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DRUG UTILIZATION PATTERN IN PREGNANCY- A SCOPE FOR IMPROVEMENT IN THE CURRENT PRESCRIBING PRACTICES

Md.Ilyaz[1]*, Dr.RoyaRozati[2], Fatima Hafeez[3], Fatima Tahniyath[3], Hasbeen Sultana[3], Md. Ashfaq Hussain[3]

[1]Asst. Professor, Department of Pharmacy Practice, Deccan School of Pharmacy, Hyderabad, Andhra Pradesh (India)
[2]MD(AIIMS), FRCOG(London), Professor & HOD, Department of Obstetrics and Gynaecology, Deccan College Of Medical Sciences & Owaisi Group of Hospitals, Hyderabad, Andhra Pradesh (India)
[3]Pharm D (PB) students of Deccan School of Pharmacy, Hyderabad, Andhra Pradesh (India)

***Corresponding author e-mail:** ilyazmd5@gmail.com

ABSTRACT

The purpose of this study is to evaluate the pattern of drug (prescription, OTC) utilization in pregnant women attending the Antenatal OPD at a Tertiary care hospital. A cross-sectional study was conducted in 400 pregnant women attending Antenatal Out Patient Department. Out of 400 women majority (40%) were in the third trimester. The average drugs prescribed were 6.25 per prescription. Iron, Folic acid and Calcium were the main drug of choice during pregnancy, either alone or in combination with other drugs. Mostly, the drugs were of US FDA risk category B and none of the category X drugs was prescribed. Self-medication was more in higher socio economic population. The study revealed prescribing behaviour to pregnant women under Antenatal care and determines the extent of prescription of drugs to provide optimum health care to improve the overall health of the mother and baby in community.

Keywords: Pregnant women, drug utilization, antenatal, OPD, risk category.

INTRODUCTION

Drugs play an important role in improving human health and promoting well-being. Therefore judicious use of drugs, adequate knowledge, positive approach and awareness towards the drug use are mandatory prerequisites for good maternal and child health [1]. More than 50% of pregnant women take prescription or non-prescription drugs (over-the-counter drugs (OTC) at some time during their pregnancy [2]. The identification of a drug's teratogenic potential is important because drug-associated malformations are largely preventable. Two important factors to consider when assessing the teratogenic potential of a medication are the stage of pregnancy at which the exposure occurred and the amount of medication taken [3].

The main causes of unfavourable outcomes continue to be infections, haemorrhage, anaemia and pre eclampsia which can be prevented by optimum antenatal care. Hence timely treatment of these conditions can reduce the perinatal morbidity and mortality. Pregnant women requiring prescription drugs pose a challenge to physicians to avoid any risk to the mother and to the fetus [4]. The US Food and Drug Administration (FDA) demonstrate safety and efficacy of any drug, before it is marketed. However, Pregnant women are generally excluded from clinical trials on ethical grounds and results

related to effect of drug on pregnant animals cannot always be extrapolated in human population [5]. Regardless of the limited information on the safety of drugs in pregnancy, drug use in pregnancy is common [6,7].

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 etc. However, 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 [8].

Presently drug utilization studies are in evolving era, to evaluate the present practices in prescribing and future trends of drug usage, to estimate disease prevalence, drug expenditures, appropriateness of prescriptions and adherence to evidence based recommendations [9]. It becomes essential to assess the drug utilization pattern in pregnancy to see to what extent there may be scope for improvement in the current prescribing practices [10].

MATERIALS AND METHODS

Study Period: The study was conducted over a period of 3 months from November 2013 to February 2014.

Study Design: Pharmacoepidemological studies can help in minimizing the inherent risk of drug use in pregnancy by establishing a profile of drug consumption, by evaluating the existing health services and by investigating the interventional measures [11]. The present cross-sectional study was conducted in Antenatal Out Patient Department of Obstetrics and Gynaecology of Owaisi Hospital and Research Centre to evaluate the drug utilization pattern during pregnancy and to study drug utilization or practices in women attending ante natal clinic of our institution.

Ethics Committee Approval: The Institutional ethics committee permission was taken on 22nd January, 2014 and Written Informed consent was obtained from all the pregnant women before their prescriptions were analysed.

Hospital Background: Owaisi Hospital and Research Centre, Hyderabad, India is a tertiary care multispecialty teaching hospital with a massive seven storied structure and 1150 beds competently managed by senior professionals, highly experienced in their respective speciality which receives referrals from other private clinics, hospitals and general physicians. Most of the women attending this centre for antenatal services belong to lower socioeconomic group.

Prescribing Practices: Pregnant women attending the OPD are examined by a team of physicians, professors, lecturers and house surgeons which are part of the unit and are given hand-written prescriptions on OPD case paper to the pregnant women. There is no facility to maintain pregnant women's health records electronically. Pregnant women receive the drugs prescribed to them either from hospital pharmacy if available, free of cost under Arogyasri Scheme or they need to purchase it from a medical store.

Patient Enrolment: Pregnant women were enrolled only after obtaining written informed consent.

Patient Data Collection Form: The demographic profiles of pregnant women along with parity, present and past history of associated medical, surgical, gynaecological and obstetrical illness, number of drugs prescribed per prescription, generic/brand names, drug dose, dosage form, frequency, duration of treatment were collected, sorted and classified in accordance with US FDA risk classification for pregnancy and the detailed information on the prescription records given in the past and at the time of enrolment documented in OPD case paper were recorded on the case record form.

Inclusion criteria: All pregnant Women were enrolled via convenience sampling, in any trimester, attending antenatal outpatient department greater than or equal to 16yrs of age, with or without co-morbidities, presented with the prescription written on the OPD case paper were included in the study.

Exclusion criteria: Pregnant women diagnosed with acute and chronic medical conditions requiring hospitalization were excluded from the study.

Statistical Analysis: Statistical analysis was done by using descriptive statistics. Data was collected, tabulated and graphs were designed in Excel-2007.

Continuous variables were presented as mean values ± Standard Deviation (SD) and categorical variables were presented as percentages.

RESULTS

Out of 428 pregnant women, 5 pregnant women opted for MTP and 23 of them did not agree to give informed consent .So 400 women who agreed to give informed consent were considered for the study. About 52.25% of women were in the age group of 21-25 years. Average age of pregnant women was 24.075 ± 4.28 years (Range 16-45 years) as illustrated in Table 1 and Fig 1.1 shows the age group of pregnant women attending Antenatal clinic.Fig 1.2 shows the literacy status of the pregnant women under study. Fig 1.3 shows the employment status of the women under study.

Out of 400 women; 150 (37.5%) were of primigravida, 112 (28%) of secondary gravida, 138 (34.5%) of multi gravida. Majority of women (40%) were in the third trimester. Fig 1.4 shows the Gravida of the pregnant women attending Antenatal care and Fig 1.5 shows the total number of pregnant women in each trimester.

Anaemia was categorised into mild, moderate, severe and non-anaemic patients. Anaemia was classified according to WHO classification- Severe anaemia (< 7 g/dl), moderate anaemia (7-8.9 g/dl) and mild anaemia (9-10.9 g/dl) [12]. Haemoglobin level more than 11g/dl was classified as non-anaemic. 69 of 400 women (18.25 %) were found to be anaemic. Table 2.1 and Fig 2.1 shows Distribution of women having mild, moderate and severe anaemia in 1^{st},2^{nd} and 3^{rd} trimester .Table 2 shows associated medical, surgical, obstetrical and gynaecological history of pregnant women and Fig 2 shows number of patients with different co-morbidities. According to WHO classification (Data expressed in percentages).

Prescription Details: A total of 400 prescriptions were analysed in which 2503 were the total no. of drugs prescribed. The average drugs per prescription were found to be 6.25 **(2-14).** The highest number of drugs prescribed was 14 and the lowest was 2 per prescription depending on the condition of the patient. According to our study, about 39 women were found to be suffering from Urinary tract infection second most common to anaemia among the associated gynaecological conditions as shown in Table 2. All pregnant women attending the antenatal OPD were prescribed iron and folic acid irrespective of the trimesters. But in our study it was noticed that Iron supplementation was not strongly recommended in the first trimester of pregnancy as most of the patients complained of Nausea and Vomiting, they were prescribed anti-emetics for morning sickness, antacids for acidity, paracetamol for fever and minor aches, thyroxin for hypothyroidism, levothyroxine for hyperthyroidism etc..

In the second trimester protein supplements, anti-microbial for the treatment of infections, methyldopa for pregnancy induced hypertension, atenolol for known case of hypertension was prescribed. In our study it was noticed that Betamethasone was prescribed in the second trimester of pregnancy and in the third trimester anti-microbials were prescribed. The drugs commonly prescribed in all trimesters were antibiotics such as amoxicillin and potassium clavunate, protein supplements (powder), proton pump inhibitors/H_2 blockers were prescribed besides Iron, Folic acid and Calcium Supplements. As illustrated in Table 3 the prescribed drugs and their US FDA Classification. As shown in Fig 3.1 different drugs prescribed in the total number of prescriptions and Fig 3.2 shows different drugs prescribed in the total number of prescriptions. Gestational Diabetes Mellitus was treated with Insulin, known case of Diabetes with Metformin, dextromethorphan for cough and Cetirizine, bromohexine, Karvol plus inhalers were given to relieve cold and congestion. Pregnant women with epilepsy were prescribed Phenytoin Sodium. Different drug utilization studies used different classification systems to assess risk of fetal harm by drug use in pregnancy.

Studies using different systems are difficult to compare; as of 2000, only 26% of the drugs are common in all three major systems (US FDA, Swedish and Australian) were placed in the same risk factor category [13]. However many drug utilization studies done in various countries including India have used US FDA classification system as a tool to evaluate the prescribing pattern of the physicians in pregnancy [13, 14, 15] hence US FDA classification system was used in our study. As illustrated in Table 4, the no. of prescribed drugs according to USFDA Classification and the same was depicted in Fig.4.

DISCUSSIONS

Main findings: According to our study, the current prescribing pattern is in compliance with the US FDA recommendations. The occurrence of high risk medicines was desirably low. Out of 400 prescriptions, only 100 prescriptions had drugs other than iron, folic acid and calcium lactate. According to the US FDA Risk category of drugs there were 286 drugs of Category A, 694 drugs of Category B, 81 drugs of Category C and 97 drugs of Category D and no drugs of Category X drugs were prescribed [Table 4].

Strengths: A prescription based survey is considered to be one of the most effective methods to assess drug utilization of medication. Recommendations of FDA drugs on pregnancy help to improve prescribing patterns of the prescriber and ultimately the Clinical Standards.

Limitations: In our study it was noticed that all the drugs were prescribed by brand name and not by generic name which is not an encouraging finding as it promotes a specific brand and creates confusion and may lead to prescribing errors for the pharmacist, involved in dispensing. Moreover it is a regional study

Interpretation: The studies conducted in developed countries where drug-prescribing practices are considered to be advanced have reported the use of prescription medicines which have teratogenic potential and hence identified the need for interventional measures [16]. Studies done in India by collaborative group on Drug Use in Pregnancy [17], have confirmed that at present, some drugs are widely used in pregnancy than in justified by the knowledge available hence there should be careful prescribing behaviour of the physicians to provide optimum care to pregnant women [18].

CONCLUSION

Generally, any medication unless absolutely necessary, should not be taken during pregnancy, particularly during the first trimester. Additional drugs were prescribed only if required. Findings of our study showed that all eligible pregnant women were provided with prophylactic iron and folic acid therapy. None of the women was prescribed category X drugs. Pregnant women with co-morbidities were prescribed considering the risk benefit ratio. Predominantly, drugs were prescribed according to brand names and not in generic names. Anaemia was common among many women and therefore accounts for high morbidity and mortality associated with pregnancy outcome which can be minimized by educating the women about the balanced diet and utilization of ante natal facilities from the first trimester of pregnancy itself and also about the risk involved in self-medication. As the study was cross sectional we were unable to obtain data on outcome of pregnancy. The data collected represents the prescribing pattern in a tertiary care hospital to provide optimum healthcare to improve the overall health of the mother and baby in the community.

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Disclosure of interests: The authors have no Conflicts of Interest to declare.

Contribution to authorship: This work was carried out in collaboration between all authors. All authors read and approved the final manuscript.

Details of ethics approval: The Ethics committee of Owaisi Hospital and Research Centre approved the study to be carried out in the Department of Obstetrics and Gynaecology and gave the IRB letter on January 22nd , 2014.

Table 1; shows the demographic information of pregnant women attending antenatal Outpatient department.

S.no	Demographic Data	Results
1	Age in years (mean±SD)	24.075±4.28
2	Literacy Status (number (%))	
A	Illiterate	45(11.25)
B	Primary education	142(35.50)
C	Secondary education	110(27.50)
D	Graduate	93(23.25)
E	Post Graduate	10(2.50)
3	Employment (number (%))	
A	Unemployed	353(88.25)
B	Employed	47(11.75)
4	Gravida (number (%))	
A	Primigravida	150(37.50)
B	Secondgravida	112(28.00)
C	Multigravida	138(34.50)
5	Trimesters (number (%))	
A	First	82(20.50)
B	Second	158(39.50)
C	Third	160(40.00)

Table 1.1 shows age in years and no. of patients involved in the study:

Age (in years)	No. of patients
16-20	71
21-25	209
26-30	87
31-35	30
36-40	2
41-45	1

Table 2; will show associated medical, surgical, obstetrical and gynaecological history of pregnant women.

S.no	Associated medical/surgical/obstetrical and gynaecological condition	No. of Patients
1.	Anaemia	69
2.	Pre eclampsia	2
3.	Gestational Diabetes	4
4.	Congenital heart disease	1
5.	Recurrent pregnancy loss	2
6.	Hypothyroidism	23
7.	Epilepsy	4
8.	PCOD(Ovarian cyst)	2
9.	Pulmonary kochi	10
10.	Asthma	2
11.	UTI	39
12.	Renal Calculi	1
13.	Rheumatoid Arthritis	1
14.	HbsAg+	2

15.	Gestational HTN	15
16.	Piles	1
17.	Eclampsia	2

Table 2.1 shows Distribution of women having mild, moderate and severe anaemia in 1st, 2nd and 3rd trimester according to WHO classification (Data expressed in percentages):

Type Of Anaemia	**No. of Patients**
Mild	44
Moderate	17
Severe	8
Non Anaemic	331

Table 3; shows the prescribed drugs and their US FDA Classification:

S.no	**Drug Class**	**No. of prescriptions**	**FDA risk**
1.	**Alimentary Tract drugs**		
A	Doxylamine succinate	113	A
B	Pantoprazole	3	B
C	Rabeprazole	177	B
D	Hyoscine Butyl bromide	6	B
E	Lactulose	11	B
F	Bisacodyl	3	A
G	Reflux forte	22	B
H	Aristozyme/Bestozyme	22	B
I	Binopyrine	6	B
2.	**Cardiovascular drugs**		
A	Methyldopa	10	B
B	Alphadopa	3	B
C	Atenolol	4	D
3.	**Nervous system**		
A	Paracetamol	46	A
B	Phenytoin Sodium	4	D
C	Diclofenac Sodium	11	C
D	Tramadol Hydrochloride	1	C
4.	**Respiratory system**		
A	Detromethorphan	5	A
B	Cetrizine	51	B
C	Levocetrizine	5	B
D	Salbatumol	4	A
E	Karvol Plus	15	A
F	Bromohexine	23	A
G	Phenylephrine	15	A
5.	**Blood and blood forming agents**		
A	Ferrous Sulphate (Iron Supplements)	280	A
B	Multi vitamins	392	A
C	Calcium supplements	200	A
D	Folic Acid	300	A
E	Amino acid supplements	178	B
F	L- Arginine Ornithine (powder)	42	A
G	Protein(powder)	356	A

6.	**Hormones**		
A	Betamethasone	29	A
B	Prednisolone	1	A
7.	**Anti Thyroid Drugs**		
A	Thyroxine	15	A
B	Levothyroxine	5	A
8.	**Endocrine Agents**		
A	Dihydroxyprogesterone	30	D
B	Drydrogesterone	58	D
C	Allylestrenol	110	B
D	EstradiolValerate	12	B
9.	**Drugs acting on Uterus**		
A	Isoxsuprine	66	C
10.	**Ovulation Inducers**		
A	HCG	1	A
11.	**Topical Vaginal Preparations**		
A	Clindamycin	17	A
B	Cotrimoxazole	5	A
C	Povidone Iodine	3	A
D	Neomycin	1	D
12.	**Hypoglycaemic Drugs**		
A	Metformin	5	A
B	Insulin (Human Mixtard)	4	C
13.	**Anti Microbials**		
A	Metronidazole	2	B
B	Satrinadazole	2	B
C	Cefpodoxime	27	B
D	Azithromycin	2	B
E	Benzyl Penicillin	1	A
F	Amoxycyllin+PotassiumClavunate(Clavulanic Acid)	166	B
14.	**Anti Tubercular Drugs**		
A	AKT 3	2	B
B	AKT 4	2	B
15.	**Renal System**		
A	Syp. Citralka	48	B

Table 4 shows the no. of prescribed drugs according to USFDA Classification:

US FDA Risk Category	**No. of Patients**
A	286
B	699
C	81
D	97
X	0

Fig 1.1 shows the age group of pregnant women attending Antenatal clinic

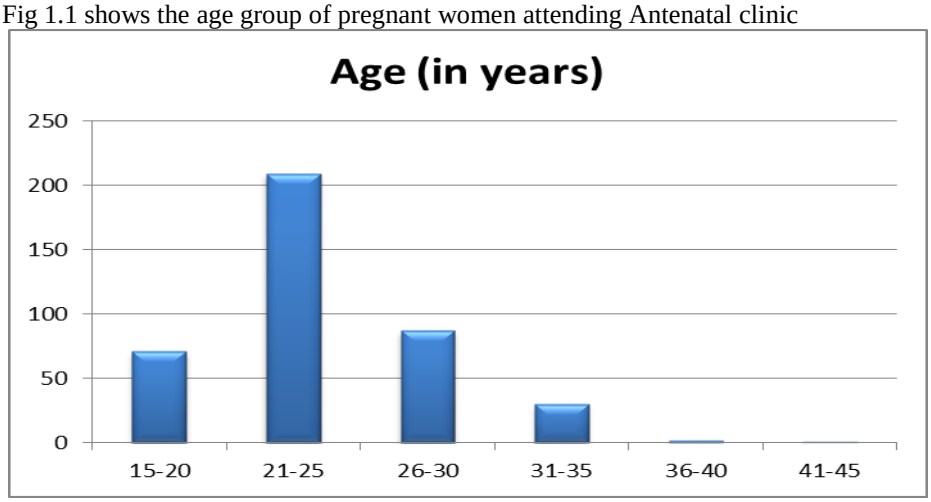


Fig 1.2 shows the literacy status of the pregnant women under study

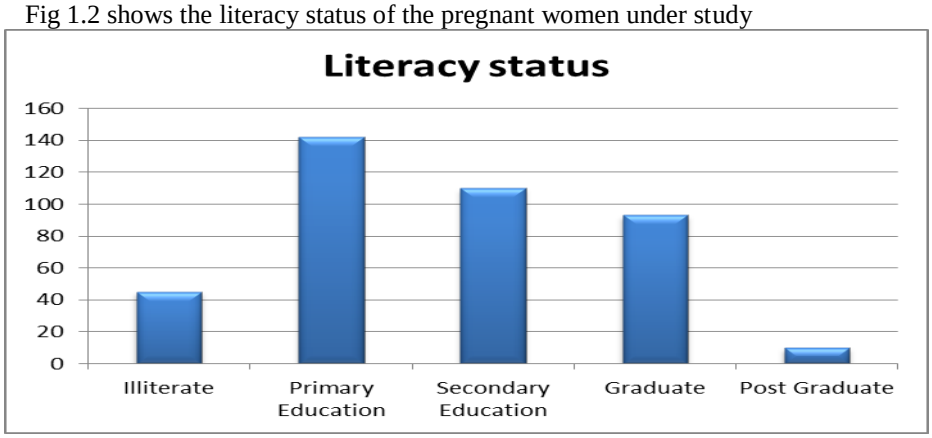


Fig 1.3 shows the employment status of the women under study

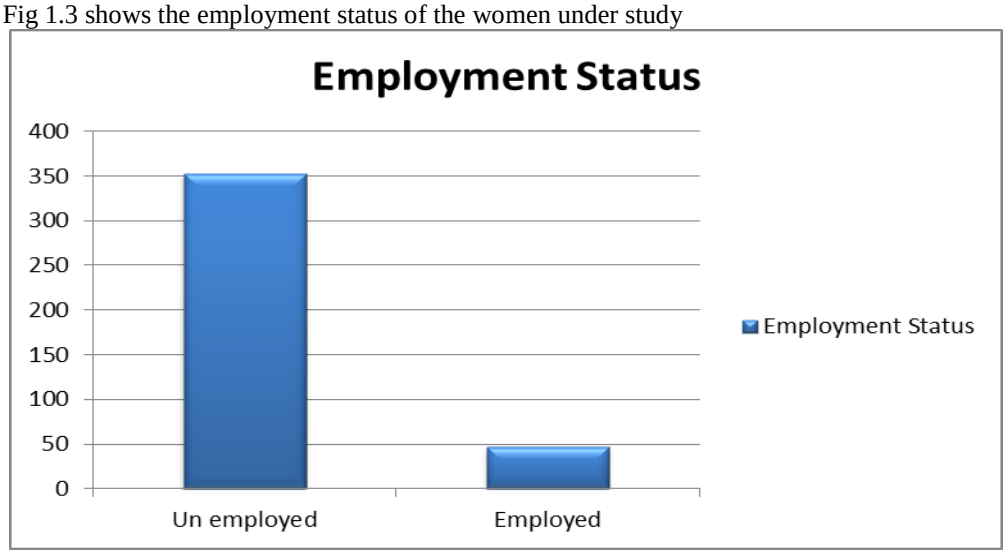


Fig 1.4 shows the Gravida of the pregnant women attending Antenatal care

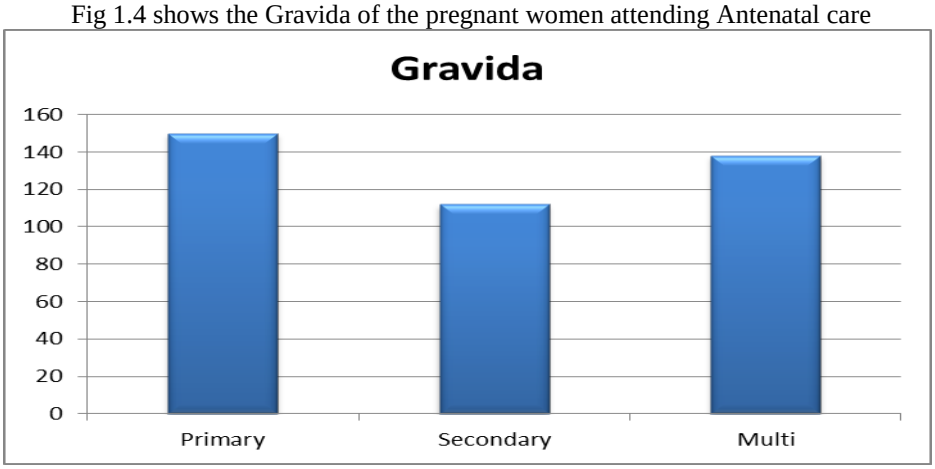


Fig 1.5 shows the total number of pregnant women in each trimester

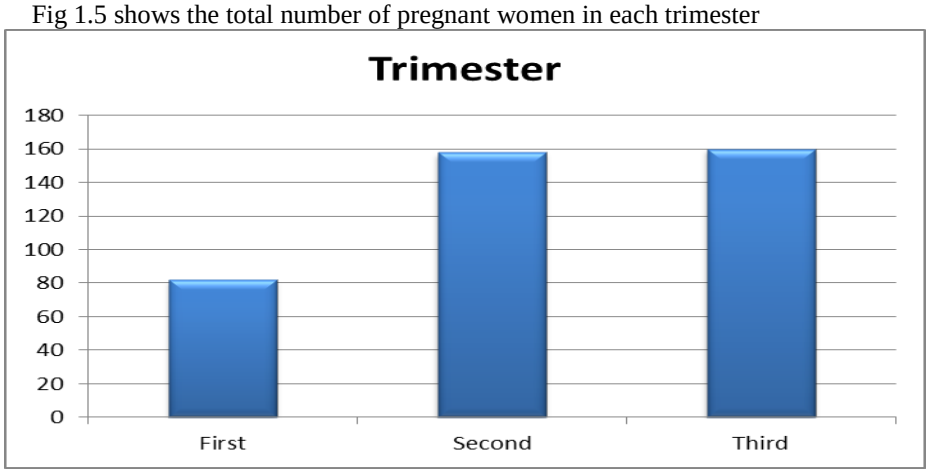


Fig 2 shows number of patients with different co-morbidities

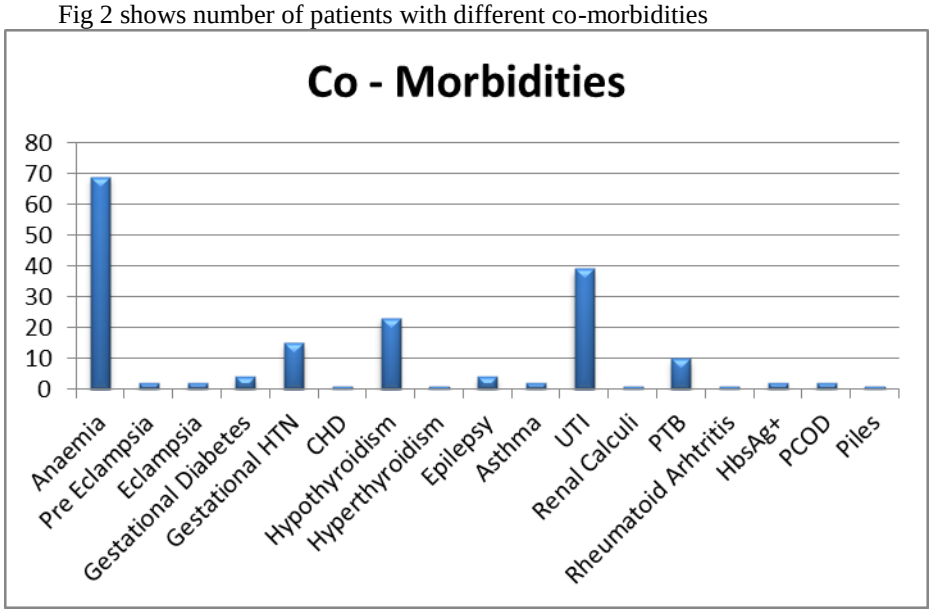


Fig 2.1 shows total number of women who are non-anaemic and anaemic (with type)

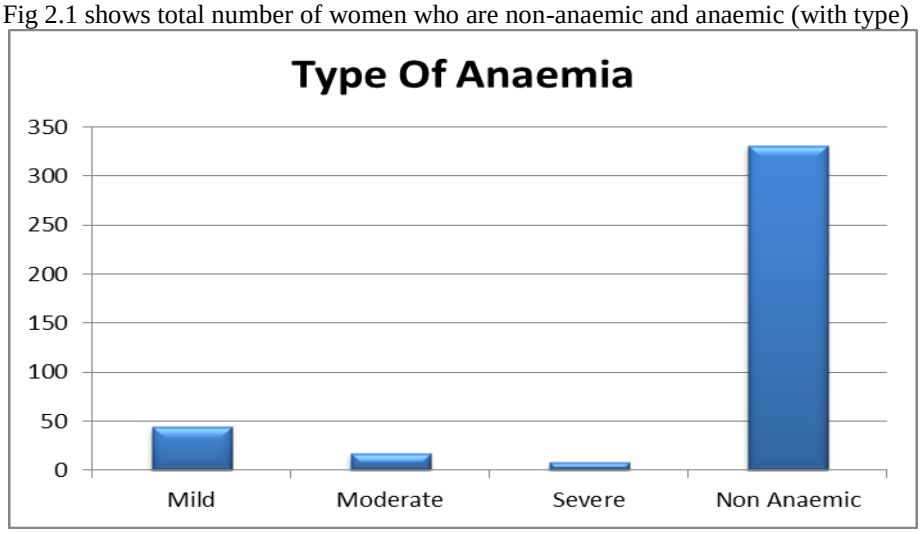


Fig 3.1 shows different drugs prescribed in the total number of prescriptions

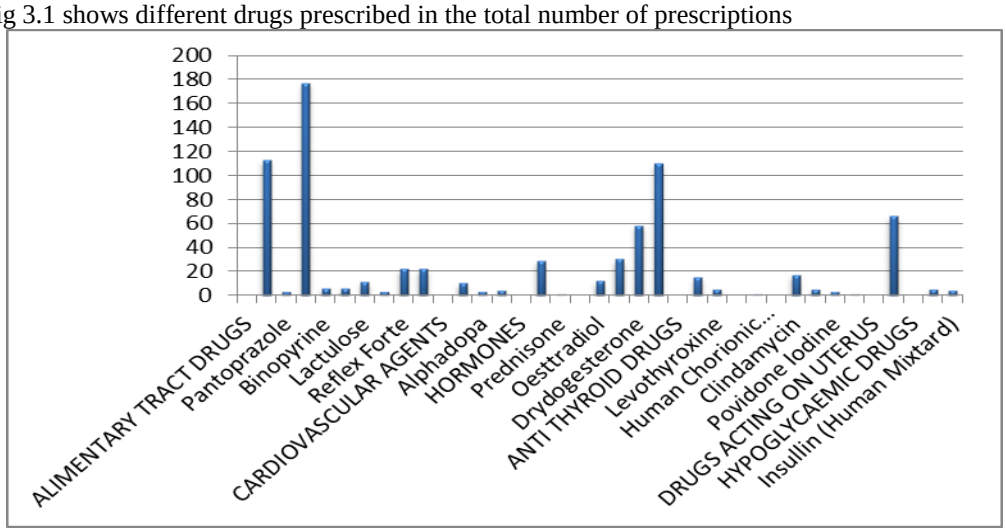


Fig 3.2 shows different drugs prescribed in the total number of prescriptions.

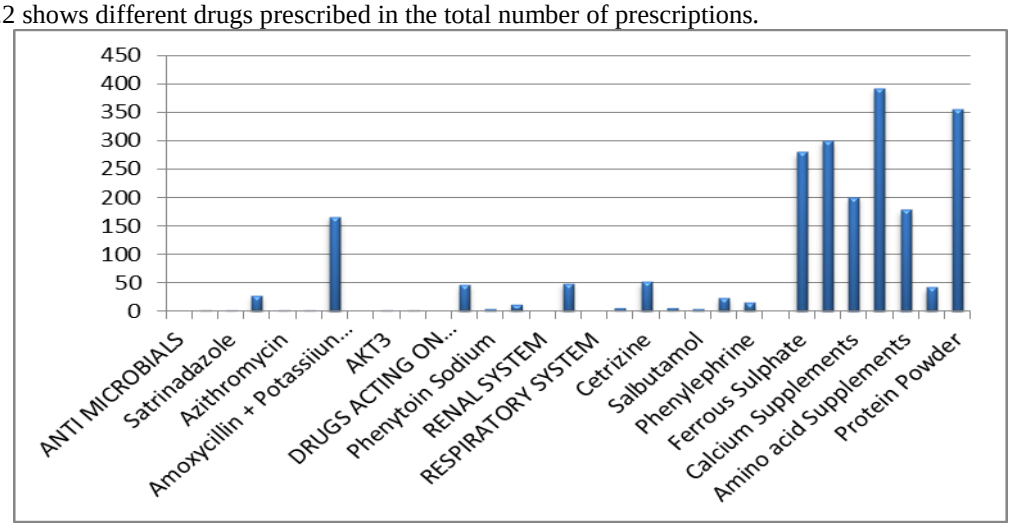
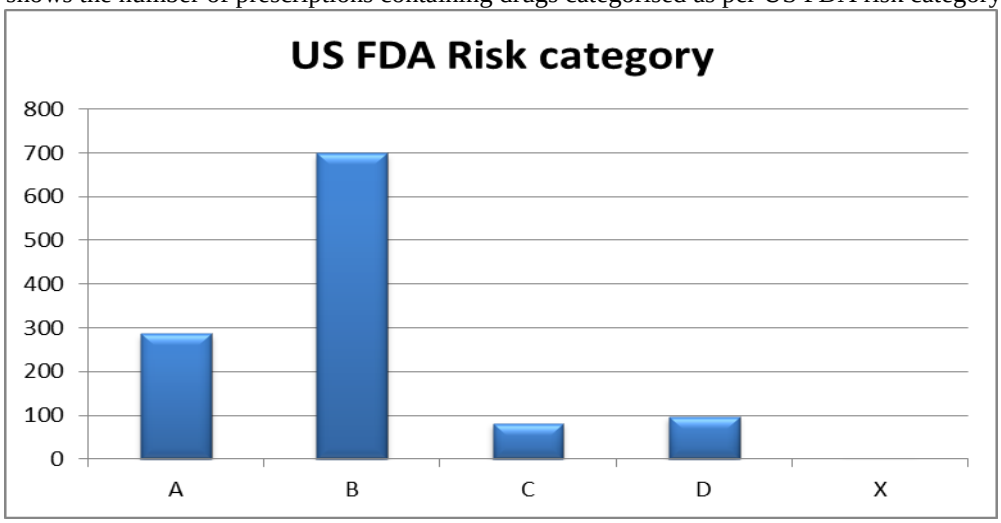


Fig 4 shows the number of prescriptions containing drugs categorised as per US FDA risk category



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