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Original Research Article

Analysis of prescription pattern of anemia in pregnancy: an observational, cross-sectional study

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ABSTRACT

Background: Anemia is a major health problem that affects 25% to 50% of the population of the world and approximately 50% of pregnant women. This research on the use of prescription medicines in anemia during pregnancy remains critically important. Prescribing patterns of the drug in the pregnant women include age, trimester, gravid condition, US-FDA risk category, WHO core indicators.

Methods: A prospective, cross sectional observational multicentric study was conducted in outpatient and inpatient departments of Indira Gandhi Hospital and Civil Hospital in Nasik, for period of 6 months. Ethical approval was taken prior to study from Independent ethics committee. A total of 197 patients were enrolled in the study. Inform consent form was obtained from the patients. After studying them; statistical analysis were done and result and conclusion were drawn.

Results: Out of 197 women's prescriptions, the average number of drug per prescription was 2.14. 27.28% drugs were prescribed their brand name and 72.72% by generic name. Iron, folic acid and calcium were prescribed to all pregnant women. The majority of the patients were prescribed category A and category C drugs. No patients were given category X drug.

Conclusions: Nearly all prescription showed a prescribing practice for writing prophylactic iron and folic acid therapy in all pregnant women. No women was prescribed category X drug. Most of the drug prescribed in generics and thus, prescription pattern of our study set a fine example of prescribing behaviour.

Keywords: Prescription pattern, Anemia, Pregnant women, Trimester

INTRODUCTION

Anemia is a major health problem that affects 25% to 50% of the population of the world and approximately 50% of pregnant women.¹ Anemia in pregnancy is associated with increased rates of maternal and perinatal mortality, premature delivery, low birth weight, and other adverse outcomes.² During pregnancy, anemia increased more than fourfold from the first to third trimester.³ It is a well-established fact that there is a physiological drop in hemoglobin (Hb) in the mid trimester.⁴ This physiological

drop is attributed to increase of plasma volume and hence decrease of blood viscosity lead to better circulation in placenta.⁵

The most common cause is iron deficiency anemia, other causes include infection, folate, and vitamin B₁₂ deficiency.⁶ The selected method for hemoglobin assessment was cyanomethemoglobin (WHO/UNICEF/UNO, 1998). According to the level of haemoglobin, patients were divided into 3 groups; Group 1; Hb=8.1-10 gm/100 ml (mild anemia) Group 2;

Hb=6.5-8 gm/100 ml (moderate anemia) Group 3; Hb<6.5 gm/100ml (severe anemia).⁷

Pregnancy usually causes dramatic reversible changes in a woman's cardiovascular system. These remarkable changes begin soon after fertilization and continue throughout gestation to maintain healthy environment for the fetus and mother. The first haemodynamic change during pregnancy seems to be a rise in the heart rate.⁸ In anemia, the oxygen carrying capacity of blood decreases. The following mechanisms operate in anemia to maintain a normal or near normal oxygen supply to the tissues.⁹ Hemodynamic mechanism includes increased cardiac output; blood flow and its distribution; the oxygen-carrying capacity of the blood, i.e., haemoglobin concentration; and oxygen extraction. Among all these, the iron requirement also increases during pregnancy for fetal blood formation and iron is required for mother's own blood and cell mass. The degree of iron requirement depends on iron stores and the amount of dietary iron that can be absorbed during pregnancy. Iron depletion and the amount of stored iron are reduced in iron deficiency anemia which limits the red cell production.¹⁰ Stored iron can be estimated by serum ferritin in iron deficiency anemia.¹¹

Pernicious anemia caused by lack of intrinsic factor resulting in lack of absorption of vitamin B₁₂ is rare during pregnancy as it usually causes infertility. Women with gastrectomy and ileal disease and resection can have vitamin B₁₂ deficiency. Acquired vitamin B₁₂ deficiency causing megaloblastic anaemia is also uncommon, as the daily requirement of vitamin B₁₂ is only 3.0 µg during pregnancy which is easily met with a normal diet.¹² Only vegans who do not eat any animal-derived substance may have a deficiency of vitamin B₁₂ and they should have their diet supplemented during pregnancy. Infestations with *diphyllobothrium latum* in some countries can cause megaloblastic anemia due to competitive utilization of ingested vitamin B₁₂ by the parasite.¹³

The provision of iron supplements to pregnant women is one of the most widely practiced public health measures. The traditional treatment of iron deficiency anemia includes oral/ parenteral iron and blood transfusion. Oral iron is associated with side effects, non-compliance and takes a long time to correct anemia. Parenteral preparations like iron dextran, iron sorbitol are associated with anaphylactic reactions and blood transfusions are associated with cross reactions and viral infections.¹⁴

Regardless of the limited information on the safety of drugs in pregnancy, drug use in pregnancy is common.^{15,16} Supplementary drug treatment like iron, folic acid, calcium, vitamins are prescribed commonly to improve overall nutritional status of mother and fetus. In addition, drugs may also be prescribed for conditions not related to pregnancy such as upper respiratory infections, urinary tract infections and gastrointestinal infections to name some. Also pregnant women are prescribed drugs

to treat pre-existing chronic conditions such as diabetes, hypertension or epilepsy or to treat pregnancy related disorders such as pregnancy induced hypertension and gestational diabetes.¹⁷ Therefore, judicious use of drugs, adequate knowledge, positive approach and awareness towards the drug use are mandatory prerequisites for good maternal and child health.¹⁸

Our objective of present study was to conduct a prescription pattern of anemia in pregnancy using WHO prescribing indicators and US-FDA drug risk categories. Our secondary objective was to analyse the average number of fixed dose combinations (FDC) per prescription.

METHODS

This cross sectional observational multicentric study was conducted in outpatient (OP) and inpatient departments of Indira Gandhi Hospital and Civil Hospital in Nasik, for period of 6 months. A total of 197 patients were enrolled in the study. Ethical approval was taken prior to study from independent ethics committee. The visit was done at the antenatal care OPD. Patient data was collected in pre-designed data collection form. Informed consent form was obtained from the patients. The data included demographics, patient history of disease and medication, medication from the prescription. The patient's was analysed and drug were categorized according to the US-FDA drug risk category.

Inclusion criteria

Pregnant woman of gestational age of 12 to 34 weeks who were suffering from mild to moderate anemia; patients with age between 18 to 40 years were included in the study.

Exclusion criteria

Patient diagnosed with severe anemia Hb <6.5 gm/dl; patient allergic to iron preparations were excluded from the study.

Prescription pattern parameters were analysed using WHO prescribing Indicators as follows:

- Average number of drugs per encounter.
- Percentage of drug prescribed by generic name.
- Percentage of encounter with an injection prescribed.
- Percentage of drugs prescribed from essential drug list.

And at end, the average number of FDCs per prescription was analysed.

The statistical package for social sciences (SPSS statistics for windows) and Microsoft excel 2010 was used for the analysis of the data. Descriptive statistics such as

percentages were also measured. Tabulation, graph and diagrams were used to present the data.

RESULTS

According to the statistical calculation of sample size, a minimum of 196 patients of anemia in pregnancy could be taken. In pre-screening, the number of potentially eligible patients was 220 whereas the number of confirmed eligible patients included in the study was 197.

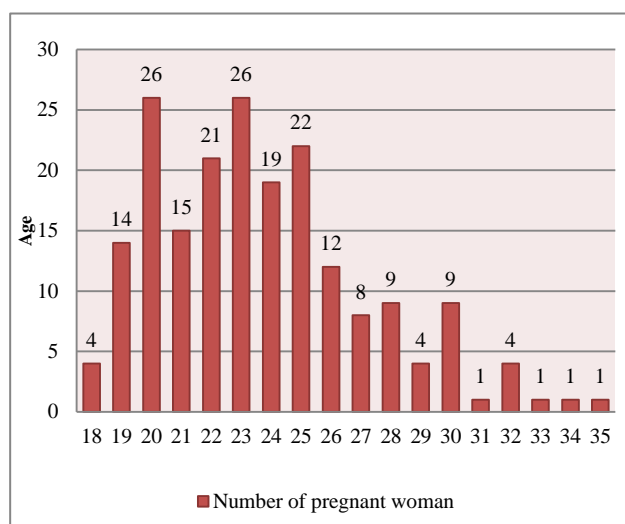


Figure 1: Age wise distribution of patients (n=197).

197 patients included in the study majority (26 pregnant women, 13.19%) were in age group of 20 and 23 years followed by 22 (11.16%) pregnant women age group of 25 years, 21 (10.05%) belonged to age group of 22 years, 19 (9.64%) pregnant women age group of 24 years, 15 (7.61%) pregnant women in age group of 21 years, 14 (7.10%) pregnant women in the age group of 19 years, while the least number were in the range of 12 (6.09%) pregnant women belonged to age group 26 years. Average age of pregnant women was 23.72 years (range 18 to 35 years). The age distribution of patient is shown below (Figure 1).

Out of 197 pregnant women 105 pregnant women of second trimester are mostly seen and followed by pregnant women 52 of third trimester and pregnant women of 40 in first trimester were seen anemic. According to the distribution 174 pregnant ladies had found mild type of anemia and 23 pregnant ladies patient had moderate type of anemia (Figure 2).

Out of 197 pregnant women 105 pregnant women of second trimester are mostly seen and followed by pregnant women 52 of third trimester and pregnant women of 40 in first trimester were seen anemic (Table 1).

Gravida condition of pregnant women were seen as multi-gravida 120 (60.92%) and followed by prime-gravida 77

(39.08%) in which the most number of multi-gravida pregnant women 60% and followed by primi-gravida 40% (Table 2).

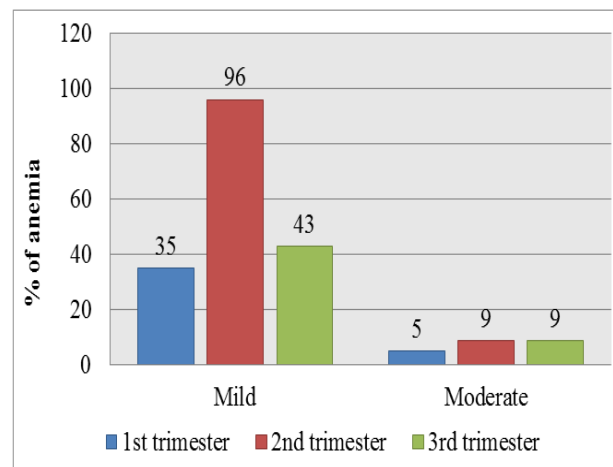


Figure 2: Distribution of woman having mild and moderate anemia in 1st, 2nd and 3rd trimester according to WHO classification.

Table 1: Trimester wise distribution of patients (n=197).

Trimester	No. of pregnant woman (N)	Percentage (%)
1 st	40	20.30
2 nd	105	53.30
3 rd	52	26.40
Total no. of pregnant woman	197	100

Table 2: Gravida condition of patients.

Gravida	No. pregnant women (N)	Percentage (%)
Primi-gravida	77	39.08
Multi-gravida	120	60.92
Total no. of pregnant women	197	100

All pregnant women attending the OPD were prescribed iron and folic acid. Out of 197 patient 195 (98.48%) prescription had drugs iron, folic acid and calcium. Total number of drug prescribed was 11. Among them 5 drugs were in A-category, 1 drug were in B-category, 3 drugs were in C-category, 2 drugs were in D-category and no women was prescribed category-X drugs. Following table shows the distribution of drugs using US-FDA drugs pregnancy category (Table 3).

Drug prescribed in OPD in anemic pregnant women classified according to US-FDA drugs pregnancy category: US-FDA drugs pregnancy category seen in mostly in the anemic pregnant women of 5 (45.45%) of risk category A and followed by anemic pregnant women

3 (27.27%) C category, anemic pregnant women 2 (9.09%) B category and anemic pregnant woman of 0 (18.18%) D category, anemic pregnant women of 1 (0.0%) X category as shown in Table 4.

Table 3: List of drug prescribed in OPD for anemic pregnant woman using US-FDA drugs pregnancy category.

Category A	Category B	Category C	Category D	Category X
Folic acid	ART (anti-retroviral drugs)	Labetalol	MVBC (multivitamin) excess dose	
Iron capsule		Amlodipine	Proxymate B6 (vitamin B6) (excess dose)	
Calcium tablet		Nifedipine		
Iron and sucrose preparation				
Doxinate				

Table 4: Percentage of prescribed drugs according to US-FDA category.

US-FDA drug pregnancy category	No. of drug prescribed (N)	Percentage (%)
A	5	45.45
B	1	9.09
C	3	27.27
D	2	18.18
X	0	0.0
Total no. of drug are prescribed	11	100

Commonly prescribed drugs in the study were mostly prescribed folic acid (98.98%) followed by iron capsule (98.47%), calcium tablet (98.47%) and iron sucrose injection (13.19%). Commonly prescribed drugs shown in the Table 5.

Table 5: Commonly prescribed drugs in the study.

Drugs	No. of pregnant women (N)	Percentage (%)
Folic acid	195	98.98
Iron capsule	194	98.47
Calcium tablet	194	98.47
Iron and sucrose injection	26	13.19

Table 6: WHO core drug prescribing indicators.

S. no.	Indicators	Value
1	Average no. of drugs per encounter	0.05
2	Percentage of drug prescribed by generic name	72.72
3	Percentage of encounter with an injection prescribed	13.19
4	Percentage of drug prescribed from essential drug list	36.36

The indicators of prescribing practices measure the performance of health care providers in several key dimensions related to the appropriate use of drugs. The

indicators are based on the practices observed in a sample of clinical encounters taking place at outpatient health facilities for the treatment of acute or chronic illness. Evaluation of drugs based on WHO prescribing indicators. Following table shows the detail findings of WHO core drug prescribing indicators (Table 6).

Out of 197 prescriptions of pregnant women almost 196 (99.49%) prescription containing fixed dose combinations, only one (0.51%) prescription without fixed dose combination (Figure 3).

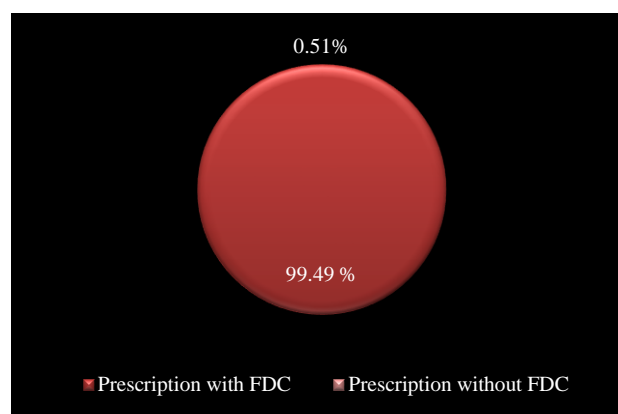


Figure 3: Prescription with and without fixed dose combinations.

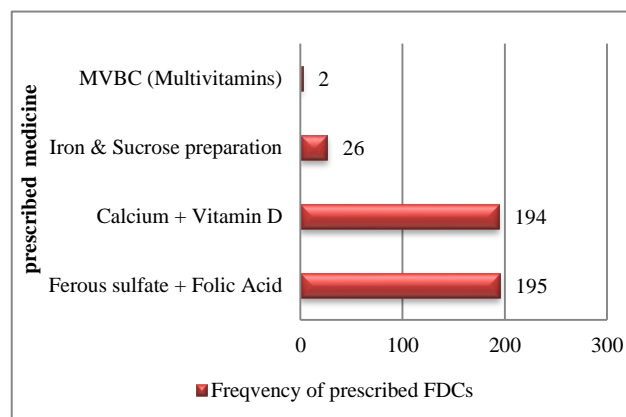


Figure 4: Frequency of prescribed FDCs.

The prescription of FDCs ferrous salt and folic acid 195 times prescribed and followed by calcium and vitamin D 194 times prescribed, iron and sucrose preparation was 26 times prescribed and MVBC (multivitamin) 2 times prescribed. There is drug interaction between iron and calcium, may affect the absorption of either drug, hence it is advisable to administrate them at some time interval. Following figure shows the frequency of prescribed FDCs (Figure 4).

DISCUSSION

This study is provided a data on prescription pattern of the drug on anemia in pregnancy in gynaecology department of Indira Gandhi Hospital and Civil hospital Nasik. A total of 197 patient were enrolled based on inclusion and exclusion criteria in the study US-FDA drug risk category out of 197 patient included in the study majority (26 pregnant women, 13.19%) were in age group of 20 and 23 years followed by 22 (11.16%) pregnant women age group of 25 years, 21 (10.05%) belonged to age group of 22 years, 19 (9.64%) pregnant women age group of 24 years, 15 (7.61%) pregnant women in age group of 21 years, 14 (7.10%) pregnant women in the age group of 19 years, while the least number were in the range of 12 (6.09%) pregnant women belonged to age group 26 years. Average age of pregnant women was 23.72 years (range 18 to 35 years). This finding was almost similar to the Yadav et al.¹⁹

Out of 197 pregnant women 105 pregnant women of second trimester are mostly seen and followed by pregnant women 52 of third trimester and pregnant women of 40 in first trimester were seen. Gravida condition of pregnant women were seen as multi-gravida 120 (60.92%) and followed by primi-gravida 77 (39.08%). This finding was similar to Yadav et al in which the most number of multi-gravida pregnant women 60% and followed by primi-gravida 40%.¹⁹

The average number of drug is found to be 2.14 (range 2-4) per prescription. The maximum number of drugs prescribed was 4 in two women. This is because one of them had hypertension and the other had vomiting. Out of 197 pregnant women, 2 women presented a history of vomiting, 2 women presented a history of hypertension and 1 woman was HIV positive patient, she was continued her ART.

The iron supplementation is strongly recommended in developing countries. Supplement of iron the treatment of choice and almost all women should be treated effectively with oral or parenteral preparation, depending on Hb level and gestational age. All pregnant women attending the OPD were prescribed iron and folic acid. Out of 197 patients 195 (98.48%) prescription had drugs iron, folic acid and calcium. Total number of drug prescribed was 11. Among them 5 drugs were in A-category, 1 drug were in B-category, 3 drugs were in C-category, 2 drugs were

in D-category and no women was prescribed category-X drugs. This finding is similar to Gawade et al.²⁰

Evaluation of drugs based on WHO prescribing indicators; average number of drug per encounter was 0.05; percentage of dug prescribed by generic name was 72.72; percentage of an encounter of an injection prescribed was 13.19; percentage of drug prescribed from essential drug list was 36.36. This result was almost similar to Yadav et al.¹⁹

Out of 197 prescriptions of pregnant women almost 196 (99.49%) prescription containing fixed dose combination. Only one prescription without fix dose combination. The prescription of FDCs ferrous salt and folic acid 195 times prescribed and followed by calcium and vitamin D 194 times prescribed, iron and sucrose preparation was 26 times prescribed and MVBC (multivitamin) 2 times prescribed. There is drug interaction between iron and calcium, may affect the absorption of either drug, hence it is advisable to administrate them at some time interval.

CONCLUSION

Nearly all prescription showed a prescribing practice for writing prophylactic iron and folic acid therapy in all pregnant women. Some of the prescription showed that additional drugs were prescribed only if required. No women was prescribed category X drug. Most of the drug prescribed in generics and. Thus, prescription pattern of our study set a fine example of prescribing behaviour.

Limitations

In this study follow up was not possible because the study participants were from small cities and rural areas with limited medical facilities.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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