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Original Research Article

# A Prospective Comparative Study of Hematological Response and Tolerability among Oral Iron Preparations in Postnatal Women with Moderate Anemia

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**Conflict of interest: Nil**

**Abstract:**

**Background:** Iron deficiency anemia is the most common and correctable cause of anemia in the postnatal period. It has significant long-term implications for maternal and infant health. Despite various government programs, anemia remains a major contributor to maternal morbidity and mortality in India.

**Objective:** To compare the efficacy, side effects, and compliance of five different oral iron preparations in postnatal women with moderate anemia.

**Methods:** This prospective comparative study was conducted at UISE Maternity Hospital, GSVM Medical College, Kanpur, on 250 postnatal women with moderate anemia (Hb 7–10 g/dl) as per ICMR criteria. Participants were randomly divided into five groups (n=50 each) and administered ferrous sulphate sustained release (Group 1), ferrous fumarate (Group 2), ferrous ascorbate (Group 3), colloidal iron (Group 4), and ferric ammonium citrate suspension (Group 5). Hemoglobin, MCV, MCH, MCHC, reticulocyte count, and serum ferritin were measured at baseline, Day 30, and Day 90. Adverse effects and compliance were also recorded.

**Results:** All five preparations produced a significant rise in hemoglobin and serum ferritin levels ($p < 0.001$). Ferrous ascorbate showed the maximum rise in hemoglobin at Day 30 (2.75±0.57 g/dl) and Day 90 (3.41±0.83 g/dl), and the greatest increase in serum ferritin (39.32±11.74 ng/dl). Ferric ammonium citrate showed the minimum rise. Side effects were least frequent with ferric ammonium citrate and most frequent with ferrous sulphate and ferrous fumarate.

**Conclusion:** Ferrous ascorbate demonstrated superior efficacy in improving hematological parameters in postnatal women with moderate anemia, with acceptable tolerability. Postnatal women represent an important target population for anemia correction, and early initiation of supplementation after delivery is recommended.

**Keywords:** Postnatal anemia, Iron deficiency anemia, Ferrous ascorbate, Ferrous sulphate, Ferrous fumarate, Ferric ammonium citrate, Hemoglobin, Serum ferritin, Postpartum, Compliance.

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## Introduction

Anemia is a decrease in haemoglobin levels and a subsequent decrease in the oxygen-carrying capacity of blood. In the postnatal period, there are a number of causes of anaemia, including blood loss, iron deficiency and other micronutrient deficiencies (e.g. folate, vitamin B12 and riboflavin), congenital haemoglobinopathies, parasitic infections and other acute and chronic infections, of which iron deficiency anaemia remains the most common and correctable cause of anaemia [1, 2].

In comparison with pregnancy, maternal iron requirements usually decline during the postpartum period, defined as the period beginning just after childbirth throughout the subsequent 6 weeks. However, this period may serve as a time to restore iron lost during pregnancy and delivery. Maternal iron stores are not utilized for the production of breast milk, since very little iron is excreted through breast milk [3,4].

Iron deficiency anemia during the postpartum period has long-term health implications for the mother and her infant. Mothers with low iron stores following childbirth may experience fatigue, altered cognition, and depressive symptoms [5]. These alterations in the mother's emotional and cognitive functioning may affect her interactions with the infant in turn and thus may negatively impact infant behaviour and development [6]. Maternal iron deficiency negatively affects mother-child interactions, and iron supplementation protects against these negative effects [7].

## Material and Methods

This prospective and comparative study was conducted on obstetrical and gynecological patients at UISE Maternity Hospital, GSVM Medical College, Kanpur, after obtaining proper ethical committee approval. A total of 250 postnatal females who delivered in our hospital and had moderate anemia, as per ICMR criteria (hemoglobin levels of 7–10 g/dL), irrespective of parity, were included in the study. Patients with intolerance to oral iron preparations, excessive emesis, bleeding piles, active peptic ulcer, hypertension, diabetes, cardiac disease, hepatic and renal diseases, other gastrointestinal problems, and tuberculosis were excluded from the study.

After detailed history taking and clinical examination, informed consent was obtained from all patients in a standard format. The patients attending the OPD were subjected to hemoglobin estimation to determine the baseline hemoglobin level. Subsequently, they were randomly divided into five groups comprising 50 participants each and were administered different oral iron preparations (Table 1).

Group 1 is ferrous sulphate - sustained release (approximately 50mg elemental iron- twice daily),

Group 2 is ferrous fumarate (98.6mg elemental iron-once daily),

Group 3 is ferrous ascorbate (100mg elemental iron, once daily),

Group 4 is colloidal iron (50mg/ml of elemental iron),

Group 5 is ferric ammonium citrate suspension (32.8mg/15ml of elemental iron).

The patients were asked to follow up after one week (7 days), and subsequently after 1 month and 3 months (30 and 90 days).

Day 0: The blood samples were taken for investigations (Hb, MCV, MCH, MCHC, and serum ferritin level) before starting medication to know baseline values

1. 1 week: For reticulocyte count
2. Day 30: for Hb, MCV, MCH, MCHC.
3. Day 90: for Hb, MCV, MCH, MCHC & Serum ferritin.

During each follow-up visit, patients underwent a general examination. They were trained to observe and record adverse effects and were instructed to report immediately in case of any serious adverse drug reaction. Adverse events such as metallic taste, nausea/vomiting, dyspepsia, diarrhea, and constipation were recorded in the case record form. Compliance was assessed by verbal enquiry and further verified by checking the empty or used drug packets brought by the patients. Statistical analysis was performed to analyze the differences between the groups using percentages and the chi-square test for categorical variables. Mean, standard deviation, paired t-test, and ANOVA test were used for quantitative variables, and the results were obtained using SPSS version 22 software.

## Observations:

**Table 1: Distribution of subjects**

| Grp | Iron Preparations | Generic Name | Composition | Elemental Iron | Recommended Dose | Patients (n) |
|---|---|---|---|---|---|---|
| 1 | Ferrous Sulphate Sustained Release | HEPP SR (HOSP SUPPLY) | $FeSO_4$ 150mg<br>folic acid 0.5mg<br>$ZnSO_4$ 61.6mg | 50mg | BD | 50 |
| 2 | Ferrous fumarate | Autrin | FF 300 mg<br>Folic acid 1.5 mg<br>Vit B12 15micro g | 98.6mg | OD | 50 |
| 3 | Ferrous ascorbate tab | Hepatoglobine-xp | FA 100mg<br>folic acid 1.5mg<br>Vit B12 15micro g | 100mg | OD | 50 |
| 4 | Colloidal iron | Syp tonoferon | Each 5 ml<br>Iron 250mg<br>Folic acid 0.5mg<br>Vit B12 5 micro g | 50mg/ml | 1 tsf once a day | 50 |
| 5 | Ferric ammonium citrate | Syp dexorange | Each 15ml<br>Iron 160 mg<br>Folic acid 0.5mg<br>Vit B12 7.5micro g<br>folic acid 550mcg | 2.2mg/ml | 2 tsf thrice a day | 50 |

**Table 2: Comparative evaluation of mean rise in hemoglobin in postnatal patients in different oral iron preparation groups after 1 month of therapy**

| Groups | Iron Preparations | Tablet/ Syrup | Hb IN g/dl | | | P Value |
|---|---|---|---|---|---|---|
| | | | Day 1 | Day 30 | Mean rise in Hb | |
| 1 | Ferrous sulphate sr (hosp supply) | Tablet | 8.70 ± 0.71 | 10.24 ± 0.73 | 1.55 ± 0.48 | <0.001 |
| 2 | Ferrous fumarate | Tablet | 8.76 ± 0.72 | 9.88 ± 0.70 | 1.14 ± 0.37 | <0.001 |
| 3 | Ferrous ascorbate | Tablet | 8.31 ± 0.71 | 11.09 ± 0.96 | 2.75 ± 0.57 | <0.001 |
| 4 | Colloidal iron | Syrup | 8.65 ± 0.68 | 11.10 ± 1.05 | 2.34 ± 0.85 | <0.001 |
| 5 | Ferric ammonium citrate | Syrup | 8.68 ± 0.81 | 10.42 ± 0.96 | 1.73 ± 0.82 | <0.001 |

Table 2 shows the mean rise in hemoglobin in each group among postnatal patients after taking 1 month of oral iron therapy. Mean rise in Hemoglobin was found to be significant and comparable on day 30 in all preparation groups under study.

**Table 3: Comparative evaluation of mean rise in hemoglobin in postnatal patients in different oral iron preparation groups after 3 months of therapy**

| Groups | Iron Preparations | Tablet/ Syrup | Hb IN g/dl | | | P Value |
|---|---|---|---|---|---|---|
| | | | Day 1 | Day 90 | Mean rise in Hb | |
| 1 | Ferrous sulphate sr (hosp supply) | Tablet | 8.70 ± 0.71 | 11.62 ± 0.65 | 2.96 ± 0.88 | <0.001 |
| 2 | Ferrous fumarate | Tablet | 8.76 ± 0.72 | 11.41 ± 0.65 | 2.68 ± 0.27 | <0.001 |
| 3 | Ferrous ascorbate | Tablet | 8.80 ± 0.71 | 12.22 ± 0.76 | 3.41 ± 0.83 | <0.001 |
| 4 | Colloidal iron | Syrup | 8.65 ± 0.68 | 11.79 ± 0.90 | 3.10 ± 0.87 | <0.001 |
| 5 | Ferric ammonium citrate | Syrup | 8.68 ± 0.81 | 11.15 ± 0.69 | 2.47 ± 0.77 | <0.001 |

Table 3 shows the mean rise in hemoglobin in each group among postnatal patients after taking 3 months of oral iron therapy. Mean rise in hemoglobin was found to be significant and comparable on day 90 in all preparation groups under study.

**Table 4. Comparative evaluation of mean rise in serum ferritin levels in postnatal patients in different iron preparation groups after 3 months of therapy**

| Groups | Iron preparations | Tablet/ Syrup | Serum ferritin in ng/dl | | | P Value |
|---|---|---|---|---|---|---|
| | | | Day 1 | Day 90 | Mean Rise in Serum Ferritin | |
| 1 | Ferrous sulphate sr hosp suppl | Tablet | 26.89 ± 12.27 | 55.18 ± 13.40 | 30.20 ± 14.33 | <0.001 |
| 2 | Ferrous fumarate | Tablet | 29.05 ± 16.13 | 55.14 ± 19.10 | 24.82 ± 12.40 | <0.001 |
| 3 | Ferrous ascorbate | Tablet | 17.55 ± 5.30 | 57.54 ± 13.23 | 39.32 ± 11.74 | <0.001 |
| 4 | Colloidal iron | Syrup | 17.38 ± 6.29 | 48.04 ± 11.19 | 30.43 ± 11.67 | <0.001 |
| 5 | Ferric ammonium citrate | Syrup | 23.04± 14.24 | 41.96 ± 13.40 | 20.20 ± 8.70 | <0.001 |

Table 4 shows the mean rise in Serum ferritin levels in each preparation group among postnatal patients after taking 3 months of oral iron therapy. Mean rise in Serum ferritin levels was found to be significant and comparable on day 90 in all preparation groups under study.

**Table 5: Comparative evaluation of number of side effects in postnatal patients in different groups**

| Groups | 1 (n=50) | | 2 (n=50) | | 3 (n=50) | | 4 (n=50) | | 5 (n=50) | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Number of side effects** | **No.** | **%** | **No.** | **%** | **No.** | **%** | **No.** | **%** | **No.** | **%** |
| **1** | 8 | 16.00 | 13 | 26.00 | 3 | 6.00 | 6 | 12.00 | 8 | 16.00 |
| 2 | 6 | 12.00 | 4 | 8.00 | 7 | 14.00 | 5 | 10.00 | 1 | 2.00 |
| 3 | 1 | 2.00 | - | - | 2 | 4.00 | 1 | 2.00 | - | - |
| 4 | 2 | 4.00 | - | - | - | - | - | - | - | - |
| **Total** | **17** | **34.00** | **17** | **34.00** | **12** | **24.00** | **12** | **24.00** | **9** | **18.00** |

Table 5 shows the distribution of postnatal patients according to the number of side effects in all preparation groups under study.

**Table 6: Comparative evaluation of side effects in postnatal patients in different groups during iron therapy**

| Groups | 1 | | 2 | | 3 | | 4 | | 5 | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Side effects | n=50 | % | n=50 | % | n=50 | % | n=50 | % | n=50 | % | |
| Metallic taste | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** |
| Nausea | 10 | 20.00 | 8 | 16.00 | 7 | 14.00 | 7 | 14.00 | 1 | 2.00 | 33 |
| Vomiting | 5 | 10.00 | 5 | 10.00 | 5 | 10.00 | 5 | 10.00 | 0 | 0 | 20 |
| Constipation | 8 | 16.00 | 7 | 14.00 | 6 | 12.00 | 4 | 8.00 | 7 | 14.00 | 32 |
| Diarrhoea | 3 | 6.00 | 2 | 4.00 | 4 | 8.00 | 3 | 6.00 | 2 | 4.00 | 12 |
| Epigastric pain | 5 | 10.00 | 3 | 6.00 | 2 | 4.00 | 0 | 0 | 0 | 0 | 10 |

Table 6 shows distribution of postnatal patients according to side effects in all preparation groups.

## Results

In our study, we found that in the postnatal group, the mean rise in hemoglobin count on day 30 was 1.55±0.48 for group 1, 1.14±0.37 for group 2, 2.75±0.57 for group 3, 2.34±0.85 for group 4, and 1.73±0.82 for group 5, which was significant ('p' <0.0001) (refer to Table 2). On intergroup comparison, it was found that the maximum rise in hemoglobin on day 30 was with tablet ferrous ascorbate and minimum with ferrous fumarate.

In our study, we found that the mean rise in hemoglobin in the postnatal group at day 90 was 2.96±0.88 for group 1, 2.68±0.27 for group 2, 3.41±0.83 for group 3, 3.10±0.87 for group 4, and 2.47±0.77 for group 5, which was significant ('p' <0.001) (refer to Table 3). On intergroup comparison, it was found that the maximum rise in hemoglobin on day 90 was with tablet ferrous ascorbate and ferric ammonium citrate.

In our study, there was a significant rise in serum ferritin levels on day 90 in postnatal patients, which was 30.20±14.33 in group 1, 24.82±12.40 in group 2, 39.32±11.74 in group 3, 30.43±11.67 in group 4, and 20.20±8.70 in group 5 (refer to Table 4). The mean rise in serum ferritin was found to be maximum with ferrous ascorbate and minimum with ferric ammonium citrate.

In our study, we found that side effects with ferrous sulphate from hospital supply were maximum, followed by ferrous ascorbate tablet, and minimum with ferric ammonium citrate suspension (refer to tables 5 and 6).

## Discussion

Despite several government programmes aimed at the prevention and control of anemia, it continues to remain a major direct or indirect contributor to maternal morbidity and mortality in India [8]. According to NFHS-5 (2019–21), approximately 50% of females in the reproductive age group are moderately anemic, 4% are severely anemic, and 42% have mild anemia. This reproductive age group, therefore, represents an important target population for the correction and prevention of anemia. The present study was conducted in the Department of Obstetrics & Gynaecology at GSVM Medical College, Kanpur, to compare different oral iron preparations in terms of efficacy, side effects, and patient compliance among postnatal females. Five oral iron preparations were evaluated, namely ferrous sulphate (sustained release), ferrous fumarate, ferrous ascorbate, colloidal iron, and ferric ammonium citrate suspension. A total of 250 postnatal women delivering at our institution were included in the study, with 50 participants allocated to each group. The socio-demographic characteristics of participants were comparable across all groups. Chi-square analysis demonstrated no statistically significant difference ($p > 0.05$) in the distribution of patients among various socio-demographic parameters.

Rai R K, Fawzi W W et al [9] reported that the burden of iron deficiency anemia among Indian females aged 15–49 years is approximately 53%. In the present study, a majority of participants belonged to the rural population, which may be attributed to inadequate dietary intake and increased nutritional requirements. Similarly, 52% of postnatal females in our study were from rural areas. A considerable proportion of participants in the present study belonged to the lower socioeconomic strata, indicating that underprivileged sections of society are more vulnerable to iron deficiency anemia. In our study, 56.4% of postnatal females belonged to the lower socioeconomic group. Bharati P, Shome S et al, 2009 [10] also observed a higher prevalence of anemia among rural, illiterate, and underprivileged adolescent females. Most participants in the present study were multiparous women, suggesting an association between increasing parity and the severity of anemia. In our study, 58.4% of postnatal females were multiparous, with more than one childbirth. EO Uche-Nwachi, R Singh et al 2010 [11] similarly reported that multiparous women were more likely to be anemic compared to nulliparous women.

Among the various oral iron preparations evaluated in the present study, ferrous ascorbate demonstrated the maximum improvement in hematological parameters with fewer side effects compared to other oral iron preparations. Savita Rani Singhal et al. (2015 [12] concluded that ferrous ascorbate and

ferrous bis-glycinate were more effective than ferrous sulfate. Smita Sagaonkar et al 2009 [13] observed a greater rise in hemoglobin levels with ferrous fumarate compared to carbonyl iron. Agarwal and Rathi 2005 [14] conducted a comparative study between ferrous ascorbate and carbonyl iron and reported a significantly greater increase in hemoglobin levels with ferrous ascorbate. Improvement in hematological parameters and replenishment of iron stores, reflected by serum ferritin levels, were also observed in postnatal patients. S.S. Patil et al 2013 [15] reported a significant increase in serum ferritin levels with ferrous fumarate therapy.

Oral iron supplementation has been associated with gastrointestinal side effects such as diarrhoea, constipation, nausea, and vomiting in some women [4]. These adverse effects generally increase with higher doses of elemental iron and are more pronounced when supplements are consumed on an empty stomach [6].

## Conclusion

Postnatal women should be considered an important target population for the correction of anemia in the reproductive age group, as side effects are comparatively fewer and treatment compliance is better during the postnatal period. For better implementation and continuity of care, postpartum iron supplementation should be initiated as early as possible after delivery. The iron supplementation regimen may either continue as prescribed during pregnancy or follow the regimen recommended for menstruating women [1]. Women diagnosed with anemia in a clinical setting should receive iron supplementation until their hemoglobin levels return to normal.

According to WHO recommendations, oral iron supplementation, either alone or in combination with folic acid, may be administered to postpartum women for 6–12 weeks following delivery to reduce the risk of anemia in regions where gestational anemia constitutes a significant public health concern [8].

A limitation of the present study is that numerous iron preparations available in the market differ in terms of elemental iron content, formulation, composition, and cost, which may result in variable therapeutic effects and represent an unavoidable source of bias in the study. Furthermore, only five iron preparations could be evaluated in the present study.

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