant to ferrous ascorbate (high-dose iron salt).	Shortness of breath, dizziness, cold palms and feet, pallor. Shortness of breath worsened with gestation.	BP: 110/70 mmHg HR: 90 bpm, RR: 18 beats/min Mild tachycardia, no murmurs	Hb: 9.0 g/dL; Hematocrit: 26% MCV: 70 fL, MCH: 24 pg, MCHC: 30 g/dL Serum iron: 30 ug/dL TIBC: 450 ug/dL TS: 7% Serum ferritin: 10 ng/mL Diagnosis: moderate IDA

BP: Blood pressure, CBC: Complete blood count, CV: Coefficient of variation, GI: Gastrointestinal, Hb: Hemoglobin, HPLC: High-performance liquid chromatography, HR: Heart rate, IDA: Iron deficiency anemia, MCHC: Mean corpuscular hemoglobin concentration, MCV: Mean corpuscular volume, OGTT: Oral glucose tolerance test, RR: Respiratory rate, Temp: Temperature, TIBC: Total iron binding capacity, TS: Transferrin saturation, TSH: Thyroid-stimulating hormone

women with moderate IDA who were treated with HIP (12 mg/day), documenting their hematologic response, ferritin kinetics, tolerability, and compliance within the broader context of emerging alternative oral iron strategies.

CASE SERIES

Four pregnant patients with IDA were included in this case series. Of the four patients, two had come in the second trimester of pregnancy, and one patient had come in the first trimester. One patient was planning for pregnancy and had come for pre-pregnancy counseling. The patient characteristics are summarized in Table 1.

The diagnosis of IDA was established based on laboratory findings and clinical presentation. The likely cause was a nutritional deficiency in the patients.

Patients 1 and 3 underwent a deworming course as a part of the comprehensive treatment plan to address potential parasitic infections contributing to anemia. Patient 2 was initially advised to use ferrous fumarate (50 mg) once a day for a month. However, she reported symptoms of severe gastritis and aversion to metallic taste, worsening her nausea and morning sickness, leading to intolerance and non-compliance with the therapy. She was counseled about the treatment options available and, after detailed discussions, initiated treatment with HIP.

The plan of care and patient outcomes are summarized in Table 2.

DISCUSSION

This case series highlights the remarkable effectiveness of HIP in rapidly correcting severe IDA within a short duration. All four women achieved substantial hemoglobin improvements (~8–9 g/dL at baseline to ~11–11.8 g/dL) over approximately 3 months. Importantly, compliance was full, and no gastrointestinal side effects were reported. Our findings are consistent with emerging evidence that heme-based iron formulations can address some of the absorption and tolerability challenges seen with conventional non-heme salts [5,6]. For example, a recent meta-analysis found HI supplementation was associated with fewer total side-effects (respiratory rate 0.62) compared with NHI, though the evidence quality was very low [7]. Mechanistically, HI is absorbed through alternative pathways less impacted by dietary inhibitors, consistent with older nutritional reviews highlighting superior bioavailability of HI [8].

In pregnancy, where iron demands escalate sharply, and conventional oral iron is frequently poorly tolerated, the clinical relevance of improved compliance is substantial [9]. Earlier work indicates that iron absorption, and by extension, hematologic response in pregnant

Table 2: Interventions and outcomes of the four pregnant women

Case	Intervention	Outcome
1	The deworming course followed by HIP at 12 mg/day (one tablet twice a day), half an hour before meals, for 3 months. Follow-up: After improvement, the HIP dose was adjusted once daily throughout pregnancy and 6 months of lactation.	Serum ferritin levels increased to 29 ug/L, continued improvement throughout pregnancy, and no anemia-related complications. Significant improvement in energy levels, no GI side effects, 100% compliance. The patient delivered a healthy baby after initial diagnosis and treatment.
2	Prescribed treatment with ferrous fumarate. It was not tolerated with symptoms of gastritis and aversion to metallic taste, with worsening nausea and morning sickness. HIP was initiated post-counseling at 12 mg/day (once a day before dinner with orange juice) for 3 months.	Hb levels increased to 11.6 g/dL after 3 months. Significant improvement in symptoms, no side effects. The patient exhibited good compliance.
3	Deworming treatment was initiated, and HIP therapy was started, 12 mg twice daily (1 h after meals) for 2 months.	Hb: 11 g/dL; Hematocrit: 33% MCV: 80 fL, MCH: 27 pg Serum iron: 85 ug/dL TIBC: 360 ug/dL Serum ferritin: 45 ng/L. The patient reported significant well-being and improved energy levels, with no GI side effects.
4	HIP at 12 mg/day for 3 months	Hb: 11.8 g/dL; Hematocrit: 35% MCV: 80 fL, MCH: 27 pg MCHC: 33 g/dL Serum iron: 80 ug/dL TIBC: 350 ug/dL TS: 23% Serum ferritin: 50 ng/mL. The patient reported marked improvements in symptoms and an overall increase in energy levels. No side effects were reported.

GI: Gastrointestinal, Hb: Hemoglobin, HIP: Heme iron polypeptide, MCH: Mean corpuscular hemoglobin, MCHC: Mean corpuscular hemoglobin concentration, MCV: Mean corpuscular volume, TIBC: Total iron binding capacity, TS: Transferrin saturation

women is sensitive to dietary and gastrointestinal tolerability factors [10].

Real-world data from India on the effectiveness and tolerability of HIP in non-pregnant and pregnant women with IDA were evaluated. The tolerability of HIP was satisfactory, with a treatment-adverse event-related discontinuation rate of <0.8%. The study found that oral HIP therapy was effective in both pregnant and non-pregnant women with iron deficiency, offering better gastrointestinal tolerability and improved hematologic outcomes [11]. Our case series findings in an Indian setting add pragmatic value because they reflect real-life patients with prior intolerance to standard iron salts, and indicate HIP may be a viable alternative when compliance is the barrier.

Broader evaluations across diverse populations and clinical contexts are needed to provide insight into its long-term role and cost-effectiveness. As recent reviews suggest, ongoing innovation in oral iron formulations represents a promising step toward improving treatment adherence and maternal health outcomes globally [12].

Enhanced bioavailability, coupled with minimal gastrointestinal side effects and no significant drug or dietary interactions, contributed to rapid anemia correction and improved adherence. These findings align with emerging evidence supporting HIP as a safe, effective, and well-tolerated alternative to conventional iron therapies for IDA, particularly in pregnant women, where tolerability and compliance profile underscore its potential to improve maternal and fetal outcomes [13].

CONCLUSION

This case series contributes to the growing evidence supporting the use of HIP in women of reproductive age and during pregnancy. HIP therapy offers a viable alternative to oral iron, ensuring rapid hematological correction and improved compliance. Clinicians should evaluate the efficacy and tolerability of individual formulations to ensure optimal treatment outcomes.

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