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Original Research Article

A prospective study to evaluate oral iron preparations in antenatal women at a tertiary care hospital

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ABSTRACT

Background: Iron deficiency is the most common cause of anemia in pregnancy worldwide. It can be mild, moderate or severe. Severe anemia can have very serious consequences for mothers and babies. Pregnant women requiring medication represent a challenge to healthcare providers to avoid any teratogenic risk to foetus. The purpose of this study was to provide information about the most effective iron preparations prescribed to pregnant women and to evaluate the haemoglobin status before and after oral iron therapy.
Methods: This was a Prospective observational study conducted in the Department of Obstetrics and Gynaecology, Rajarajeswari Medical College and Hospital, between October 2013 and March 2014.This study was conducted by reviewing the antenatal care Outpatient department case papers of 200 pregnant women who were anaemic.
Results: Demographic profile, detailed medical history and drug intake in current pregnancy was noted. The prescription pattern was assessed. Of the three common iron preparations prescribed, Ferrous sulphate was the most common preparation. Findings of our study showed that all pregnant anaemic women included in the study were provided with iron and folic acid therapy and the most effective oral iron preparation was Ferrous sulphate.
Conclusions: Present study shows that ferrous sulphate is the most common iron preparation prescribed. Ferrous sulphate and ferrous fumarate preparations showed better improvement in Hb levels. Anaemia is common among all pregnant women and therefore it raises the concern about high morbidity and mortality associated with pregnancy outcome. This can be minimized by educating pregnant women about importance of balanced diet and utilization of antenatal facilities even during early pregnancy.

Keywords: Drug utilizalion, Ferrous-sulphate, Iron preparations, Pregnant women

INTRODUCTION

Iron deficiency anaemia is the most common nutritional deficiency in the world. Anaemia is defined by World Health Organization as a state where haemoglobin (Hb) is less than 11gm/dl and haematocrit less than 33%.[1] Estimates from the WHO report that 35-75% (average 56%) of pregnant women in developing countries and 18% of women from industrialized countries are anaemic. The most common cause of anaemia is iron and folate deficiency. Iron deficiency anaemia accounts for 75-95% cases of anaemia in pregnancy. It can occur because of poor nutrition, malaria, hookworm infestation and closely spaced pregnancies.

The net Iron requirements for pregnancy is 840 mg approximately.[2] Per WHO Daily oral iron and folic acid supplementation with 30 mg to 60 mg of elemental iron is recommended for pregnant women to prevent maternal anaemia, puerperal sepsis, low birth weight, and preterm birth.[3]

Pregnant women commonly develop iron deficiency anaemia because of increasing iron demand of the developing foetus and placenta and the increased blood circulating volume in the body during pregnancy.[4] In pregnancy, the total volume of plasma is dramatically increased (50%) along with increase in red cell mass (18-25%), because of this disproportionate increase in plasma

volume, there is physiological heamo dilution and the haemoglobin is consequently reduced to a varying extent, making anaemia the most common haematological abnormality diagnosed during pregnancy.[5] Iron requirement increases notably during the second half of pregnancy because of the expansion of the red blood cell mass and the transfer of increasing amount of iron to both the growing foetus and the placental structures.[2] Iron deficiency in pregnant therefore limits oxygen delivery to cell resulting in fatigue, poor work performance and decreased immunity.[2] Iron deficiency anaemia may be associated with detrimental effects on maternal and infant function. Anaemia results in an increased number of preterm deliveries, low birth weight, impaired cognitive development of children, postpartum haemorrhage, postpartum depression.[2] Diet alone cannot supply such amounts of iron in non-industrialised countries making iron supplementation a necessity in all pregnant women.[6] Iron can be supplemented by oral route, intramuscular or intravenous injection. Alternatively, blood transfusion and recombinant erythropoietin are used.

The choice of treatment in iron deficiency anemia is oral iron replacement because it is safest and least expensive. The equivalent of 60 mg of elemental iron is 300 mg ferrous sulfate heptahydrate, 180 mg ferrous fumarate or 500 mg of ferrous gluconate.[3] lntolerance to iron and non-compliance in some women may make oral iron therapy inadequate and these can he benefited from parenteral iron therapy. The traditional treatment by blood transfusion involve significant drawbacks. Therefore, intravenous iron alone or in association with recombinant human erythropoietin (rHvEPO) therapy has been considered as an alternative in the management of iron deficiency in this setting.[7]

Major disadvantages are cost, need for hospitalization or an out-patient setting and invasive nature of procedure. Presently drug utilization studies are in an evolving era. Their scope is to evaluate the present practices in prescribing of drugs and adherence to evidence based recommendations.[8] It therefore becomes vital to study the drug utilization pattern during pregnancy to estimate to what extent there may be a scope for improvement in the current prescribing pattern.[9] Hence, present study was therefore conducted to evaluate the most effective oral iron supplementation on Hb levels and assessment of the prescription pattern in pregnant anemic patients.

METHODS

After obtaining approval from the Institutional ethical committee, a prospective open labelled observational study was conducted between October 2013 and March 2014. Data was collected from 200 outpatients attending the antenatal out Patient Department Gynaecology and Obstetrics of Rajarajeswari Medical College and Hospital, Bangalore, India. A pre-designed Proforma consisting of demographic data of pregnant women along with obstetric history and history of associated medical, surgical, gynaecological and obstetrical illness was documented in the OPD. The detailed information on the iron supplements, drug dose, dosage form, frequency, duration of treatment was recorded. The haemoglobin status at the 1st (4th month) and the 3rdantenatal visit (9th month) was recorded. Informed consent was obtained from all the study subjects after fully explaining the study procedure in both English and regional language. They were given a simple calendar to tick mark whenever they took their daily dose to record and maintain compliance. Subjects satisfying the inclusion criteria were recruited into the study. Pregnant women with Hb% levels less than 11 g dl were included in the study. Pregnant women having any allergy to iron, women with malabsorption syndrome, women with thalassemia and women diagnosed with acute and chronic medical conditions requiring hospitalization were excluded from the study. women with Hb level <7g/dl were also excluded.

Statistical analysis

Results on continuous measurements are presented on Mean ± SD and results on categorical measurements are presented in Number (%). Significance is assessed at 5 %level of significance. Student t test has been used to find the significance of study parameters on continuous scale between two group. Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale. ANOVA test was used to assess the level of significance between the groups. P value of <0.05 was considered significant. The results were also depicted in the form of tables and graphs where necessary. Microsoft Word and Excel are used to generate graphs and tables.

RESULTS

The demographic profile of the 200 pregnant women recruited in the study is depicted in Table 1.

Table 1: Demographic data of pregnant women attending OPD.

Demographic data	Results
Age in years (mean±SD)	23.65±5.07
Literacy status, number (%)	
Illiterate	26 (13.8)
Primary education	29 (15.4)
Secondary education	122 (64.8)
Graduate	11 (5.8)
Employment, number (%)	
Unemployed	165(87.7)
Employed	23(12.2)
Gravida, number (%)	
Primigravida	103(51.5%)
Second Gravida	81(40.5%)
Multigravida	16(08%)

Average age of pregnant women was 23. 65±5.07 years (Range 18 to 40 years). Age distribution coincides with pregnant women profile seen in literature.[10] Majority of pregnant women Included in the study were housewives and only few (12.2%) were working.

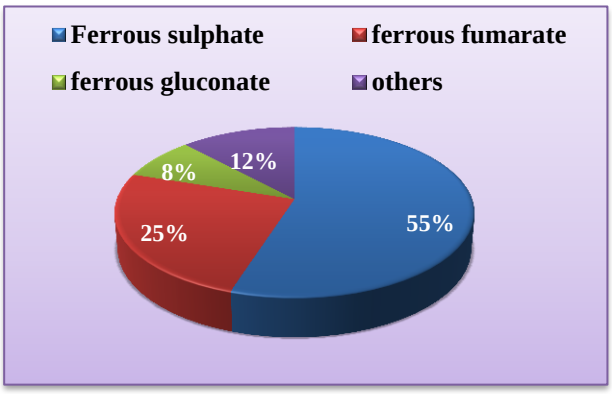

Figure 1: Percentage of different iron preparations prescribed at the OPD.

Side effect profile

In the ferrous sulphate treated group, 12 women complained gastric irritation; in the ferrous fumarate group 9 women complained of constipation but were not significant.

Table 2: Dose and elemental iron content per tablet of various oral iron preparations prescribed.

Iron salt	Dose per tablet	Elemental iron	Total elemental iron
Ferrous Sulphate	300mg	60mg	120mg
Ferrous Fumarate	200mg	65mg	130mg
Ferrous Gluconate	300mg	35mg	70mg

DISCUSSION

Iron deficiency anaemia in pregnancy is an important preventable cause of maternal and perinatal morbidity and mortality. According to WHO Iron deficiency anaemia in pregnant women is defined as Hb <11%. A total amount of about 700-850mg of iron is needed to meet the iron requirements of a mother and foetus during pregnancy, at delivery and during the perinatal period. Iron requirement increases during the second half of the pregnancy and especially during the last trimester. This excess iron demand can be met either from mother's endogenous iron stores or from iron supplements. However, the mean iron content of the body reserves ferritin and hemosiderin is often only around 200-250mg.[11]

Table 3: Mean hemoglobin concentration pre-and post-oral iron therapy.

	Mean HB (gm/dl) mean±SD*	Mean HB (gm/dl) mean±SD**	Improvement %
Ferrous sulphate	8.2±0.79	12.4±0.79	45.5
Ferrous fumarate	8.3±0.69	12.2±.36	42.2
Ferrous gluconate	8.2±0.69	10.2±.49	22.5

*1st visit was at 4th month of pregnancy/first antenatal check up; **2nd visit was at 9th month of pregnancy/ third antenatal check up

Physicians often face poor compliance among mothers in daily practice with oral therapy because of digestive side effects which can lead to worsening of anaemia. In these cases, parenteral forms of administration are indicated as well as in those patients in whom oral treatment is ineffective. like in those suffering from inflammatory bowel disease, many of whom are iron deficient and show digestive intolerance to ferrous salt.[12,13]

Table 4: Comparison between the groups for statistical difference in the outcome of treatment.

Groups	p value	Remarks
Ferrous sulphate vs ferrous fumarate	0.27	No significant difference seen
Ferrous sulphate vs ferrous gluconate	0.027	Significant difference seen
Ferrous fumarate vs ferrous gluconate	0.031	Significant difference seen

Average age of pregnant women was 23.6±5.07 years (Range 18 to 40 years). Majority of pregnant women were housewives and only few (12.2%) were working. Approximately half of the women were primigravida (51.5%). 40.5% of women were second gravida and only 8% of women were multigravida. In the present study, three oral iron formulations were prescribed to antenatal women with ferrous sulphate being the most common preparation. Ferrous sulphate was prescribed to 110 (55%) patients and has an elemental iron of 60mg. Ferrous Fumarate was prescribed to 50 (25%) patients and has an elemental iron of 65mg. Ferrous Gluconate was prescribed to l6 (8%) patients and has an elemental iron of 35mg.

In this study, the baseline Hb level of patients who were prescribed with ferrous sulphate, ferrous fumarate and ferrous gluconate was 8.2g/dl, 8.3g/dl, and 8.2g/dl respectively.

The Hb level of post oral iron therapy of ferrous sulphate treated group, ferrous fumarate treated group and ferrous gluconate treated group was 12.4g/dl, 12.2g/dl and 10.2g/dl respectively. Following the third visit of patients

in the last trimester the percentage improvement in Hb level of patients treated with ferrous sulphate was 45.5% and ferrous fumarate was 42.2% (Table 3).

Similar results in a study conducted by Lekha Saha et al. showed a significant increase in Hb level, the increase in Hb concentration after treatment was statistically significant when compared to the baseline value.[14] Oral iron supplementation is the treatment of choice in iron deficiency anaemia in pregnancy and almost all women can be treated effectively with oral preparations.[13]

Limitation

The study has been done in a small population with restricted study period. The improvement of anaemia could have included other iron parameters like serum Ferritin levels; estimation of TIBC.

CONCLUSION

Findings of our study showed that all eligible pregnant women were provided with iron and folic acid therapy. Pregnant women with diseases like hypertension, epilepsy and diabetes were continued with the appropriate drugs considering the risk benefit ratio. Data analyzed from our study shows that ferrous sulphate is the most common iron preparation prescribed which is in accordance with other studies.

Ferrous sulphate and ferrous fumarate preparations showed better improvement in Hb levels in comparison to ferrous gluconate which was statistically significant. Anaemia is common among all pregnant women and therefore it raises the concern about high morbidity and mortality associated with pregnancy outcome. This can be minimized by educating pregnant women about importance of balanced diet and utilization of antenatal facilities even during early pregnancy.

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