

Study of Effectiveness of Iron Supplements in Iron Deficiency Anemia during Pregnancy

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ABSTRACT

Objectives: Present study was conducted to compare 2 conventional iron supplements (ferrous sulphate, ferrous fumarate) with a newer iron supplement (carbonyl iron) in the antenatal women.

Materials and Methods: Present study was conducted in the Outpatient Department, Department of obstetrics and gynecology and department of pharmacology of Rama Medical College Hospital & Research Centre, Hapur, UP, INDIA. 90 pregnant women between 20 to 40 years of age with ≥ 14 weeks of gestation and serum hemoglobin levels between 9 - 11gm/dl were included in the study. They were divided into three groups, 30 in each group. They were treated with ferrous sulphate, ferrous fumarate and carbonyl iron for 2 months. Hemoglobin estimation was done at 0 day, 1 month and 2 months.

Results: Data analysis showed an increase in haemoglobin levels in all three groups after the 1 month ($p < 0.05$). Carbonyl iron showed highly significant increase ($p < 0.05$) in the haemoglobin level as compared to the other two drugs at the end of the 2 months.

Conclusion: Provision of iron supplements has long been recognized as a key strategy for reaching target populations at high risk of iron deficiency. Most commonly, iron supplements

have been provided to women during pregnancy to prevent maternal anemia and to provide adequate iron to meet the needs of the fetus. In present study, Carbonyl iron showed highly significant increase in the haemoglobin level as compared to the conventional preparations (ferrous sulphate and ferrous fumarate). It is superior in efficacy when compared to other two drugs and is better tolerated.

Keywords: Antenatal women, Carbonyl iron, Ferrous sulphate, Ferrous fumarate, Iron deficiency anemia.

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INTRODUCTION

Iron deficiency is the most common single nutrient deficiency in the world with estimates of $>50\%$ of women of reproductive age being affected.¹ According to WHO, in developed countries prevalence of anemia in pregnant women is 14% and 51% in developing countries.² In India the prevalence of anemia is 65-75% in pregnant women, this high prevalence is due to poor socioeconomic status, dietary habits, poor health status, multi parity and less birth spacing. 20% of all maternal deaths are contributed to anemia.^{3,4}

Pregnancy is a time in which the risk for developing iron deficiency anemia is highest, because iron requirements are substantially greater than average absorbable iron intakes. Physiologic demands for iron increase from 0.8 to ≤ 7.5 mg absorbed Fe/d, although there is considerable debate about the exact upper limits of this increased iron demand in the third trimester of pregnancy.^{5,6} Such demands result in a decline in iron stores during pregnancy and ultimately can produce iron-deficient erythropoiesis and anemia because a positive or even neutral iron

balance is difficult to attain. The median need for iron in the second and third trimesters of pregnancy is calculated to be nearly 4.6 mg Fe/d, whereas the 90th percentile is 6.7 mg Fe/d.⁵ These calculations are based on the estimation that the median iron need during pregnancy is 840 mg, with a 90th percentile of 1210 mg. If the iron needs for 6 month of lactation are considered, the median total iron requirement would be 1018 mg absorbed Fe. This calculation translates into an additional median need of 426 mg Fe for this 15-mo period.

Iron absorption in food is less than 10%, this requires at least 40-60 mg of iron in the diet to achieve 4-6 mg of absorption and if the pre pregnancy iron stores are low then the amount of iron needed during the last half of the pregnancy cannot be met with diet alone.^{7,8} Primary focuses have been to increase the amount and bioavailability of iron in the diet,^{9,10} to control infections that contribute to iron losses from the body, and to improve economic, educational, and social conditions that contribute to the high prevalence of iron deficiency.¹¹⁻¹⁴

The worldwide anemia prevalence data suggest that normal dietary intakes of iron are insufficient to meet peak daily requirements for a significant proportion of pregnant women.¹⁵ In the industrialized world, estimates suggest that $\geq 30\%$ of pregnant women will have depleted iron stores by the end of pregnancy, and in some population groups (eg, adolescents) depleted iron stores could occur in $\geq 80\%$ of the population.^{15,16} In the developing world, these estimates are higher. For example, 47% of pregnant women in Africa, 39% of pregnant women in Latin America, 80% of pregnant women in Southeast Asia, 65% of pregnant women in the eastern Mediterranean, and 40% of pregnant women in the West Pacific are believed to be anemic.¹⁷ Worldwide, at least one-half of anemia cases occurring during pregnancy are due to nutritional iron deficiency. Subclinical iron deficiency is nearly as widespread as iron deficiency anemia. Therefore, it is not possible to maintain the iron status of a pregnant woman with normal dietary practices and that iron prophylaxis is necessary.

Current control programs include supplementation, fortification, dietary modification, and parasitic disease control. Ministry of Health, Government of India recommends 200 mg of elemental iron with 1mg folic acid in the second half of pregnancy for a period of 100 days.

As ferrous iron is most efficiently absorbed, ferrous salts like ferrous sulphate, ferrous fumarate and ferrous gluconate are commonly used. Carbonyl Iron is a pure form of elemental iron which was mainly used for the fortification of foods. Carbonyl does not refer to the composition of iron particles but rather to the manufacturing process in which the controlled heating of vaporized iron pentacarbonyl leads to the deposition of uncharged elemental iron as microscopic spheres of $< 5 \mu$ in diameter.¹⁸ Present study was conducted to compare 2 conventional iron supplements (ferrous sulphate, ferrous fumarate) with a newer iron supplement (carbonyl iron) in the antenatal women.

MATERIALS AND METHODS

Present study was conducted in the Outpatient Department, Department of obstetrics and gynecology and department of pharmacology of Rama Medical College Hospital & Research Centre, Hapur, UP, INDIA. Ethical approval was taken from institutional ethics committee prior to study.

Pregnant women between 20 to 40 years of age with ≥ 14 weeks of gestation and serum hemoglobin levels between 9 - 11gm/dl were included in the study.

Pregnant women of < 14 weeks of gestation, hemoglobin levels < 9 gm/dl, patients with complications like bleeding piles, excessive emesis, active peptic ulcer, diabetes, hypertension, eclampsia, hypothyroidism and hyperthyroidism, patients not willing to sign written informed consent, those with history of oral iron intolerance and multiple pregnancy were excluded from the study.

90 antenatal women were selected to participate in study after taking informed written consent. They were randomly allocated into 3 groups with 30 antenatal women in each group. Iron supplements were given to participants for 2 months.

- Group A received Carbonyl Iron 100 mg once daily
- Group B received ferrous sulphate 200 mg thrice daily
- Group C received Ferrous fumarate 200 mg twice daily.

Before start of the study random blood sugar, urine routine and stool for ova, cyst and occult blood were done for all the participants.

A preformed questionnaire was used to evaluate their nutritional status and tolerability to the given iron supplements. The following details were obtained, regarding - age, occupation, Educational status, anthropometric measurements, diet history, gestational age, method of contraception used, previous obstetric history i.e. Type of delivery (normal or caesarean), number of abortions, duration between this pregnancy and the last one. Also baseline haemoglobin status and side effects to the iron supplements given were noted.¹⁹

Table 1: Hemoglobin (gm %) of the patients in the treatment groups

| Group | Drugs | Haemoglobin (gm%) | | | | | | p value |
|-------|------------------|-------------------|-----|---------|------|---------|------|---------|
| | | Baseline 0 day | | 1 month | | 2 month | | |
| | | MEA | SD | MEA | SD | MEAN | SD | |
| A | Ferrous Sulphate | 9.35 | 0.6 | 10.12 | 0.72 | 10.76 | 0.69 | <0.05 |
| B | Ferrous Fumarate | 9.63 | 0.5 | 9.92 | 0.86 | 10.69 | 0.88 | <0.05 |
| C | Carbonyl Iron | 9.38 | 0.6 | 10.49 | 0.79 | 11.42 | 0.62 | <0.05 |

Haemoglobin estimation was done on day 0, 1 month and 2 month after enrolment. The patients were advised to take iron rich foods like jaggery, liver, egg yolk, dry fruits, green leafy vegetables, cereals and sprouted pulses. At each follow up visit, the patients were subjected to general and obstetric examination. The patients were noted for their improvement and enquired about any drug induced side effects.

RESULTS

In present study, each group of 30 participants were administered with three different iron supplements carbonyl iron, ferrous sulphate and ferrous fumarate for a period of 2 months. Haemoglobin estimation was done on day 0, 1 month and 2 month after enrolment.

The baseline hemoglobin values did not differ significantly at the beginning of the study in all the 3 groups ($p > 0.05$)

The table 1 shows hemoglobin percentage (gm %) of the patients at baseline and during the study period in the treatment groups. The improvement in the haemoglobin levels at the end of 2 months was significant ($p < 0.05$) for all the three treatment groups.

Differences in the mean hemoglobin levels between the three groups at the end of the 2 months was found to be highly significant ($p < 0.001$).

Most frequently encountered side effects were black stools seen commonly in all three groups. Other gastro intestinal disturbances like dyspepsia, pain abdomen etc were somewhat lesser in group C, as compared to the group A and group B.

DISCUSSION

Anemia is defined as a qualitative or quantitative deficiency of circulating haemoglobin, leading to decreased oxygen carrying capacity of the red blood cells to the tissues.²⁰ Iron deficiency, which depends on the nutritional state of the patient is the principal cause. Various iron formulations are available for supplementation in iron deficiency anaemia. Ferrous sulphate (32% elemental iron) and ferrous fumarate (33% elemental iron) are the commonly used iron preparations. Carbonyl Iron is a newer oral iron preparation which was mainly used for the fortification of foods.

Haemoglobin estimation was done on day 0, 1 month and 2 month after enrolment, in order to assess the efficacy of the iron supplements in improving the degree of anemia. Mild reticulocytosis usually begins within four to seven days of giving the iron supplements and peaks at 1 ½ weeks. In our study, increase in mean haemoglobin levels was seen after 1 month in all 3 groups. At the end of the 2 months, the mean haemoglobin increase in the Carbonyl iron group was 2.04 gm% as compared with the ferrous sulphate and ferrous fumarate group which showed a mean increase in hemoglobin by 1.41 gm% and 1.06 gm% respectively.

After 2 months, when the final values in the treatment group were compared with their respective baseline values, the improvement in the haemoglobin percentage (gm %) was significant ($p < 0.05$) for all the three treatment groups. Similar results were observed in the study conducted by N Chandrika & KC Vasudha²¹ and R. Geetha et al.¹⁹

Conflicting results were obtained by sagaonkar smita et al. They found that the increase in hemoglobin level was more in ferrous fumarate group as compared to the carbonyl iron group, also the percentage of patients reporting constipation and diarrhoea were more in the carbonyl iron.²² But in present study, carbonyl iron showed highly significant increase in hemoglobin levels and better gastric tolerance as compared to the others. Devasthali et al. compared ferrous sulphate and carbonyl iron in healthy blood donors and found that the overall bioavailability of carbonyl iron was 70% more than that of ferrous sulphate.²³

It can be suggested by findings of present study that carbonyl iron is more effective in the treatment of iron deficiency anemia in pregnant women as compared to the conventional preparations (ferrous sulphate and ferrous fumarate).

Iron deficiency anemia in pregnancy is associated with greater risk of perinatal mortality and morbidity, low birth weight leading to preterm delivery and lower infant APGAR scores. Since dietary absorption cannot keep up with the increased iron demands during pregnancy, it is mandatory to recommend oral iron supplements in the latter half of the pregnancy.^{19,24,25}

CONCLUSION

Provision of iron supplements has long been recognized as a key strategy for reaching target populations at high risk of iron deficiency. Most commonly, iron supplements have been provided to women during pregnancy to prevent maternal anemia and to provide adequate iron to meet the needs of the fetus. In present study, Carbonyl iron showed highly significant increase in the haemoglobin level as compared to the conventional preparations (ferrous sulphate and ferrous fumarate). It is superior in efficacy when compared to other two drugs and is better tolerated.

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