

## **Morbidity and drug utilization pattern among admitted pregnant anemic women and to find out rationality of drug by using Indian guidelines**

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### **ABSTRACT**

**Background:** Pregnancy represents a special physiological state during which the use of drug is of growing concern due to risk of teratogenicity. Anemia is common threat to mother. Therefore, our aim was to study the drug utilization, teratogenic risk among patients of anemia in pregnancy and check rationality of prescriptions.

**Methods:** An observational, prospective study was carried out in 150 indoor patients in the tertiary care hospital. Protocol was approved by the Institutional Review Board. The data were collected in a pre-designed proforma. Data were analyzed using SPSS version 20.0 Software.

**Results:** Among 150 patients, 23, 111, and 16 were of <20, 20-30 and more than 30 years of age respectively. Among anemic patients Pregnancy induced hypertension (18.7%), antepartum hemorrhage (12.7%) were common. About 71% women have complaint of weakness, followed by headache. Iron (93.3%) and calcium (86.0%) were the most common drugs prescribed. Iron sucrose and packed cell volume given in severe anemia. Drug risk category, Category A (90.21%) was most frequently prescribed, which is followed by Category B (8.0%) and Category C (1.8%). Percentage of drugs prescribed by generic name and from essential drug list was 70.3 and 89.2. Overall prescribing habit was rational according to Indian guideline.

**Conclusion:** Iron, calcium, and folic acid were most commonly prescribed drugs in anemic patients. No teratogenic risk was found out during drug use. Drug and dose of the drug was rational and appropriate. There is lesser number of drugs prescribed by generic name and hospital supply.

**Keywords:** Anemia, Drug utilization, World Health Organization core drug prescribing indicators

### **INTRODUCTION**

Anemia is the most common nutritional deficiency disease among the world. World Health Organization (WHO) has presumed that prevalence of anemia in developed and developing countries in pregnant women is 14% in developed and 51% in developing countries and 65-75% in India.<sup>1</sup> About one-third of the global populations are anemic.<sup>2</sup> Prevalence of anemia is higher in India when compared with other developing countries.<sup>2</sup> Among the Asian countries, India has the highest prevalence of anemia. About half of the global maternal deaths due to anemia occur in South Asian countries; India contributes to about 80% of the maternal deaths due to anemia.<sup>3</sup>

In India, the prevalence of anemia is high because of poor diet intake, less iron (<20 mg/day) and folic acid intake (<70 mg/day); poor bioavailability of iron (3%) in diet; and infection like hookworm infestations and malaria.<sup>4,5</sup>

Poor iron stores at birth, low iron content of breast milk and low dietary iron intake through infancy and childhood results in high prevalence of anemia in childhood.<sup>6</sup>

Women with mild anemia in pregnancy have decreased work capacity. Premature births are more common in women with moderate anemia. Three distinct stages of severe anemia - compensated, decompensated, and that associated with circulatory failure. Cardiac decompensation usually

occurs when hemoglobin (Hb) falls below 5.0 g/dl. When Hb is <5 g/dl, cardiac failure occurs in a third of cases. A blood loss of even 200 ml in the third stage produces shock and death in these women.

Studies to define the effect of maternal anemia on the fetus indicate that different types of decompensation occur with varying degrees of anemia. Most of the studies suggest that a fall in maternal hemoglobin below 11.0 g/dl is associated with a significant rise in perinatal mortality rate. There is usually a 2-3-fold increase in perinatal mortality rate when maternal hemoglobin levels fall below 8.0 g/dl and 8-10-fold increase when maternal hemoglobin levels fall below 5.0 g/dl.<sup>7</sup> Hence prevention and treatment of anemia is very important, especially during pregnancy. Our objective of this study was to study the drug use pattern in indoor patients of anemia with pregnancy at Obstetrics and Gynecology Department in a tertiary care teaching hospital, to evaluate the drug use pattern using US-Food and Drug Administration (FDA) drug risk category,<sup>8</sup> WHO core drug prescribing indicators<sup>9</sup> and to find out the rationality of drug usage.

**MATERIALS AND METHODS**

This study was carried out in obstetrics and gynecology department at a tertiary care teaching hospital in Ahmedabad, India for 6 months. All the patients admitted to obstetrics department and diagnosed anemia were included in our study. The protocol and other documents like proforma, patient information sheet and informed consent form in English and Gujarati were approved by Institutional Review Board (IRB). The study was started after getting written approval from IRB.

The data were collected from all the patients irrespective of age in a pre-designed proforma after taking written informed consent from the patients and/or patient's relatives. The proforma includes patient's demographic details, religion, indoor number, pregnancy duration, provisional diagnosis/chief complaints, investigations and complete prescription. Data of all the 150 indoor patients were analyzed using SPSS version 20.0 Software. Prescription pattern was evaluated by using WHO core drug prescribing indicators and US-FDA drug risk category and guidelines for pregnancy care and management of common obstetric complication, 2005.

**RESULTS**

The demographic data concerning the age and trimester reveals that out of total 150 admitted patients, 23, 111 and 16 were of <20, 20-30 and more than 30 years of age respectively. Out of 150, 6, 71 and 73 patients were admitted during first, second and third trimester of pregnancy respectively (Table 1). Among 150, 62 (41.3%) and 88 (58.7%) patients were primiparous and multiparous, respectively. Several diseases are common along with

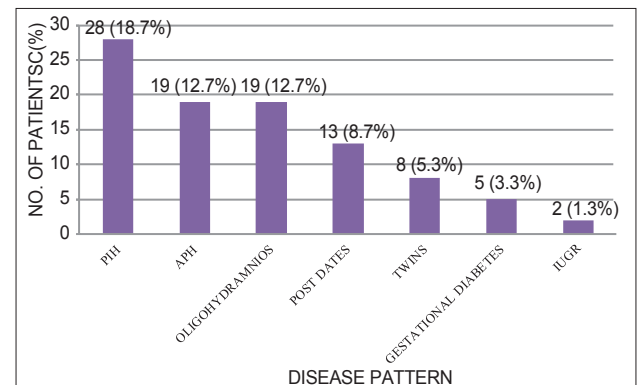
anemia during pregnancy. It reveals among anemic patients pregnancy induced hypertension (PIH) (18.7%), antepartum hemorrhage (APH) (12.7%), oligohydramnios (12.7%), postdates (8.7%), twins (5.3%), gestational diabetes (3.3%) and intrauterine growth retardation (IUGR) were common (Figure 1).

About 78.7% women have complaint of weakness, followed by abdominal pain (71.3%), headache/bodyache (50.0%), itching in vagina (16.7%), vomiting (13.3%), and edema (13.3%) (Figure 2). Average number of drugs prescribed was 5.21±2.1. Seven drugs per patients were prescribed to 26.7%, while 10 drugs prescribed to 4 (2.6%) patients (Table 2).

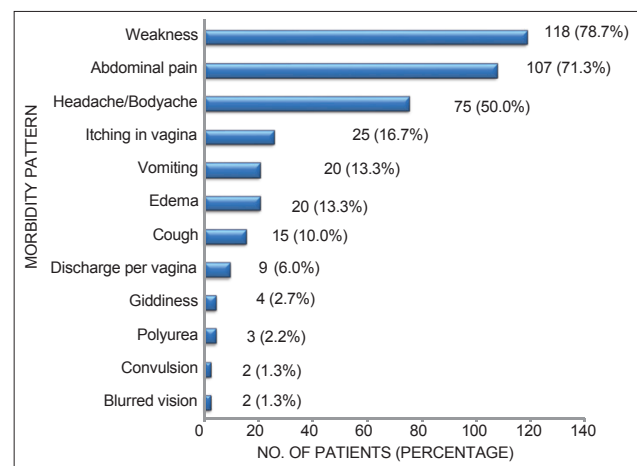
Eleven most frequently prescribed drug/drug groups were iron (93.3%), calcium carbonate (86.0%), vitamins

**Table 1: Demographic details.**

Age group (years)	Trimester (number of patients)			Total
	First	Second	Third	
<20	1	9	13	23
20-30	4	57	50	111
>30	1	5	10	16
Total	6	71	73	150



**Figure 1: Disease pattern among anemic patients.**



**Figure 2: Morbidity pattern.**

(59.6%), folic acid (66.7%) and protein powder (59.3%), followed by antihypertensive drugs (20.0%), uterine relaxants (19.8%), antimicrobial agents (14.7%) antifungal drug (12.7%), hypoglycemic (3.3%), and amino acids (2.0%) (Figure 3).

In the first trimester folic acid and iron given to all patients followed by protein powder (83.3%), paracetamol (66.7%) and antiemetic drugs (50.0%). Amoxicillin, ranitidine and nifedipine was given to 33.3% patients. In the second trimester iron (98.6%), calcium (87.3%) and folic acid (62.0%) commonly used followed by vitamin C (59.1%), protein powder (53.5%), isoxsuprine (28.1%), amoxicillin (17.0%), nifedipine (14.1%), paracetamol (14.0%), clotrimazole (10.0%) and ranitidine (11.2%). In the third trimester iron (95.9%), calcium (91.8%), and folic acid (67.1%) were most frequently prescribed, followed by protein powder (63.0%), vitamin C (60.2%), paracetamol (16.4%), nifedipine (13.7%), isoxsuprine (12.3%), essential amino acids (4.1%), antifungal drugs (9.5%) and betamethasone (6.8%) (Table 3).

Of 150 patients of anemia 43, 69 and 37 suffered from mild, moderate (Hb - 7-10 g%) and severe anemia (Hb - <7 g%) respectively. Oral iron was given to mild and moderate anemia. Among oral iron ferrous fumarate (78.7%) and ferrous ascorbate (14.6%) were commonly used in the dose of 300 mg and 100 mg once daily for mild anemia and twice daily for moderate anemia. Injectable iron like iron sucrose

was given to 29 (19.3%) patients. After dilution in normal saline, it was given intravenously slowly. Iron sucrose was given to nine patients of mild anemia which was not responding to oral iron therapy. Twenty patients of moderate anemia receive one or two dose of iron sucrose according to response to therapy. Severe anemic patients (24.7%) received packed cell volume (PCV). Trimester-wise drug use is given in Table 4. After each PCV, injection furosemide (40 mg) was given intravenously.

Among the drugs prescribed, most of them (78.7%) were prescribed in tablet form. The rest were capsules (14%), injection (12%), pessary (12.7%), suppository (4.6%), syrup (2.0%) and gel (0.6%) (Table 5). Most of the drugs were given orally, followed by intravenous, intramuscular, vaginal and rectal. No drug was given to intrathecal or subcutaneous route (Table 6).

In this study, majority of drugs were from Category A 90.2%, which is the safest category, followed by Category B 8.0%, Category C 1.8%, Category D 0.0%, and Category X 0.0% (Figure 4).

WHO has given three types of indicators namely prescribing indicators, patient care indicators and facility indicators as determinant of rational prescribing. Out of this, in this

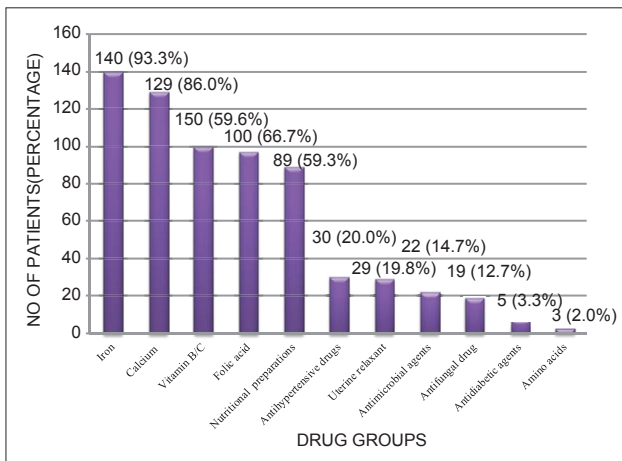


Figure 3: Most frequently prescribed drug groups.

Table 2: Number of drug wise distribution pattern.

Number of drugs	Number of patients	Percentage
4	22	14.7
5	30	20.0
6	28	18.6
7	40	26.7
8	21	14.0
9	5	3.3
10	4	2.6

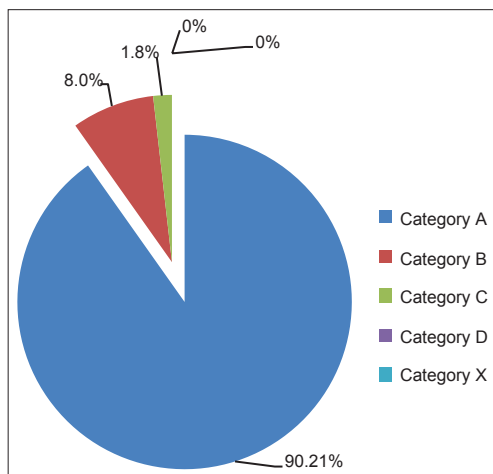
Table 3: Trimester wise distribution of prescribed drugs/drug groups.

Drugs	First trimester number of patients (%)	Second trimester number of patients (%)	Third Trimester number of patients (%)
Iron	6 (100.0)	71 (98.6)	70 (95.9)
Calcium	0 (0.0)	62 (87.3)	67 (91.8)
Folic acid	6 (100.0)	44 (62.0)	49 (67.1)
Protein powder	5 (83.3)	38 (53.5)	46 (63.0)
Vitamin C	0 (0.0)	42 (59.1)	44 (60.2)
Nifedipine	2 (33.3)	10 (14.1)	10 (13.7)
Labetalol	0 (0.0)	2 (2.8)	2 (2.7)
Methyldopa	0 (0.0)	0 (0.0)	2 (2.7)
Isoxsuprine	0 (0.0)	20 (28.1)	9 (12.3)
Clotrimazole (vaginal)	2 (33.3)	10 (14.0)	7 (9.5)
Amoxicillin	2 (33.3)	12 (17.0)	8 (11.0)
Ranitidine	2 (33.3)	8 (11.2)	8 (11.0)
Insulin	0 (0.0)	3 (4.2)	2 (2.7)
Antiemetic drugs	3 (50.0)	2 (2.9)	0 (0.0)
Paracetamol	4 (66.7)	10 (14.0)	12 (16.4)
Betamethasone	0 (0.0)	0 (0.0)	5 (6.8)
Essential amino acids	0 (0.0)	0 (0.0)	3 (4.1)

**Table 4: Drug use pattern among anemic patients.**

	First trimester (%)	Second trimester (%)	Third trimester (%)	Total number of patients (%)
Oral iron				
Ferrous fumarate	4 (2.7)	64 (42.7)	50 (33.3)	118 (78.7)
Ferrous ascorbate	2 (1.3)	11 (7.3)	9 (6.0)	22 (14.6)
Injection iron sucrose	1 (0.7)	8 (5.3)	10 (6.7)	29 (19.3)
Injection PCV	1 (0.7)	9 (6.0)	27 (18.0)	37 (24.7)

PCV: Packed cell volume



**Figure 4: Food and drug administration drug risk category wise prescription pattern.**

study, only prescribing indicators has been used (Table 7). Percentage of drugs prescribed by generic name and from essential drug list was 70.33 and 89.2, respectively. About 40% of drugs were prescribed from hospital drug supply.

Rationality of drug utilization was checked by using Guidelines for Pregnancy Care and Management of Common Obstetric Complications by Medical Officers, Ministry of Health and Family Welfare, India. Prescriptions were checked according to guidelines. It was revealed that in mild anemia 97% of drugs prescribed were rational. In moderate anemia 80% while in severe anemia 93% of drug usage was according to guidelines and within rational dose, duration and frequency.

**DISCUSSION**

Drug utilization studies are used as pointer to the prescribing behavior. They also help in identifying the problems and studying the impact of interventions designed to rectify the problems.<sup>10</sup>

Anemia is very common during pregnancy and there is high demand of micronutrients during the second and third trimester. Poor dietary status reflected by low socio-economic status and repeated pregnancy is also contributing factor for poor nutritional status of the mother.<sup>11</sup> All these factors deplete the micronutrient stores of the mother, to the

**Table 5: Dosage form of drugs prescribed to pregnant women.**

Dosage form	Number of patients (%)
Tablet	118 (78.7)
Capsule	21 (14.0)
Injection	38 (24.7)
Syrup	3 (2.0)
Pessary	19 (12.7)
Suppository	7 (4.6)
Gel	1 (0.6)
Suspension	0 (0.0)

**Table 6: Route of administration of prescribed drugs for pregnant women.**

Route of administration	First trimester	Second trimester	Third trimester
Oral	5	67	70
Intravenous	1	9	27
Intramuscular	1	8	10
Vaginal	2	10	7
Rectal	0	0	10
Intrathecal	0	0	0
Subcutaneous	0	0	0

**Table 7: WHO core drug prescribing indicators.**

Indicator	Value
Average number of drugs per prescription	5.21
Percentage of drugs prescribed by generic name	70.33
Percentage of encounters with antibiotic prescribed	13.33
Percentage of encounters with an injection prescribed	40.0
Percentage of drugs prescribed from essential drug list	89.2
Percentage of drugs prescribed from hospital drugs list	40.91

WHO: World Health Organization

extent that she becomes anemic even in the first trimester. This brings adverse outcome for mother and fetus.<sup>12,13</sup>

Periconceptional folic acid supplementation can prevent neural tube defects and other congenital abnormalities of the cardiovascular system, urinary tract and limb deficiencies of fetus.<sup>14</sup> It is associated with the decreased incidence of habitual spontaneous abortion, placental abruption and preeclampsia.<sup>15</sup>

A much higher incidence of anemia (47.6%) is recorded in present study. It is in accordance with study done in Bangladesh (49.0%).<sup>16</sup> It is less than one study done in Uganda (84.4%)<sup>17</sup> and more than one study done in Pakistan (40.0%).<sup>18</sup>

During the study period of 6 months, the demographic data concerning the age of the study population shows that out of total 150 pregnant women, 23 (15.3%), 111 (74.0%) and 16 (10.7%) were of <20, 20-30 and more than 30 years of age respectively (Table 1). This is not in accordance with the study carried out in Australia<sup>19</sup> showed women <20, 20-30 and more than 30 years of age were 4%, 70% and 26%, respectively. Trimester wise distribution of the study population shows that 6, 71 and 73 patients were admitted during first, second and third trimester of pregnancy respectively, which is not accordance with study done in Ethiopia in which 82.5% of patients from third trimester.<sup>20</sup>

Among anemic patients PIH was the most common (Figure 1), these finding is in accordance with study done in Mexico in which PIH, postpartum hemorrhage, and chronic hypertension were common.<sup>21</sup> As shown in Figure 2 weakness was the most common symptom, followed by abdominal pain and headache. These are typical symptoms of anemia. Low oxygen carrying capacity of blood causes these symptoms.

In anemic patients, PIH and other diseases were common. Hence seven drugs were prescribed to 26.7% patients. A comorbid conditions cause more drugs to be used in these patients. 10 drugs prescribed to four patients (Table 2).

Iron and calcium were most commonly prescribed drug groups. Antihypertensive drugs were given to PIH patients. Abdominal pain was very frequently observed symptom, hence uterine relaxant was given. For cough and cold antimicrobial agents and for fungal infection like candida antifungal agents were prescribed. Amino acids were used for IUGR and oligohydramnios (Figure 3).

Iron and calcium were commonest drugs used during three trimesters. During first trimester folic acid, antiemetic drug like combination of doxylamine and pyridoxine was given to three patients. If associated with hypertension nifedipine was used respectively. Paracetamol was used for bodyache. In second folic acid, protein powder, vitamin C, nifedipine, isoxsuprine, clotrimazole, amoxicillin, antacids

and insulin were prescribed. In third trimester folic acid, protein powder, vitamin C, isoxsuprine, nifedipine and clotrimazole. Essential amino acids were given to patients of oligohydramnios. This is not in accordance with one study where vitamins were most commonly used followed by iron.

Among anemic patients, ferrous fumarate was used in once or twice a day. Oral iron was given to mild and moderate anemia. Iron sucrose was used to 29 patients of moderate anemia as faster response and better absorption profile. In severe anemia, impending complications like heart failure, severe dyspnea or apnea, PCV was given rather than whole blood transfusion. Frequency of PCV was according to severity of anemia and response to transfusion. For prompt and satisfactory response oral iron was started after PCV (Table 4). These findings are similar to other studies in United States (72%),<sup>22</sup> Switzerland (65%),<sup>23</sup> West Nepal (72%)<sup>24</sup> and Egypt (86%)<sup>25</sup> but less than one study.<sup>26</sup>

As shown in Table 5, tablets were commonly used followed by capsules. Injection was given for giving iron sucrose, PCV and amino acids. Vaginal pessary used for vaginal candidiasis. Suppository was used for constipation. No drugs given by subcutaneous and intrathecal route (Table 6).

In our study, 90.21% drugs were prescribed from FDA drug risk Category A. This finding is not in accordance with one study<sup>20</sup> in which the most prescribed drugs were under FDA Category "B" and "C". Comparing the drug risk categories for pregnancy, introduced by USFDA in 1979, in this study majority of drugs were from Category A 82.21%, which is the safest category, followed by Category B 15.64% Category C 2.15% and Category D 0.00%. No drug were prescribed from Category X which are absolutely contraindicated in pregnancy. The similar pattern of category distribution was seen in which drugs were from Category A 81.7% Category B 10.9%, Category C 6.3% Category D 1.1%, Category X 0.0%.<sup>27</sup>

In a retrospective, register based cohort study in Finland, it was found that 20.4% of women purchased at least one drug classified as potentially harmful during pregnancy and 3.4% purchased at least one drug classified as clearly harmful.<sup>28</sup> In a study from Bratislava and Nitra, it was reported that a vast majority of prescribed drugs during pregnancy, belonged to Category C.<sup>29</sup> Hence from the above data, we can say that the prescription habit in our set up is quite safe.

As shown in Table 7, percentage of drugs prescribed from hospital drugs list and by generic names were less.

Rationality of drug utilization was checked by using Guidelines for Pregnancy Care and Management of Common Obstetric Complications by Medical Officers India. It was seen that drug prescriptions in mild, moderate and severe anemia were rational. As per guidelines, in moderate anemia oral iron should be started and if not respond parenteral iron should be given as per guideline,

but in our study it was seen that in some patients injectable iron started along with oral therapy. Otherwise treatment of anemia was appropriate.

## CONCLUSION

Among anemic patients PIH, APH and oligohydramnios were common. Headache and abdominal pain were the most common symptoms. Iron, calcium and folic acid were most frequently used. Ferrous fumarate and ferrous ascorbate were prescribed in mild anemia. Iron sucrose was given to mild and PCV to severe anemia. Most of the drugs were from FDA Category A. Over-all prescribing habit in this set-up is appropriate and rational to a large extent. However, there is lesser number of drugs prescribed by generic name and from hospital supply suggesting need for sincere efforts to improve situation. This is the preliminary study and further studies are required to find out broader evaluation of the drug utilization. Hence, such periodic studies are further required in diverse environment, social, educational and cultural conditions, so that the therapeutic guidelines could be revised accordingly to give proper care to the community.

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