Original Article

Clinical Evaluation on Usage of Drugs during Antinatal Care in Tertiary Care Hospital

S. Abarna[1*], N. Anu Prasad[1], S. Abirami[1], S. Gopi Krishnan[2]
[1.] Doctor of Pharmacy, Arulmigu Kalasalingam College of Pharmacy, Krishnankoil-626126, India.
[2] Associate Professor, Depratment of Pharmacology, Arulmigu Kalasalingam College of Pharmacy, Krishnankoil-626126, India.
*Corresponding author's E-mail: abarnaabar31@gmail.com

ABSTRACT

Background: Pregnancy lasts for a period of 40 weeks from the last menstrual period. Babies born before 37 weeks are considered as „preterm". Complications during gestation may contain gestational hypertension, gestational diabetes, iron-deficiency anemia, and severe nausea and vomiting. Pregnancy normally lasts for 40 weeks and is broken up into three trimesters. Each trimester of pregnancy brings about changes to both the developing foetus and the pregnant woman's body. The teratogenic impact is dependent on the substance as well as the various phases of pregnancy where the teratogen is exposed. Drugs given instantly after fertilisation may kill the foetus or end the pregnancy, but there won't be any birth abnormalities because no organs have started to form. When dangerous medications are administered during the period of organogenesis, birth abnormalities or malformations are discovered. Developmental and functional problems start when the foetus is exposed to a teratogen during the fetogenesis stage.

Result: According to this study, the highest numbers of subjects are in the age group of 18-25 years (58%). The maximum age of pregnant women in the study group is 43 years while the minimum age is 18 years. According to US FDA Pregnancy risk categorization, in this study 34% of the drugs prescribed from category A, 19% from category B, 16% from category C, 0.4% from category D and 0.2% from category X.

Keywords: Pregnancy, Trimester, Teratogen, Prescription indicators.

INTRODUCTION

Drug prescribing during pregnancy is common and essential for treating a pre-existing condition or a condition that develops during pregnancy. It is estimated that 33–69% of pregnant women are prescribed medications, including vitamins and minerals, during their pregnancy. Medications should be used when there has been prior experience, with newer drugs avoided if feasible. A prescription should be issued only if there is a clear indication, particularly during the first trimester, when exposure to a culprit drug is most likely to be associated with an increased risk of congenital malformation, though exposure in the second or third trimesters may be associated with other teratogenic effects[1]. Pregnancy is a complex condition where adaptations in maternal physiology may modify the pharmacokinetics (PK) or pharmacodynamics (PD) that defines drug dosing and present physiological complications during pregnancy[2]. When administering medications during pregnancy, careful evaluation of the benefit to the mother and the danger to the foetus is necessary. The crucial topics for discussion are lowering medication mistakes and enhancing patient safety[3]. Drug transmission to the foetus is primarily influenced by the placental barrier's permeability, which serves as the interface between the foetal and maternal circulations. The placenta is the only organ that contains cells from both the mother and the foetus, and it facilitates their functional relationship. Some medicines including vitamins, minerals, iron, and dietary supplements are crucial for the health of the expectant mother and the

foetus. As a result of different chronic diseases and difficulties associated to pregnancy, it has been stated that 8% of pregnant women require pharmacological therapy[4]. In the first few weeks of pregnancy, many women take drugs before they even know they are pregnant. A prescription other than a vitamin or mineral supplement is administered to about 59% of pregnant women. A dietary herbal supplement is consumed by about 13% of pregnant women[5]. Based on the existence or absence of information on the safety of its usage during pregnancy, the study findings, each medicine is categorised into 1 of 5 categories. Instead than offering advice on how to manage the pregnancy after exposure, the FDA categories are meant to influence treatment selection prior to foetal exposure. The FDA categorization has drawn criticism for oversimplifying the complexity of balancing dangers to the foetus versus the necessity to effectively manage maternal medical issues, despite the system's ease of use[6].

AIM AND OBJECTIVES

Aim

To evaluate the usage of drugs during pregnancy in antenatal period.

Objectives

- To assess the drug utilization pattern during antenatal period.

- To analyse the demographic and other characteristics of pregnant women.

- To analyze drugs for WHO Prescribing indicators.

- To analyze the prescription of drugs based on USFDA pregnancy risk categorization.

METHODOLOGY

Sample Size

There are several methods used to calculate the sample size depending on the type of study or study design. The sample size was calculated by using the following formula:

$$Sample\ size\ n = \frac{N * [Z^2 p * \frac{(1-p)}{e^2}]}{[(N-1) + \left(Z^2 p * \frac{(1-p)}{e^2}\right)]}$$

where,

N = Population size,

Z = Critical value of the normal distribution at the required confidence level,

p = Sample proportion,

e = Margin of error.

Calculation

$$Sample\ Size, n$$

$$= 250\frac{[(1.96)^2 * 0.5 * \left[\frac{(1-0.5)}{(0.05)^2}\right]]}{[(250-1) + ((1.96)^2 * 0.5 * \frac{1-0.5}{0.05^2})]}$$

$$= 250 \times 0.606$$

$$n = 151.5$$

Therefore, we need to collect 151 cases.

Study Design

Prospective observational study was conducted on Obstetrics and gynaecology department in Government Medical College Hospital, Virudhunagar.

Study Duration

This study was carried out over a period of 6 months.

Study Instruments

- Prescription of patients.
- Laboratory report of patients.
- Interviewing the patient.

Complete Study Procedure

- To analyze drugs for WHO Prescribing indicators.
- Patient data was collected in the pre-designed data collection form
- Informed consent form was obtained from the patients.
- WHO drug prescribing indicators data were analyzed for:

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

- The data include demographics, patient history of disease & medication, medication from the prescription.
- The patient's prescription was analyzed and drugs were categorized according to the US FDA drug risk category.

Patient Selection

Inclusion criteria

- All Pregnant women who have been admitted in OBG - IPD who are on atleast one drug treatment.
- Pregnant women who are willing to participate in the study.
- Pregnant women between the age of 18 – 45 years.

Exclusion criteria

- Abortion cases
- Pregnant women who are not willing to participate in the study.
- HIV positive pregnant women.
- Incomplete files
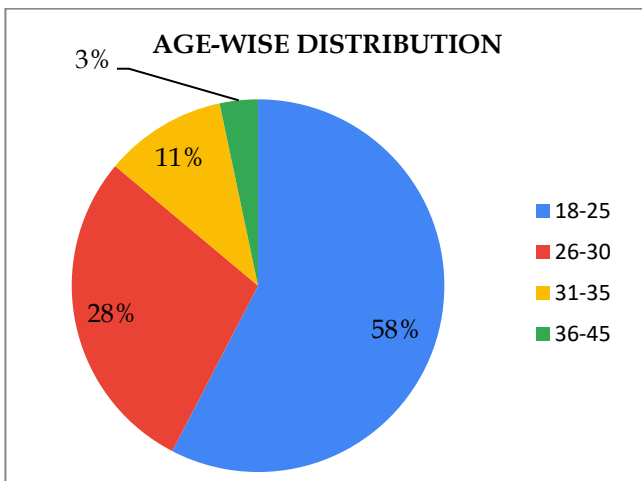
Statistical Analysis

- ✓ Data were entered and analysed using Microsoft Excel.
- ✓ Data analysis were expressed with frequency and percentage.
- ✓ Graphical representation is used for representation of analysed data.

RESULTS

**Table 1:** Age-Wise Distribution

Age	Frequency
18-25	87
26-30	43
31-35	16
36-45	5

AGE-WISE DISTRIBUTION

Graph-1

Table 2: Classification based on trimester

Age	Trimester		
	I	II	III
18-25	8	21	58
26-30	3	9	31
31-35	1	5	10
36-45	0	0	5

Table 3: Complication

Complications	Frequency	Percentage
Anemia	33	17.28
Pre eclampsia	30	15.71
GDM	29	15.18
Hypothyroidism	19	9.95
Oligohydramnios	14	7.33
Vaginal bleeding	12	6.28
Pedal edema	10	5.24
Polyhydramnios	8	4.19
Uti	5	2.62
Lung disease	5	2.62
Seizure	4	2.09
Heart diseases	4	2.09
Age	3	1.57
Puppp	3	1.57
Low lying placenta	2	1.05
Ectopic pregnancy	1	0.52
Cervical incompetence	1	0.52
Hyperemesis gravidarum	1	0.52
Left ovarian cyst	1	0.52
Rheumatoid arthritis	1	0.52
Thrombocytopenia	1	0.52
Spleenomegaly	1	0.52
Vulvovaginitis	1	0.52
Varicose vein	1	0.52

TRIMESTER DISTRIBUTION
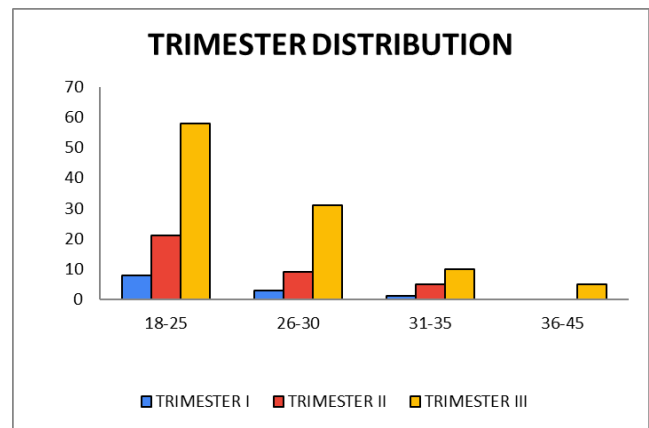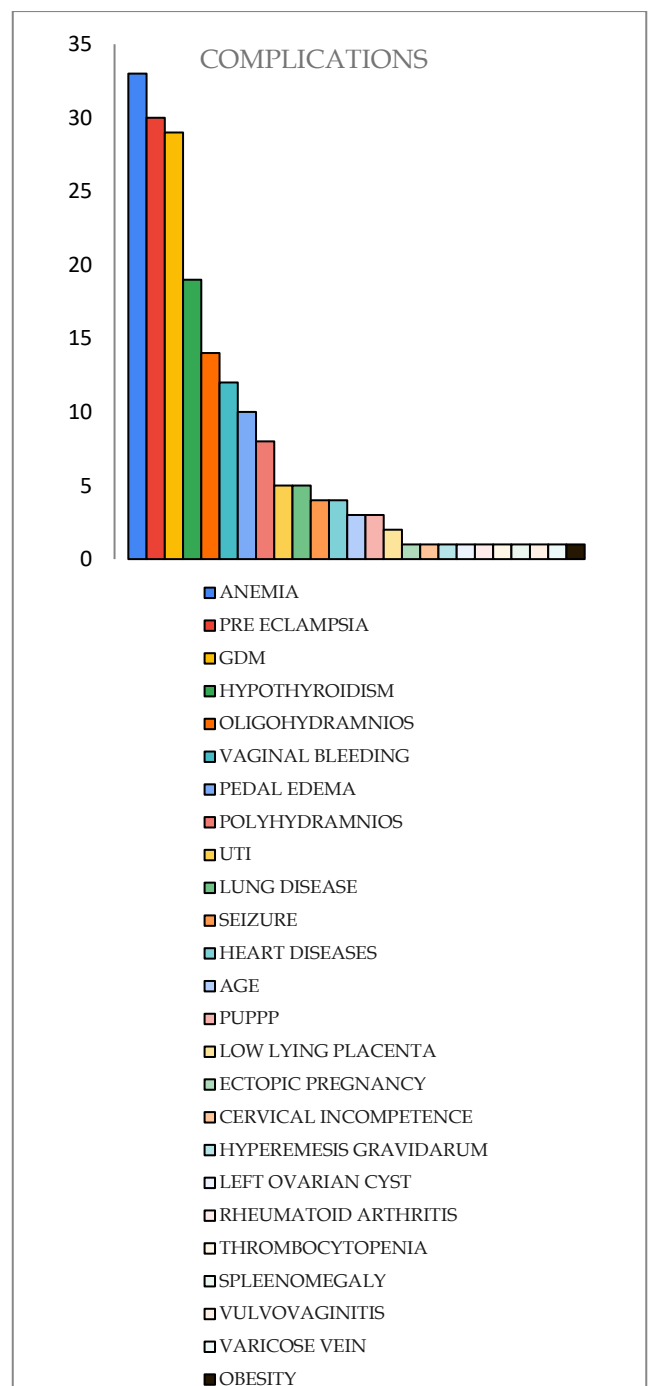
Graph-2

Graph-3

Table 4: Drug Utilization Pattern

Class	No. of drugs
Vitamins	277
Hematinics	192
Supplements	143
Antibiotics	64
Hormones	51
Corticosteroids	50
Antihypertensives	46
Antiulcer	19
Antiplatelet	17
Antispasmodics	14
Analgesics	14
Antihistamines	9
Antiprotozoal	9
Antidiabetics	8
Antiemetics	4
Antiepileptics	4
Bronchodilators	2
Antifibrinolytics	1

Table 5: Who Prescribing Indicators

Prescribing indicators	Frequency	Value	Optimal value
Total No. of Patients prescriptions analysed		151	
Total No. of drugs prescribed		924	
Average No. of drugs per encounter		6.12	1.6-1.8
Percentage of drugs prescribed in generic name	908	98.27	100
Percentage of encounters with antibiotics prescribed	54	35.76	20-26.8
Percentage of encounters with injections prescribed	116	76.82	13.4-24.1
Percentage of drugs prescribed from national essential medicine list 2022	556	60.17	100

Table 6: Classification of Drug Based on Dosage Forms

Dosage form	No. of medications prescribed	Percentage
Tablets	697	75.43
Injectables	174	18.83
Capsules	30	3.25
Sachets	20	2.16
Creams	3	0.32
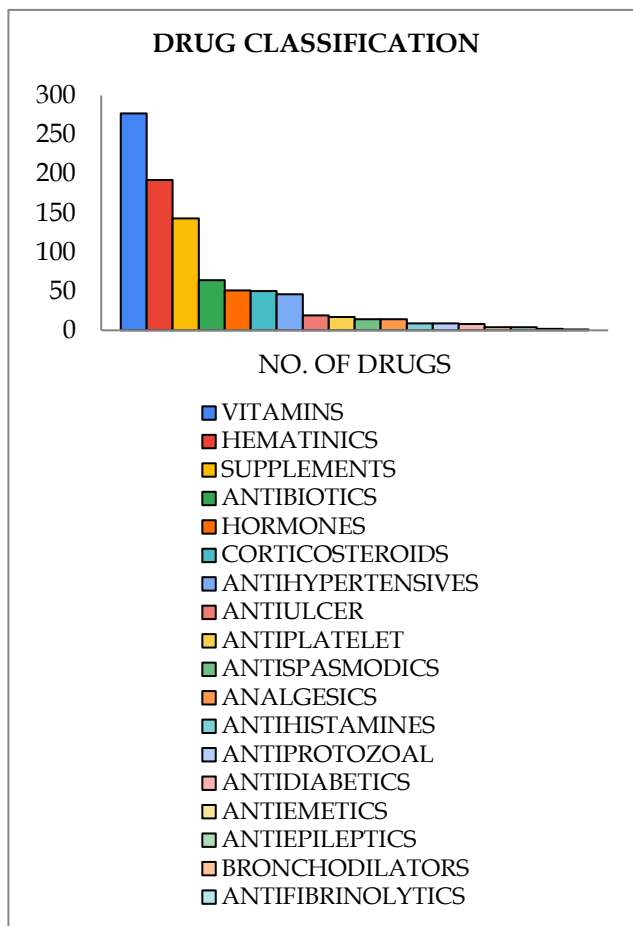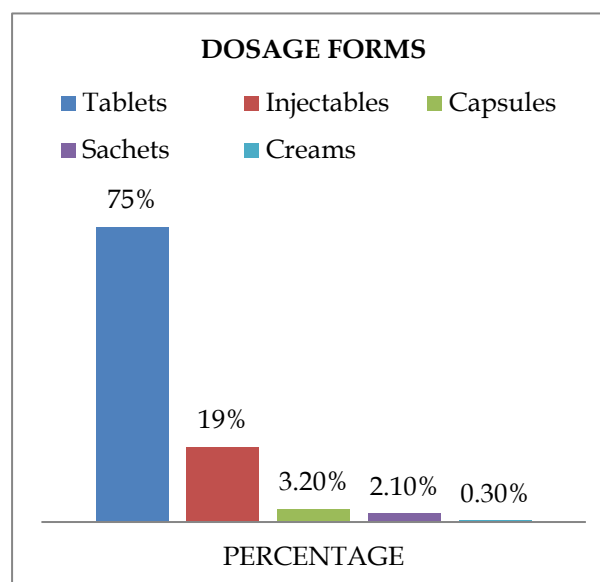
Graph-4

Graph-5

Table 7: Drug Used

Drugs	No. of drugs	Percentage
Albendazole	2	0.22
Amoxicillin	13	1.41
Ampicillin	16	1.73
Arginine	25	2.71
Aspirin	17	1.84
Astymin forte	23	2.49
Azithromycin	2	0.22
Budecort	1	0.11
Calcium carbonate	117	12.66
Carvedilol	1	0.11
Cefoperazone/sulbactam	1	0.11
Cefotaxime	19	2.06
Ceftriaxone	2	0.22
Cetirizine	3	0.32
Chloroquine	1	0.11
Chlorpheniramine maleate	6	0.65
Cotrimoxazole	1	0.11
Deriphylline	1	0.11
Dexamethasone	49	5.3
Dicyclomine	14	1.52
Ferrous sulphate	130	14.07
Folic acid	20	2.16
Furosemide	2	0.22
Gentamycin	1	0.11
Hydroxy chloroquine	1	0.11
Insulin	25	2.71
Iron sucrose	20	2.16
Labetalol	34	3.68
Levetiracetam	4	0.43
Magnesium sulphate	1	0.11
Metaclopromide	1	0.11
Metformin	8	0.87
Metoprolol	3	0.32
Metronidazole	7	0.76
Mts	1	0.11
Multivitamin	1	0.11
Nifedipine	6	0.65
Nitrofurantoin	3	0.32
Norfloxacin	2	0.22
Ondansetron	3	0.32

Pantoprazole	3	0.32
Paracetamol	12	1.3
Pencillin	2	0.22
Probiotic	1	0.11
Progesterone	6	0.65
Ranitidine	15	1.62
Salbutamol	1	0.11
Serratiopeptidase	1	0.11
Thiamine	2	0.22
Thyroxine	20	2.16
Tramadol	1	0.11
Tranexamic acid	1	0.11
Vitamin-b12	21	2.27
Vitamin-b-complex	139	15.04
Vitamin-c	111	12.01
Vitamin-k	1	0.11

Table 8: USFDA category

Pregnancy category	No. of drugs
A	315
B	182
C	146
D	4
X	2
NOT DEFINED	275
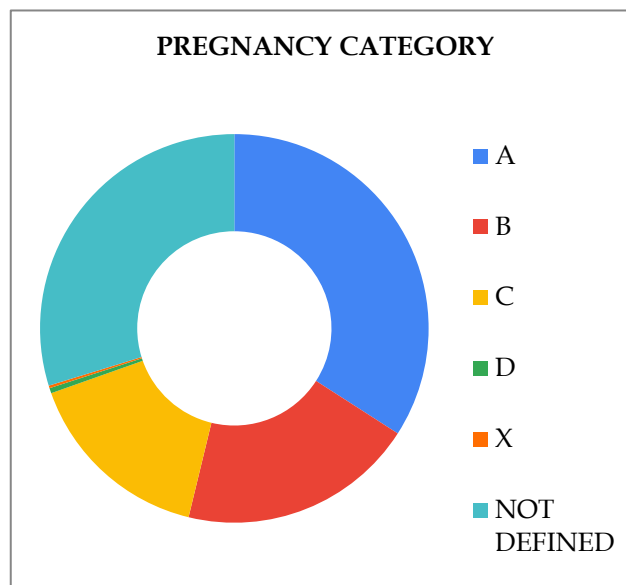
Graph 6
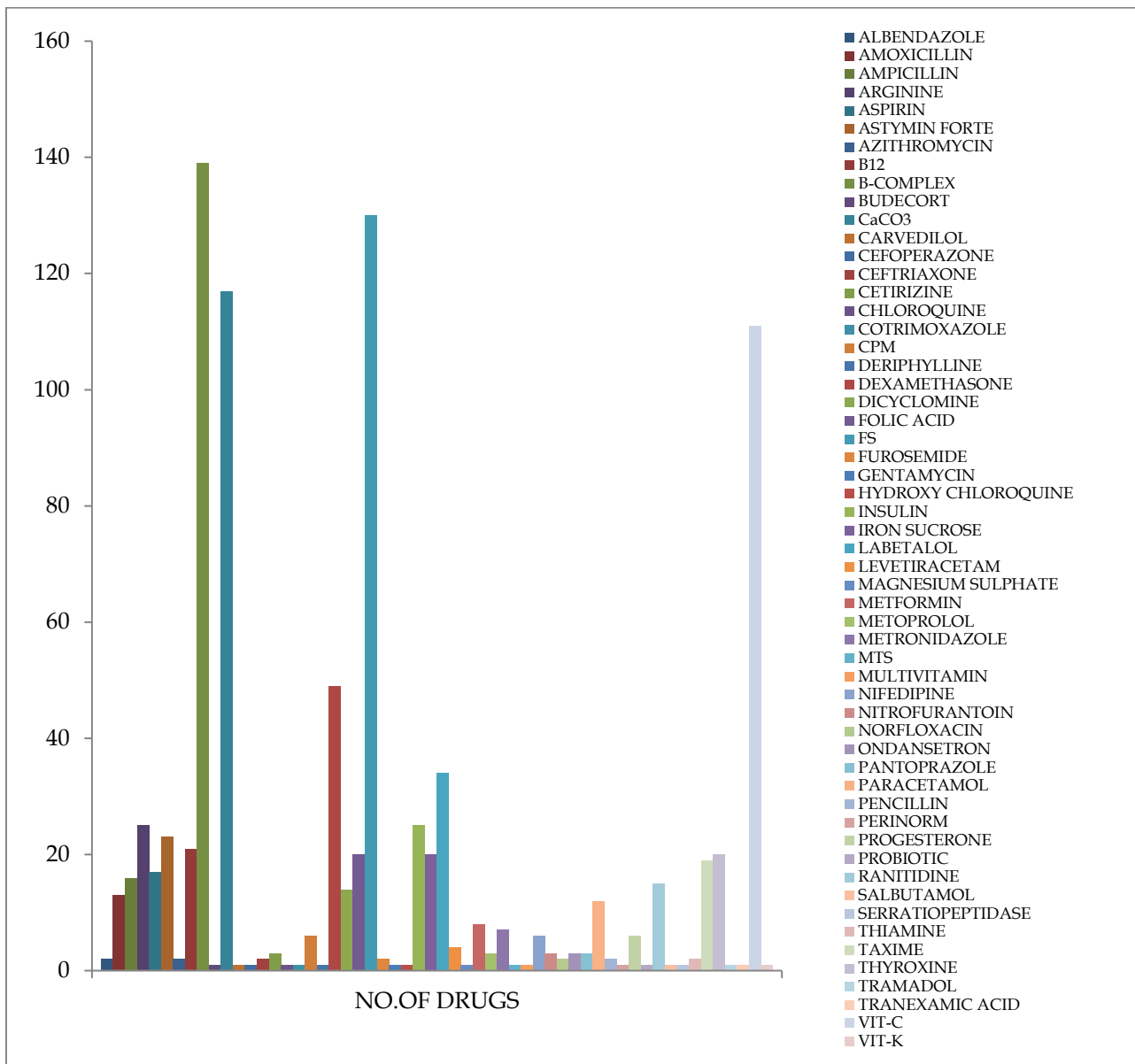
Graph 7

DISCUSSION

In the study, as seen in Table-6 and Graph-2 more number of subjects was found in the age group of 18-25 years, where the number of pregnant women in first trimester was 8, in second trimester was 21 and in third trimester was 58.

The major complications in the subjects of this study were, Anemia (17%), Pre-eclampsiaa (16%) and Gestational Diabetes mellitus (15%). Some of them had the other co-morbid conditions like pedal edema, breathlessness, vaginal bleeding, etc. All the complications are listed in Table-7 and Graph-3.

Prescription pattern analysis are shown in Table-8 and Graph-4, vitamins were the most commonly prescribed (30%) followed by Hematinics (20.7%) and Supplements (15.4%), anti-biotics (7%), hormones (5.5%), corticosteroids (5.4%), anti-hypertensive drugs (5%), anti-ulcer (2%), anti-platelets (1.8%), antispasmodics and analgesics (1.5%), anti-histamines and anti-protozoal (0.9%), anti-diabetics (0.8%), anti-epileptics and anti-emetics (0.4%), bronchodilators (0.2%) and antifibrinolytics (0.1%).

The WHO Prescription Indicators were determined in Table-9. Totally 151 prescriptions having 924 drugs were analysed. The average number of drug per encounter was 6.12, but the optimal value should range between 1.6 – 1.8. Polypharmacy is some instance becomes necessary especially when the patient has some co-morbid conditions associated with the pregnancy. The percentage of encounters with antibiotics prescribed was 35.76%: the standard value is 20.0 – 26.8. Cefotaxime was the most prescribed antibiotic (2.06%) followed by Ampicillin (1.73%) and Amoxicillin (1.14%). The percentage of drugs prescribed in generic name was 98.27 (908) which should be 100. Percentage of prescription with an injection prescribed was 76.82 but the reference value is 13.4 – 24.1. The percentage of drug prescribed from national essential

medicine list 2022 was 60.17 (556), should be 100 to increase the rational prescribing pattern.

The classification of drugs based on dosage forms are tabulated in Table-10 and Graph-5. Tablets were the most prescribed dosage form (75%), followed by other dosage forms including capsules and injections.

According to US FDA Pregnancy risk categorization, in this study 34% of the drugs prescribed from category A, 19% from category B, 16% from category C, 0.4% from category D and 0.2% from category X. Are shown in Table-12 and Graph-7 The number of drugs belonged to category D and category X which might be constructed as a very high degree of risk undertaken by the prescribing physician. But, the fact that these pregnant women required admission is the evidence of seriousness of their condition providing compelling reasons for their prescription, taking risk-benefits ratio into account. Therefore, the usage of D and X category drugs in these patients seems rational. *Farooq MO et al., 2014*.

Limitations : One of the limitations of this study was the low number of admission of pregnant women in their first and second trimesters as a result of which comparative drug utilization between the 3 trimesters could not be performed. Secondly it was not possible to conduct a follow up of the fetus after birth to ascertain the actual impact and linkage of the drug prescription on the fetal teratogenicity as this was beyond the scope of the study.

CONCLUSION

The observed prescription pattern shows that vitamins like vitamin B complex and vitamin C are prescribed more commonly for the subjects. And 34% of drugs prescribed are from category A of US FDA pregnancy risk category. The prescribing indicators deviate from WHO optimal values due to the conditions of study subjects. This study finds that the prescription patterns of subjects were rational.

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