



An Observational Study on Drug Utilization Pattern in Anaemic Pregnant Women in the Tertiary Care Teaching Hospital

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2021/v33i40B32292

Editor(s):

(1) Dr. Rafik Karaman, Al-Quds University, Palestine.

Reviewers:

(1) Sathya.S, Melmaruvathur Adhiparasakthi Institute of Medical Sciences and Research, India.

(2) Byron Baron, University of Malta, Malta.

Complete Peer review History: <https://www.sdiarticle4.com/review-history/72365>

Original Research Article

Received 02 June 2021

Accepted 07 August 2021

Published 13 August 2021

ABSTRACT

Background: Anemia is a disease that is more prevalent among pregnant women in India.

Objective: To Study the Drug Utilization Pattern, compare and evaluate better drug selection in Anaemic Pregnant Women.

Methodology: A total of 300 pregnant women ranging in the age group of 17 to 38 years and having 1 month to 9 months of pregnancy was included in a study. The medical records of patients were checked and information was recorded. The prescriptions were analyzed for drug utilization patterns. Statistical analysis was done.

Result: Out of all 300 pregnant women 176 patients having iron deficiency Anemia, 99 patients having sickle cell Anemia, 20 patients having folate deficiency Anemia, and the rest of the patients

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having Vitamin B12 deficiency or hemolytic or beta-thalassemia. The average number of drugs prescribed per patient was 3-4 and the average monthly cost per patient was 920.68 Rs. The most commonly prescribed drug was Vitamin C it is of Category C drug which could be harmful to the fetus followed by MVBC (Multivitamin B complex).

Conclusion: Anemia was commonly seen in 2nd trimester. Sickle cell Anemia was seen in 1/3rd of the patients. Study data highlights that Vitamin C, Calcium & Multivitamin B complex were the most prescribed drugs in anemic patients. Drugs prescribed were produced risk to the fetus according to USFDA criteria.

Keywords: Pregnant women; drug utilization pattern; anemia.

1. INTRODUCTION

Anemia is a condition in which there is a deficiency in red cells or quantity of blood hemoglobin. It leads to decrease blood carrying oxygen capacity. In developing countries, the main causes of anemia are less intake and poor absorption of iron, malaria, hookworm infection, diarrhea, HIV/AIDS, and genetic disorders [1]. Mainly Anemia is caused by active bleeding but there are some other causes like iron deficiency, poor nutrition, Anemia of chronic disease (Cancer), less red cell production [2]. According to World Health Organization (WHO), the prevalence of anemia among pregnant women in India is about 14%, whereas it is still as high as 51% in the developing world. The prevalence of anemia in India has been reported to be 33%-89% [3]. National Family Health Survey (NFHS) - III, found that the prevalence of anemia in pregnant women is 55.3%. As a comprehensive strategy Ministry of Health and Family Welfare launched National Iron Plus Initiative. When Pregnant women went to their ante-natal visits they were provided iron and folic acid tablets under the universal screening of pregnant women for anemia which is a part of ante-natal care [4]. To educate pregnant women on dietary diversified they were distributed an MCP card and safe motherhood booklet. There was another initiative taken by the government like National Nutritional Anemia Control Programme (NNACP) [5,6]. There are many types of anemia for example Iron-deficiency Anemia, Vitamin B12 deficiency anemia, anemia of chronic disease, Sickle cell anemia, Aplastic anemia, Thalassemia, Folate deficiency Anemia, etc. There are many tests to check pregnant women having SCD (sickle cell disease) or SCT (sickle cell trait). For Example, Blood test, HPLC test, Direct Coombs test, Haemoglobin test, and Haematocrit test [7]. In iron deficiency anemia is mostly seen in Pregnancy. During pregnancy, women need extra folate but sometimes they don't get enough folate

from their diet. In this case, man-made supplements of folate give to pregnant women, this supplement is called folic acid. Folate deficiency causes certain types of birth defects for example neural tube abnormalities (spina bifida) and low birth weight [8]. For some women with sickle cell trait in this woman, the disease may get worse. Some painful events occur during pregnancy called sickle cell crises; these events may be treated by medications that are safe to use during pregnancy. Generally, women with sickle cell trait don't have problems from the disorder but they may have chances of urinary tract infections during pregnancy. Pregnant women with sickle cell traits may need to take iron supplements [3,9]. In hemoglobin test measures the amount of Hb. In hematocrit test measures the percentage of the RBCs in the blood sample. Thalassemia is a blood-related disorder; it occurs when there is a defect in a gene that is used to control the production of hemoglobin proteins [10,11]. Trimesters in pregnancy are generally considered to be about 3 months each, there are 40 weeks (or 280 days) in pregnancy, starting from the first day of your last menstrual period. Drug Utilization Evaluation (DUE) is an audit and feedback intervention in which medicine use can be reviewed against approved criteria [12]. This study is about the evaluation of drug utilization in pregnant women having any type of anemia. The prescriptions would be analyzed and compared with guidelines followed by the hospital. The study will conclude that treatment modalities can be modified per the patient condition and guidelines. Poor self-care because of psychological factors can affect compliance in some patients. Excessive blood loss, less production of erythropoietin, fluid overload, iron deficiency, folic acid deficiency, and worsen their health status. Also, the cost-effectiveness of the drug can be estimated by calculating the number of drugs administered by the patients.

2. METHODOLOGY

It was a prospective cross-sectional study conducted for 6 months at the Department of Gynaecology, Dhiraj General Hospital, Vadodara. All pregnant women from the Department of Gynaecology to check the hemoglobin level according to the criteria of FOGSI and diagnosed with any type of anemia were included in a study after explaining to the patients, the details of the study, the Informed consent form was taken. The patient's medical records were checked and the following information was noted in the Patient Medical Record sheet: Patient's demographic details, Patient Medical History, Diagnosis of the anemia and duration, family history of anemia, presence of other co-morbidities, Prescribed drugs including Anti-anaemic agents (Frequency, Dose and Duration) was also collected, the number of Anti-anaemic agents, doses were collected along with details of anemic control on Anemia, Cost of drugs, Lab investigations reports (which are already mentioned inpatient medical records). All the relevant data was obtained from the patients' medical records and through counseling the patients who visited the Out- Patient Department (OPD) or In-Patient Department (IPD). All the relevant data is collected and recorded electronically. Descriptive statistics were used for the analysis of the data. After the data collection, all the data were exported to statistical software for statistical analysis. All the quantitative data were represented in mean \pm standard deviation. Comparative statistical differences were calculated using appropriate parametric tests.

3. RESULTS

A total of 300 prescriptions of outpatients and inpatients of anemic pregnant women were collected from the Department of Gynecology. Patient Demographics: Patient distribution based on trimesters: Out of all 300 patients 78 (26%) patients have 1st trimester of pregnancy and 171(57%) patients have 2nd trimester of pregnancy and 51 (17%) patients have 3rd trimester of pregnancy (Table: 1).

Patient distribution based on pregnancy months: There were only 2% (N=5) patients had 1 month of pregnancy, 5% (N=15) patients had 2 months of pregnancy, 20% (N=59) patients had 3 months of pregnancy, 23% (N=70) patients had 4 months of pregnancy, 21% (N=62) patients had 5 months of pregnancy, 13% (N=38) patients had 6 months of pregnancy, 9% (N=27) patients had 7 months

of pregnancy, 5% (N=15) patients had 8 months of pregnancy and 3% (N=9) patients had 9 months of pregnancy (Table: 2).

Patient distribution based on patient's age: In the age group ≤ 18 years there were 2% (N=5) (mean age \pm SD 17.8 \pm 0.4) patients have anemia, in the age group 19-23 years there were more patients have anemia (61%) (N=184) (mean age \pm SD 21.04 \pm 1.26). This pattern was followed by the age group 24- 28 years (31%) (N=94) (mean age \pm SD 25.26 \pm 1.22), 29-33 years (5%) (N=14) (mean age \pm SD 30.36 \pm 1.04) and 34-38 years (1%) (N=3) (mean age \pm SD 32.67 \pm 1.70) (Table: 3).

Patient distribution based on hemoglobin criteria: There are mainly 4 types of Hb criteria according to severity. According to classification, there were 10% (N=29) patients have mild decrease Hb level, 70% (N=209) have moderate decrease Hb level, 6% (N=19) patients have severe decrease Hb level and 14% (N=43) patients have Normal Hb level. In all 300 patients, there were the maximum number of patients have a Moderate decrease in Hb level (Table: 4).

Type of anemia according to trimesters: There is a total of 3 trimesters in pregnancy. Of all 300 patients there were 99 patients have sickle cell anemia and only 3 patients have Beta-thalassemia. In these 99 patients there were 38 (38%) patients of 1st trimester have sickle cell anemia, 55 (56%) patients of 2nd trimester have sickle cell anemia and only 6(6%) patients of 3rd trimester have sickle cell anemia. There is only one patient of each trimester who has Beta-thalassemia.

Type of hemoglobin level according to trimesters: There was a total of 78 patients in 1st trimester. Of these 78 patients, there were 14 (18%) patients have a mild decrease in Hb level, 47 (60%) patients have a moderate decrease in Hb level, 5 (6%) patients have severe decrease Hb level and 12 (15%) patients have normal Hb level. Followed by 2nd trimester there was a total of 171 patients. Of these 171 patients there were 13(8%) patients have a mild decrease in Hb level 120(70%) patients have a moderate decrease in Hb level, 10(6%) patients have a severe decrease in Hb level and 28(16%) patients have normal Hb level. In 3rd trimester there was a total of 51 patients. In these 51 patients, there were 2 (4%) patients have a mild decrease in Hb level 42 (82%) patients have a moderate decrease in Hb level, 4(8%) patients have a

severe decrease in Hb level and 3 (6%) patients have normal Hb level. Overall, there was a more moderate decrease in Hb level in all trimesters.

Patient distribution based on the type of anemia: There was a total of 300 patients, in this 58.67% (N=176) patients suffering from iron deficiency anemia, 33.00% (N=99) patients suffering from sickle cell anemia, 6.67% (N=20) patients suffering from folate deficiency anemia, 1.00% (N=3) patients suffering from thalassemia, 0.33% (N=1) patients suffering from Vitamin B12 deficiency anemia and 0.33% (N=1) patients suffering from hemolytic anemia. Improvement in Haemoglobin level: There was a total of 29 patients whom we compare past and present hemoglobin levels. There was a total of 15 patients in which the Haemoglobin level was improved in the range of 0.1-4 and there were 14 patients in which the Haemoglobin level was decreased in the range of 0.2-1.2.

Drugs Prescribing Pattern: Drug used in several patients: Among all anemic patients Tab. Vitamin C (21.22%) (N=243) was the highest prescribed drug followed by Tab. Multi-Vitamin B Complex (20.35%) (N=233), Tab. Calcium (19.56%) (N=224), Tab. Tonofolic XT (7.16%) (N=82), Tab. Iron (7.07%) (N=81), Tab. Folic Acid (6.11%) (N=70), Tab. Sodamint (3.84%) (N=44), Tab. Zincovit (3.76%) (N=43), Tab. Feb XT (3.32%) (N=38), Tab. Albendazole (2.71%) (N=31), Cap. Austin (1.92%) (N=22) and Tab. Tonofolic DS (1.22%) (N=14). There were other 3 drugs like Inj. Iron Sucrose, Tab. Doxinate, Tab. Rantac was prescribed in only 2 patients and there were more than 14 drugs that were prescribed in only one patient (Table: 9).

Drugs used to treat sickle cell anemia: There were 14 drugs used to treat sickle cell anemia. Tab. Vitamin C (19.44%) (N=70) was the highest prescribed drug followed by Tab. Calcium (16.67%) (N=60), Tab. Multi-Vitamin B Complex (16.39%) (N=59), Tab. Folic Acid (9.72%) (N=35), Tab. Iron (9.17%) (N=33) and Tab. Tonofolic XT (3.33%) (N=12). Tab. Zincovit (11.39%) (N=41) and Tab. Sodamint (11.39%) (N=41) were prescribed in the same number of patients. There were 3 patients prescribed with Tab. Tonofolic DS, 2 patients with Tab. Albendazole and one patient prescribed with Cap. Autrin, Inj. TT, Tab. FDSON MP and Tab. Doxinate. Drugs used to treat iron deficiency anemia: Among all iron deficiency anemic patients Tab. MVBC (22.46%) (N=170), Tab. Vitamin C (22.32%) (N=169) and Tab. Ca+

(22.46%) (N=170) were equally highest prescribed drugs followed by Tab. Tonofolic XT (9.11%) (N=69), Tab. Iron (6.21%) (N=47), Tab. Febac XT (5.02%) (N=38), Tab. Albendazole (3.83%) (N=29), Cap. Autrin (2.64%) (N=20), Tab. Folic Acid (2.11%) (N=16) and Tab. Tonofolic DS (1.45%) (N=11). Inj. Iron Sucrose is prescribed twice and other drugs like Tab. Sodamint, Tab. Zincovit, Tab. Lupiheme, Tab. Metro, Tab. Option, Tab. Rantac, Tab. Azoran, Tab. Dolo, Tab. Doxinate, Syp. Aristozyme, Iron Sucrose, Inj. Vitcofol + Iron Sucrose, Inj. Sucrose, Inj. RL with DNS, Inj. Rantac, Inj. Emset is prescribed only once. Drugs used to treat folate deficiency anemia: There were only 2 drugs like Tab. Folic Acid and Tab. Rantac is prescribed for folate deficiency anemia. There was Tab. Folic Acid was prescribed in 20(95%) patients and Tab. Rantac was prescribed in only one patient (5%). Drugs used to treat sickle cell + Beta thalassemia: There were mainly 6 drugs prescribed in sickle cell anemia + beta-thalassemia. Tab. Vitamin C (22.22%), Tab. Multi-Vitamin B Complex (22.22%) and Tab. Sodamint (22.22%) was prescribed in 2 patients. Tab. Ca+ (11.11%), Tab. Tonofolic XT (11.11%) and Tab. Zincovit (11.11%) were prescribed in only one patient.

Type Of Drug Risk Categories: There was a total 4 types of drug risk categories Category A, Category B, Category C, and Category D. There was a total of 58.19% (N=386) patients prescribed with Category A, 7.89% (N=90) patients prescribed with Category B, 58.19% (N=664) patients prescribed with Category C and 0.088% (N=1) patients prescribed with Category D. There were total 8 drugs which were prescribed under "Category A". Among all these drugs Tab. MVBC prescribed highest around 60.36% (N=233), Tab. Folic acid prescribed around 18.13% (N=70), Tab. Zincovit 11.14% (N=43), Cap. Autrin 5.70% (N=22), Tab. Tonofolic DS 3.63% (N=14), Tab. Doxinate 0.52% (N=2) and Tab. FDSON MP and Inj. Emset prescribed only 0.26% (N=1). There was a total of 7 drugs that were prescribed under "Category B". The highest prescribed drug was Tab. Iron 90.00% (N=81), Inj. Iron Sucrose 3.33% (N=3), Tab. Rantac 2.22% (N=2) than all rest of drugs prescribed only once for example Tab. Dolo, Tab. Metro, Tab. Lupiheme and Inj. Sucrose (1.11% N=1). There was a total of 8 drugs that were prescribed under "Category C". Highest prescribed drug was Tab. Vit C 36.60% (N=243), Second highest was Tab. Ca+ 33.73% (N=224), Tab. Tonofolic XT 12.35% (N=82), Tab.

Sodamint 6.63% (N=44), Tab. Febac XT 5.72% (N=38), Tab. Albendazole 4.67% (N=31), rest of two drugs Syp. Aristozyme and Inj. RL with DNS was prescribed in the same amount of 0.15% (N=1). There was only one drug that was prescribed under "Category D". This drug was Tab. Azoran was prescribed only in one Patient.

Table 1. Number of patients according to trimester

Trimester	Number of Patients (%)
1st	78 (26%)
2nd	171 (57%)
3rd	51 (17%)
Grand Total	300 (100%)

Table 2. Number of patients according to pregnancy months

Months	Number of Patients (%)
1	5 (2%)
2	15 (5%)
3	59 (20%)
4	70 (23%)
5	62 (21%)
6	38 (13%)
7	27 (9%)
8	15 (5%)
9	9 (3%)
Grand Total	300 (100%)

Table 3. Number of patients according to age group

Age group	Number of Patients (%)
<=18 (Mean age \pm SD)	5 (2%) (17.8 \pm 0.4)
19-23 (Mean age \pm SD)	184 (61%) (21.04 \pm 1.26)
24-28 (Mean age \pm SD)	94 (31%) (25.26 \pm 1.22)
29-33 (Mean age \pm SD)	14 (5%) (30.36 \pm 1.04)
34-38 (Mean age \pm SD)	3 (1%) (32.67 \pm 1.70)
Grand Total (Mean age \pm SD)	300 (100%) (22.89 \pm 3.17)

Table 4. Number of patients according to hemoglobin criteria

Hb Criteria	Number of Patients	Percentage (%)
Mild	29	10 %
Moderate	209	70 %
Severe	19	6 %
Normal	43	14 %
Grand Total	300	100 %

Table 5. Number of patients in a different type of anemia according to trimesters

No. of patients	Sickle cell anemia	Beta-thalassemia	Iron deficiency	Folate deficiency
1st trimester	38 (38%)	1 (33%)	24 (13.64%)	15 (75%)
2nd trimester	55 (56%)	1 (33%)	109 (61.93%)	4 (20%)
3rd trimester	6 (6%)	1 (33%)	43 (24.43%)	1 (5%)
Grand Total	99 (100%)	3 (100%)	176 (100%)	20 (100%)

Table 6. Total number of anemic patients according to Hb level in different trimesters

Hb Criteria	1st Trimester	2nd trimester	3rd Trimester
Mild	14 (18%)	13 (8%)	2 (4%)
Moderate	47 (60%)	120 (70%)	42 (82%)
Severe	5 (6%)	10 (6%)	4 (8%)
Normal	12 (15%)	28 (16%)	3 (6%)
Grand Total	78 (100%)	171 (100%)	51 (100%)

Table 7. Total number of patients according to a different type of anemia

Condition	Number of Patients
Patient having sickle cell anemia	99 (33.00%)
Patient having folate deficiency anemia	20 (6.67%)
Patient having vitamin B12 deficiency anemia	1 (0.33%)
Patient having hemolytic anemia	1 (0.33%)
Patient having iron deficiency anemia	176 (58.67%)
Patients having thalassemia	3 (1.00%)
Grand Total	300 (100%)

Table 8. Changes in Haemoglobin level

Hb Level	Total Number of Patients	Range	Percentage (%)
Increased	15	0.1-4	51.72
Decreased	14	0.2-1.2	48.28
Total	29		100 %

Table 9. Drug used in several prescriptions

Drugs (Generic name)	The total number of drugs prescribed
T. Vit C (Ascorbic acid)	243 (21.22%)
T. MVBC	233 (20.35%)
T. Ca + (Calcium carbonate + Vitamin D3)	224 (19.56%)
T. Tonofolic XT (Ferrous ascorbate + Folic acid + Zn sulfate monohydrate)	82 (7.16%)
T. Iron (Elemental iron)	81 (7.07%)
T. Folic Acid (Folic acid)	70 (6.11%)
T. Sodamint (Sodium bicarbonate)	44 (3.84%)
T. Zincovit (Vitamin C, B3, E, B5, B2, B1, B6, A, B12, D3 + Folic acid + Biotin)	43 (3.76%)
T. Febac XT (Ferrous ascorbate + Folic acid)	38 (3.32%)
T. Albendazole (Albendazole)	31 (2.71%)
Cap. Autrin (Vitamin B12 + Ferrous Fumarate + Folic acid)	22 (1.92%)
T. Tonofolic DS (Vit. B12 + Ferrous Fumarate + Folic acid)	14 (1.22%)
T. Rantac (Ranitidine)	2 (0.17%)

Drugs (Generic name)	The total number of drugs prescribed
T. Doxinate (Doxylamine succinate + Vit. B6)	2 (0.17%)
Inj. Iron Sucrose (Iron Sucrose)	2 (0.17%)
T. Lupiheme (Elemental iron)	1 (0.09%)
T. Metro (Metronidazole)	1 (0.09%)
T. Option (Levonogestrel)	1 (0.09%)
T. Azoran (Azathioprine)	1 (0.09%)
T. Dolo (Acetaminophen)	1 (0.09%)
T. FDSON MP (Folic acid + Pyridoxine Hydrochloride + Methylcobalamin)	1 (0.09%)
Syp. Aristozyme (Diastase + Pepsin)	1 (0.09%)
Iron Sucrose (Iron Sucrose)	1 (0.09%)
Inj. Vitcofol + Iron Sucrose (Nicotinamide + Folic acid + Cyanocobalamin)	1 (0.09%)
Inj. TT (Tetanus toxide)	1 (0.09%)
Inj. Sucrose (Sucrose)	1 (0.09%)
Inj. RL with DNS (Ringer lactate + Dextrose + Sodium chloride)	1 (0.09%)
Inj. Rantac (Ranitidine)	1 (0.09%)
Inj. Emset (Ondansetron)	1 (0.09%)
Grand Total	1145 (100%)

Table 10. Number of drugs used to treat sickle cell anemia

Drugs	The total number of drugs prescribed
T. Vit C	70 (19.44%)
T. Calcium	60 (1.67%)
T. MVBC	59 (16.39%)
T. Sodamint	41 (11.39%)
T. Zincovit	41 (11.39%)
T. Folic Acid	35 (9.72%)
T. Iron	33 (9.17%)
T. Tonofolic XT	12 (3.33%)
T. Tonofolic DS	3 (0.83%)
T. Albendazole	2 (0.56%)
Cap. Autrin	1 (0.28%)
Inj .TT	1 (0.28%)
T. FDSON MP	1 (0.28%)
T. Doxinate	1 (0.28%)
Grand Total	360 (100%)

Table 11. Number of drugs used to treat iron deficiency anemia

Drugs	The total number of drugs prescribed
T. Ca +	170 (22.46%)
T. MVBC	170 (22.46%)
T. Vit C	169 (22.32%)
T. Tonofolic XT	69 (9.11%)
T. Iron	47 (6.21%)
T. Febac XT	38 (5.02%)
T. Albendazole	29 (3.83%)
Cap. Autrin	20 (2.64%)
T. Folic Acid	16 (2.11%)
T. Tonofolic DS	11 (1.45%)
Inj. Iron Sucrose	2 (0.26%)

Drugs	The total number of drugs prescribed
T. Sodamint	1 (0.13%)
T. Zincovit	1 (0.13%)
T. Lupiheme	1 (0.13%)
T. Metro	1 (0.13%)
T. Rantac	1 (0.13%)
T. Option	1 (0.13%)
T. Azoran	1 (0.13%)
T. Dolo	1 (0.13%)
T. Doxinate	1 (0.13%)
Syp. Aristozyme	1 (0.13%)
Iron Sucrose	1 (0.13%)
Inj. Vitcofol + Iron Sucrose	1 (0.13%)
Inj. Sucrose	1 (0.13%)
Inj. RL with DNS	1 (0.13%)
Inj. Rantac	1 (0.13%)
Inj. Emset	1 (0.13%)
Grand Total	757 (100%)

The economic burden on the anemic pregnant women: Among all 300 patients 3 patients have not been prescribed drugs because blood transfusion was done. So, among 297 patients the average cost of treatment was 920.68Rs. per month. The highest cost per month was 1809Rs. and the lowest cost per month was 16.18Rs. Total 19.87% (N=59) patients paid less than 500Rs., 64.31% (N=191) patients paid between 501-1000 Rs., 12.12% (N=36) patients paid between 1001-1500Rs. and around 3.70% (N=11) patients paid highest between 1501-2000Rs.

Drug Interactions: There were 3 different drug-drug interactions found which were very minor.

The first one was ascorbic acid and folic acid which was in 96.23% (N=153) patients. the second one was calcium carbonate and iron which was in 1.89% (N=3) patients and the last one was iron + sodium bicarbonate which was in 1.89% (N=3) patients. Side Effects: There were no serious ADR reported but some minor side effects were found because folic acid that is a pain in the abdomen seen in only 1 patient out of 70 patients. Use of drugs according to WHO guideline: According to WHO guideline the daily dose of iron is 120mg and a daily dose of folic acid is 0.4 mg. In this study, only two drugs fulfill these criteria, Cap. Autrin and T. Tonofolic DS. This standard treatment was found only in 36 patients (Table:21).

Table 12. Number of drugs used to treat Folate deficiency anemia

Drugs	The total number of drugs prescribed
T. Folic Acid	20 (95%)
T. Rantac	1 (5%)
Grand Total	21 (100%)

Table 13. Number of drugs used to treat sickle cell + beta-thalassemia

Drugs	The total number of drugs prescribed
T. Vit C	2 (22.22%)
T. MVBC	2 (22.22%)
T. Ca +	1 (11.11%)
T. Sodamint	2 (22.22%)
T. Tonofolic XT	1 (11.11%)
T. Zincovit	1 (11.11%)
Grand Total	9 (100%)

Table 14. Different types of drug risk categories

Type of categories	Total Number	%
Category A	386	33.83 %
Category B	90	7.89 %
Category C	664	58.19 %
Category D	1	0.088 %
Grand Total	1141	100 %

Table 15. Category A Drug list

Category A		
Drugs	Total number of patients	%
T. Folic Acid	70	18.13 %
T. Doxinate	2	0.52 %
Inj. Emset	1	0.26 %
Cap. Autrin	22	5.70 %
T. Tonofolic DS	14	3.63 %
T. FDSO MP	1	0.26 %
T. MVBC	233	60.36 %
T. Zincovit	43	11.14 %
Grand Total	386	100 %

Table 16. Category B Drug list

Category B		
Drugs	Total number of patients	%
T. Dolo	1	1.11 %
T. Rantac	2	2.22 %
T. Metro	1	1.11 %
Inj. Iron Sucrose	3	3.33 %
T. Iron	81	90.00 %
inj. Sucrose	1	1.11 %
T. Lupiheme	1	1.11 %
Grand Total	90	100 %

Table 17. Category C Drug list

Category C		
Drugs	Total number of patients	%
Inj. RL with DNS	1	0.15
T. Albendazole	31	4.67
T. Sodamint	44	6.63
T. Ca+	224	33.73
Syp. Aristozyme	1	0.15
T. Tonofolic XT	82	12.35
T. Febac XT	38	5.72
T. Vit C	243	36.60
Grand Total	664	100 %

Table 18. Category D Drug list

Category D		
Drugs	Total number of patients	%
T. Azoran	1	100%
Grand Total	1	100 %

Table 19. Number of drugs prescribed per patient

Total Number of Patients	300
Total Number of Drugs	1145
Average	3.82 (3 to 4 drugs)

Table 20. Economic burden on patients

Range of cost	No. of patients
>500	59 (19.87%)
501-1000	191 (64.31%)
1001-1500	36 (12.12%)
1501-2000	11 (3.70%)
Total	297 (100%)

Table 21. Drug interactions

Interactions	Number	Indication
Ascorbic acid + folic acid	153 (96.23%)	concurrent use of ascorbic acid may result in a decrease in the level of folic acid
Calcium carbonate+ Iron	3 (1.89%)	concurrent use of iron may result in a decrease in iron effectiveness
Iron + Sodium bicarbonate	3 (1.89%)	use of bicarbonate decreases the level of iron
Total	159 (100%)	

Table 22. Side Effects

Drug	Side effect
Folic acid	Pain in abdomen

Table 23. Use of drugs according to WHO guideline

Cap. Autrin	22
T. Tonofolic DS	14
Total	36

4. DISCUSSION

In our study, it was observed that there were 300 anemic pregnant patients which state that only female was included in our study. This is similar to the previous study in which female patients were 336. Out of 336 patients, 58.5% patients were diagnosed with iron deficiency anemia, 19% were having moderate anemia, and 7.4% of severe anemia [13]. According to the FOGSI guidelines we have selected anemic pregnant women having Hb levels <9 gm/dl which is also seen in another study performed that included a total of 100 anemic pregnant women [14]. The reason for females to get

anemic may be due to an increased workload on females in Indian society, taking care of their family, household work, and poorly balanced diet. In our study highest prevalence of anemia was found in the second trimester having 171 women contributing (57%) from total patients which came similar to the previous study having the highest prevalence of anemia in the second trimester in that study total of 32.4% women means 57 patients had anemia in second trimesters [15]. In our study females in the 4th month of pregnancy means 23% of patients were seen to have the highest prevalence of anemia when compared with other months. The least prevalence was seen in 1st month of

pregnancy which was found to be 3%. Analysis of the age-wise distribution of anemia revealed that the degree of anemia was highest in the age group 19-23 years which is 61% of the total population including 184 women and, followed by age group 24-28 years that are 31% consisting 94 women, the age group 29-33 years include 5% women contributing 14 women. All the data related to the age group were found to be similar in another study where the degree of anemia was highest in the age group 20-25 including 63% women, age group 26-30 years had 2.4% anemic women, age group 31-35 years had 5.6% anemic women [16]. In our study showed 10% of women having mild Hb level of anemia, 70% women with moderate anemia, and 6% women having severe anemia. Increased breakdown of RBC may be due to genetic conditions like sickle cell anemia, thalassemia, and certain autoimmune infections. It was found that the maximum number of patients in the 2nd trimester showed sickle cell anemia and thalassemia was evenly distributed each trimester of the patients.

Hemoglobin levels according to the trimester were also studied which resulted in that total of 78 patients were from trimester 1st and out of which a maximum number of women had the moderate type of anemia contributing to 47 patients, 171 patients from 2nd trimester also showed the highest number of patients with the moderate type of anemia they included 120 patients, in 3rd trimester total 51 patients were there out of which most patients were seen to have a moderate type of anemia and contributed 4 women. In our study, there were total 58.67% of iron deficiency anemic pregnant women which were similar to the previous study that had 58% of iron deficiency anemic pregnant female patient which includes 40% anemia which was mild [17]. In our study total, 69 prescriptions were having ferrous sulfate – folic acid combination drug which came similar to the study in which a total of 56 prescriptions were found to have ferrous sulfate, and the folic acid combination is given to the pregnant anemic female patient [17]. Nevertheless, hookworm has been found a major predictor for iron deficiency anemia. A moderate hookworm infection according to studies will gradually produce iron deficiency anemia as the body iron reserves are used up, with severity on the worm load and dietary intake of iron. Out of 300 patients, only 31 patients were prescribed albendazole tablets that contributed to 2.71% of women which was not according to the previous

study in which a total of 17.6% albendazole tablets were prescribed [15].

In our study maximum women had 59% (iron deficiency) 33% (sickle cell anaemia) 7% (folic deficiency), 1% (thalassemia) ,0.33% (Vit. B12 deficiency) ,0.33% (haemolytic anaemia). The result showed that the Drugs used to treat sickle cell + Beta-thalassemia were found to have Tab. Vitamin C (22.22%), Tab. Multi-Vitamin B Complex (22.22%) and Tab. Sodamint (22.22%) was prescribed on 2 patients. Tab. Ca+ (11.11%), Tab. Tonofolic XT (11.11%) and Tab. Zincovit (11.11%) were prescribed in only one patient.

Drug risk category: Maternal drug use during pregnancy could cause a teratogenic risk for the fetus, however, it could be dangerous if the recommendation of drug usage is avoided during pregnancy. Using USFDA risk category-wise classification of prescription in which the % of women receiving drugs from the different class were documented. The majority of drugs used by our study participants were from category C which is prescribed in 58% of women that are Inj RL with DNS, Tab. albendazole, Tab. sodamint, Tab. calcium, Syrp. Aristozyme, Tab. Tonofolic XT, Tab. Febac XT, Tab. Vit C. shows the risk to the fetus. Followed by category A drugs 33.83% include Tab. folic acid, Tab. Doxinate, Inj. Emset, Cap. Autrin, Tab. Tonofolic DS, Tab. FDSON MP, Tab. MVBC, Tab. Zincovit. Category B drugs 7.89% include Tab. Dolo, Tab. Rantac, Tab. Rantac, Inj Iron sucrose. Tab. iron, Inj sucrose, Tab. Lupiheme and category D 0.088% only Tab. Azoran. The category D drug is potentially harmful to the fetus. It is noted that the prescriptions were quite safe. Our study is not according to the previous study where most prescribed drugs were from category B. followed by category A and only a few drugs were from category C [16].

Iron deficiency appeared to be the dominant cause of anemia in patients and was found to be significantly associated with hookworm infection 2.71% that shows 31 patients were infected with helminth infection in our study which was not similar to the study previously conducted. However, any helminth ova or larvae present would be in very low intensity and possibly undetectable. A single course of anthelmintic therapy in addition to iron-folate supplementation significantly increased hemoglobin concentrations and improved iron status [15]. In our study the number of women who consumed

folic acid tablets was in 70 patients which came similar to a previous study in which a total 76 women had taken folic acid tablets during their treatment [18].

Irrational drug use: This shows the quality of treatment that can be provided in presence of a clinical pharmacist. It also shows that the role of the clinical pharmacist is increasing in the community for better patient care. A total of 300 patients were included in the study and were prescribed 1145 drugs, so the average number of drugs prescribed per patient was found to be 3.82 (3 to 4 drugs). In our study, we followed the standard treatment guidelines given by WHO, according to which the daily dose of iron prescribed should be 120 mg with 0.4 mg folic acid. And it was found in two drugs: Cap Autrin, Tab Tonofolic DS which were seen only in 36 prescriptions. There were 3 different drug-drug interaction which was found and was minor. The first one was ascorbic acid and folic acid which was in 96.23% of patients. The effect was: concurrent use of ascorbic acid may result in a decrease in the level of folic acid. Another interaction was calcium carbonate and iron which was in 1.89% concurrent use of iron may result in a decrease in iron effectiveness and the last one was iron + sodium bicarbonate which was in 1.89% of patients which resulted: that concurrent use of bicarbonate may decrease in the level of iron. There was not any serious ADR reported but some minor side effects were seen only in 1 patient because of folic acid which was a pain in the abdomen. Among all 300 patients, 3 patients have not been prescribed drugs because blood transfusion was done. So, among 297 patients the average cost of treatment was 920.68Rs. per month. The highest cost per month was 1809Rs. and the lowest cost per month was 16.18Rs. Total 19.87% patients paid less than 500Rs., 64.31% patients paid between 501-1000 Rs., 12.12% patients paid between 1001-1500Rs. and around 3.70% of patients paid highest between 1501-2000Rs.

5. CONCLUSION

An observational study was conducted to gain knowledge about the drug utilization pattern of drugs prescribed in anemic pregnant women. In our study highest number of patients were observed in iron deficiency type of anemia when compared with other types of anemia including folic acid deficiency, sickle cell anemia, thalassemia, vitamin B12 deficiency, and hemolytic anemia. From various trimesters

during pregnancy in the 2nd trimester (4th month) the maximum number of patients were anemic. In our study severity of anemia was assessed by FOGSI guidelines which revealed that the moderate type of anemia was found in all trimesters, in which Hb ranges between 7-9gm/dl were found to be highest in patients. Most commonly prescribed drugs were in their oral form and few drugs were given via intravenous route. When the prescription pattern was analyzed it showed that the maximum prescribed drugs were from brand names. The study showed that an average of 3-4 drugs was prescribed per patient. From the Drug risk category by US FDA Category C was the most commonly prescribed which could be found to be harmful to the patients and have a high risk to a fetus that is followed by category A. Three common drug-drug interactions were found that were ascorbic acid + folic acid, concurrent use of ascorbic acid may result in a decrease in the level of folic acid. The other was calcium carbonate +iron, concurrent use of calcium carbonate may result in a decrease in the level of iron. Sodium bicarbonate + iron resulted in a decrease in iron levels by concurrent use of sodium bicarbonate. There were no ADR reported but some side effects like pain in the abdomen were seen because of folic acid tablet use and were found in 1 patient out of 70 patients. According to the standards given by WHO in treatment for anemic pregnant women, the prescriptions were analyzed and it was found that in only 36 patients the treatment was according to the standard guidelines whereas in 264 patients the treatment guidelines were not followed. The economic burden was calculated every month which showed that the maximum cost per person ranges between 500-1000 Rs. We conclude from our study that Cap Autrin and Tab Tonofolic DS were rational and fulfilled the WHO standard treatment guidelines.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

The study obtained ethical approval from the Sumandeep Vidyapeeth Institutional Ethics Committee (Ref no: SVIEC/ON/Phar/BNPG18/D19008).

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by the personal efforts of the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
<https://www.sdiarticle4.com/review-history/72365>