ASSESSMENT OF DRUG UTILISATION PATTERN DURING PREGNANCY IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Aim and Objectives: The principle aim of this study is the assessment of drug utilization pattern during pregnancy in a tertiary care hospital. **Materials and Methods:** A prospective study was conducted on 100 pregnant women. Statistical analysis was performed to assess whether the drugs were being used appropriately, safely and effectively. **Result:** A total of 100 cases of pregnant women were analyzed. Among the 732 drugs prescribed, the mean number of drugs per prescription was found to be 7.38. Percentage of encounters with an injection was 39.08%, antibiotics was 15.67%. The percentage of drugs prescribed in generic name was 38.26 and 89.39% were prescribed from the Kerala essential medicine list. The drugs were classified according to USFDA pregnancy risk category with 24.9% drugs from category A, 50.2% from category B, 18.23% from category C and 6.67% drugs from category X. A statistically significant difference was seen with mode of delivery and body mass index in pregnancy. The maternal body mass index was higher for pregnant women who underwent Caesarean section. **Conclusion:** The study depicts the current health scenario of pregnant women in Kerala and prescribing pattern in pregnancy.

KEYWORDS: Drug Utilization Evaluation, WHO Prescribing Indicators, USFDA risk category, Pregnancy, Drug Utilization Pattern.

INTRODUCTION

Drug utilization research is used to enable the rational use of drugs in people. The rational use of a drug is to prescribe a well documented drug at the right dose, at the right time with the right information at an affordable price.

Pregnancy is a special physiological condition of having implanted products of conception located either in the uterus or elsewhere in the body. The mother's body undergoes several changes which affects all organ systems which affects the pharmacokinetics of medication use. Pharmacological therapy in pregnancy cannot be completely avoided. Pregnant women encounter medical conditions that need continuous or episodic drug treatment. But the strength and dose of the drug may affect the foetus's development.

During pregnancy, there is a decrease in the concentration of drug excreted by kidney as the plasma volume rises by 30-50%. The gastric emptying time declines in the third trimester which delays the onset of drug effect due to high levels of progesterone. Oestrogen and progesterone may cause drug accumulation or reduce the elimination of some drug as estrogen and progesterone alter hepatic enzyme activity. During the third trimester, maternal and placental blood flow and surface area increases which lead to increase in transplacental transfer of drugs. Such changes give reason for careful use of drugs during pregnancy. Irrational use of drugs during pregnancy can cause abnormal development which may result in birth defects or event deaths.

Despite the rigorous need for data about drug use and pregnancy, pregnant women are usually excluded from medical trials due to ethical reasons. Such data is often extrapolated from animal studies. Therefore, clinicians usually have restricted approach to drug use during pregnancy. Drug utilization studies provide a medium to obtain medication safety information in pregnancy. WHO prescribing indicators are a set of core drug use indicators which measures prescribing practice, patient and facility related factor. Each indicator has a proposed reference value which can help to describe drug use in a specific region or a health care facility. These values may vary based on the region and case mix.

FDA classified drugs based on their risks in pregnancy in to 5 categories A, B, C, D and X. This was introduced due to the discovery of the teratogenic effect of Thalidomide in 1960s and Diethylstilboestrol in 1971.From these, category A is considered to be the safest while category X is contraindicated for use during pregnancy. Category B, C and D can be used if it is strictly warranted. This classification provide a rough concept about the level of teratogenic risk from the drug to the feotus.

Effective research of medication in pregnant women has a vital role in improving the prescribing pattern. Our study evaluates the pattern of drug use, its safety according to US

FDA guidelines and also assesses pregnancy outcomes. Such studies can illustrate current prescribing trends and ensure rationality in prescribing.

The studies of drug utilization pattern during pregnancy in Kerala are few, hence this study aims to add to the current knowledge available from India. This can ultimately help in the safe, efficacious and rational use of drugs in pregnancy.

METHODOLOGY

Study site
Gynaecology department of a tertiary care hospital, Trivandrum.

Sample size
100 Pregnant women.

Study design
Prospective study design.

Duration of study
6 Months (January 2021 to July 2021)

Inclusion criteria
All pregnant women in any trimester, attending antenatal outpatient and inpatient department.

Exclusion criteria
Pregnant women with incomplete medical records.

Data collection
A convenient sample size of 100 pregnant women at the gynaecology department was enrolled in the study. The data collection started during the period of January 2021 to July 2021. The samples were collected based on the inclusion criteria. The statistical analysis was conducted with the aid of IBM SPSS version 25, while the confidence interval and margin of error was set at 95% and 5% respectively. Our concerned data obtained from patient's case records include demographics, social history, number of drugs, diagnosis, and all prescribed drugs including their frequency, dosage and route of administration. Based on the data, we assessed the drug utilization evaluation and analysed whether the given medications were properly utilized in patients.

Data analysis:

Descriptive statistics were used to describe socio-demographic details. ANOVA test is done to determine relationship between the two variables. All statistical analysis was performed using the IBM SPSS statistical, version 25. A p-value <0.05 was considered statistically significant.

Sample size calculation

$$\text{Sample size, } n = \frac{\left[\left(Z1 - \left(\frac{\alpha}{2}\right) + Z1 - \beta\right)^2 * \sigma^2\right]}{d^2}$$

where, $Z1 - \frac{\alpha}{2}$ is the value at significance level 5%

$Z1 - \beta$ is the value of Z at power 95%

σ is the standard deviation of the population

d is the difference between means

Sources of data

Patients case records which contain demographics, social history, number of drugs, diagnosis and all prescribed drugs.

RESULTS

The prospective study was conducted in 100 patients on the Drug Utilization Pattern during Pregnancy. Here we tried to analyze the data and present in detail using appropriate principles and measures. The data analysis consists of two parts:

i) Descriptive Part

ii) Inferential Part

In the descriptive part, we tried to describe the data pertaining to the pregnant women in detail using percentage, mean, median & standard deviation wherever appropriate and in the inferential part, we have included the outcome variables on the basis of objectives.

Descriptive part

In this part we described the patient characteristics with respect to following variables:

❖ Age

❖ Gravida

❖ Parity

❖ Gestational Age

❖ Height

❖ Weight

❖ BMI

❖ Occupation

❖ Educational Status

❖ Comorbidities

Sociodemographic details of patients

Table 1: Sociodemographics details of patients.

Variables	Percentage (%)
Age groups	
<20	2.00
20-35	91.00
≥35	7.00
Gestational period	
First trimester	2.00
Second trimester	3.00
Third trimester	95.00
Gravida	
Prime gravida	59.00
Multi gravida	41.00
Parity	
0 time	62.00
1 time	28.00
2 or more time	10.00
Body mass index	
normal weight	22.00
over weight	42.00
Obese	36.00
Educational status	
High school	15.00
under graduate	40.00
post graduate	39.00
Phd	6.00
Occupation	
staff nurse	14.00
house wife	42.00
teacher	12.00
manager	5.00
Others	27.00
Mode of delivery	
normal delivery	18.00
caesarean section	75.00
instrumental delivery	7.00

Comorbidities	
Hypothyroidism	28.00
Diabetes mellitus	12.00
Epilepsy	1.00
Hypertension	7.00
Msaf	2.00
Polyhydramnios	1.00
Oligohydramnios	3.00
Asthma	1.00

Distribution of patient based on age

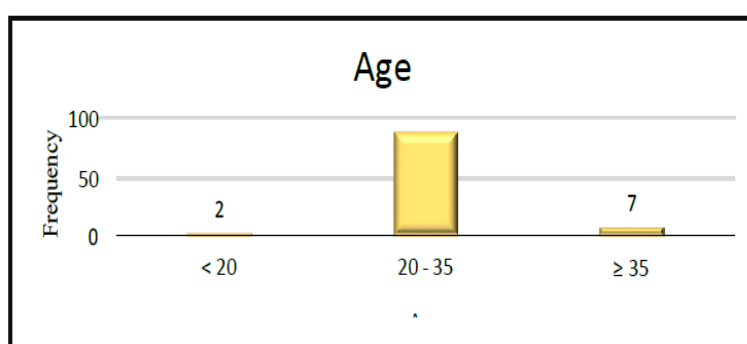It can be observed that majority of the respondents (91 %) belong to '*20 – 35*' Age Group.

Figure 1: Percentage distribution of age.

Distribution of patient based on gestational age

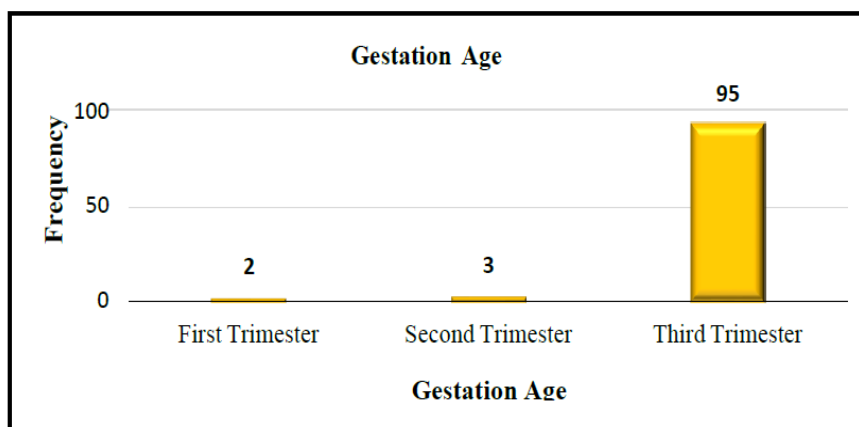It can be observed that majority of the respondents (95 %) are from '*Third Trimester*' of pregnancy.

Figure 2: Percentage distribution of gestational age.

Distribution of patient based on gravida

It can be observed that 59 % of the respondents belong to '*Prime Gravida*' categoryand 41% belong to '*Multi Gravida*' category.
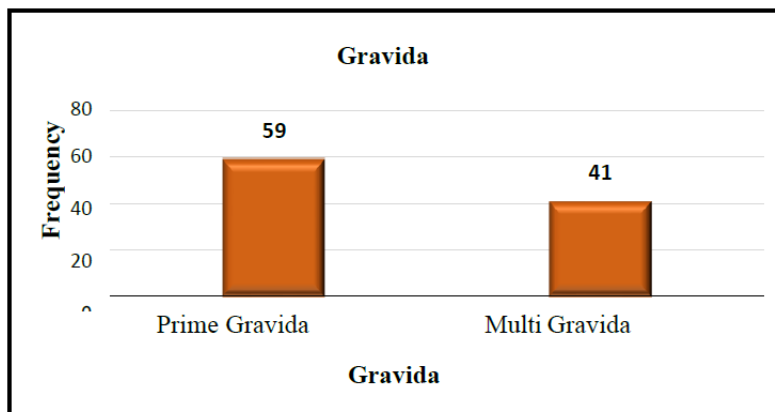
Figure 3: Percentage distribution of gravida.

Distribution of patient based on parity

It can be observed that 62 % of the respondents belong to '*0 times*' category, 28 % of the respondents belong to '1 *time*' category and 10 % belong to '*2 or more times*' category.
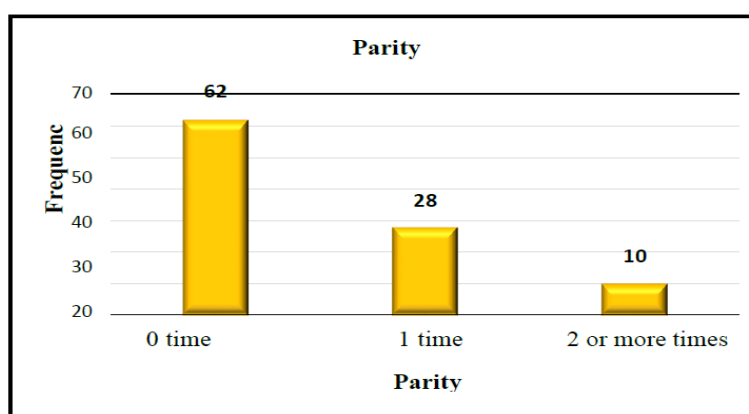
Figure 4: Percentage distribution of parity.

Distribution of patient based on body mass index

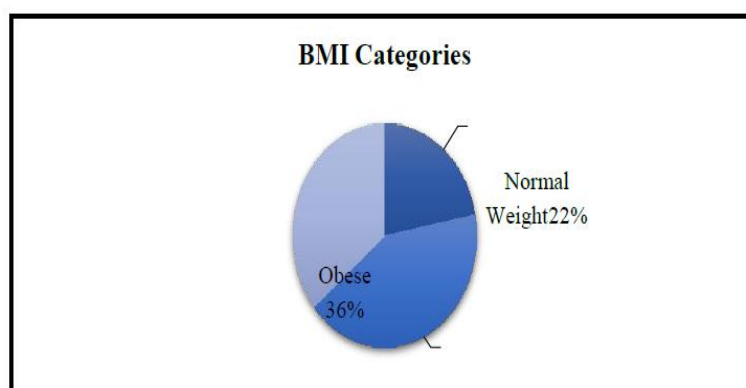It can be observed that majority of the respondents (42 %) are '*Obese*'

Figure 5: Percentage distribution based on body mass index.

Distribution of patient based on educational status

It can be observed that majority of the respondents (40 %) are '*Under Graduates*'.
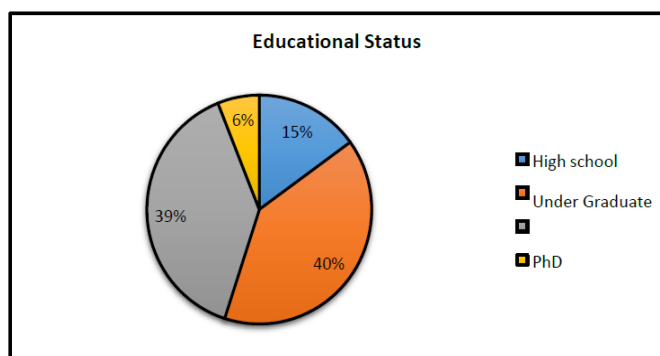

Figure 6: Percentage distribution of educational status.

Distribution of patient based on occupation

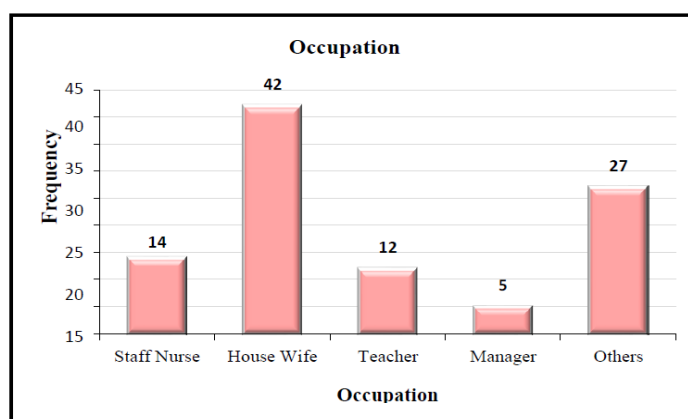It can be observed that majority of the respondents (42 %) are '*House Wives*'.

Figure 7: Percentage distribution of occupation.

Distribution of patient based on mode of delivery

It can be observed that majority of the respondents (75 %) had '*Caesarean Section*'.
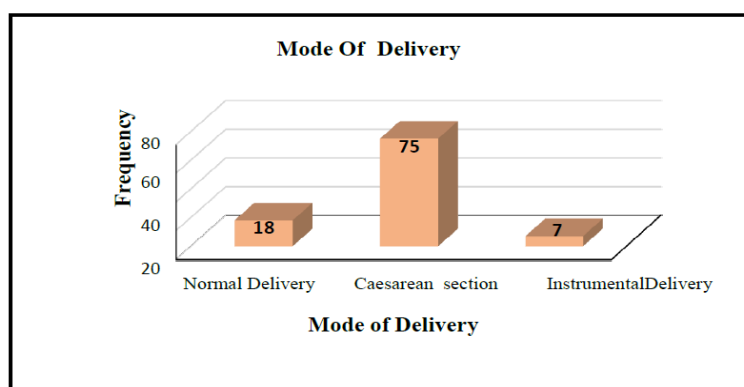

Figure 8: Percentage distribution of mode of delivery.

Distribution of patient based on comorbidities

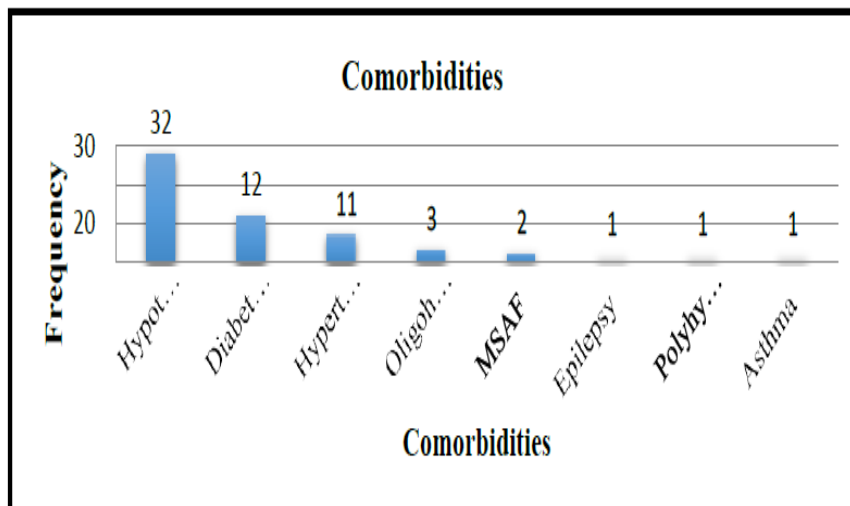It can be observed that majority of the respondents (28 %) are affected by *'Hypothyroidism'*.

Figure 9: Percentage distribution of comorbidities.

Inferential part

In inferential part we have included the following

Drug utilization pattern of commonly prescribed drugs

Table 2: Drug utilization pattern of commonly prescribed drugs.

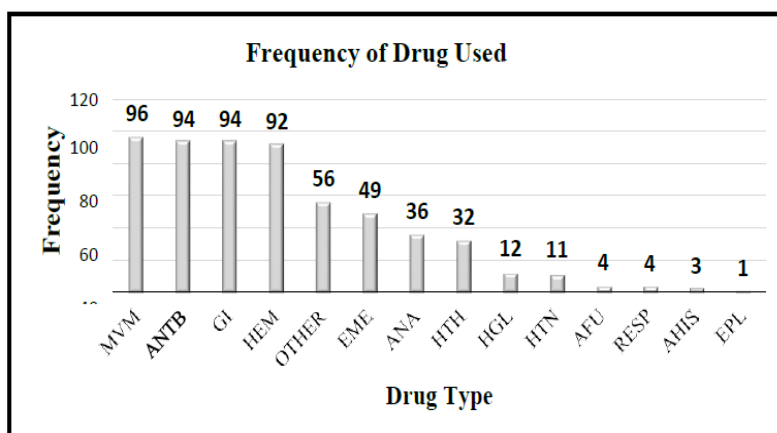| Drug Category	Frequency	Percentage
Vitamin and Mineral Supplements	96	96.00
Antibiotics	94	94.00
GI drugs	94	94.00
Hematinics	92	92.00
Others	54	56.00
Anti-Emetic	49	49.00
Analgesic	36	36.00
Anti-Thyroid	32	32.00
Anti-Diabetics	12	12.00
Anti-Hypertensive	11	11.00
Anti-Fungal	4	4.00
Respiratory Drugs	4	4.00
Anti-Histamine	3	3.00
Anti-Epileptic	1	1.00

Figure 10: Percentage distribution based on commonly prescribed drugs.

In the present study, Vitamins and supplements (96%) was the most commonly prescribed drug followed by Antibiotics (94%), GI Drugs (94%) Hematinics (92%) and others (54%). Other categories of drugs such as Antiemetics, analgesics, Antithyroid, Antidiabetic, Antihypertensive, Antifungal, Respiratory drugs, Antihistamine and antiepileptic were prescribed respectively.

Drug utilization pattern based on Monotherapy & Combination therapy

Table 3: Drug utilization pattern based on monotherapy.

Drugs	Frequency	Percentage(%)
Antibiotics	**84**	**13.10**
Ceftriaxone	47	7.33
Azithromycin	2	0.31
Cefpodoxime	13	2.03

Drugs	Frequency	Percentage (%)
Cefixime	13	2.03
Metronidazole	3	0.47
Cefotaxim	6	0.94
Vitamin and mineral supplements	**77**	**12.01**
Calcium	75	11.70
Ascorbic acid	2	0.31
Gi drugs	**107**	**16.69**
Pantoprazole	94	14.66
Lactulose	6	0.94
Ranitidine	2	0.31
Dicyclomine	4	0.62
Metoclopromide	1	0.16
Hematinics	**163**	**25.43**
Iron	86	13.42
Folic acid	77	12.01

Others	69	10.76
Progestrone	10	1.56
Oxytocin	36	5.62
Betamethasone	6	0.94
Misoprostol	9	1.40

Drugs	Frequency	Percentage (%)
Dydrogesterone	1	0.16
Isoxsuprine	1	0.16
Anti d antibody	2	0.31
Aspirin	4	0.62
Anti-emetic	**47**	**7.33**
Ondansetron	47	7.33
Analgesic	**38**	**5.93**
Paracetamol	35	5.46
Tramadol	3	0.47
Anti-thyroid	**21**	**3.28**
Thyroxine	21	3.28
Anti-diabetic	**11**	**1.72**
Metformin	10	1.56
Insulin aspart	1	0.16
Anti-hypertensive	**11**	**1.72**
Dydrogesterone	1	0.16
Isoxsuprine	1	0.16
Anti d antibody	2	0.31
Aspirin	4	0.62
Anti-emetic	**47**	**7.33**

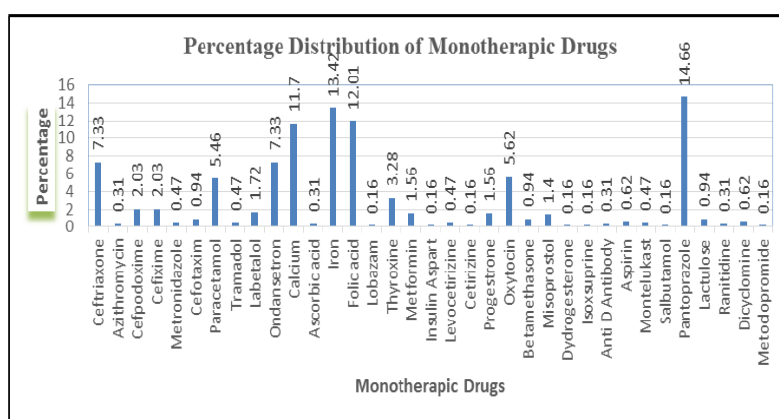| Drugs	Frequency	Percentage (%)
Salbutamol	1	0.16
Antihistamine	**4**	**0.62**
Levocetirizine	3	0.47
Cetirizine	1	0.16
Anti-epileptics	**1**	**0.16**
Lobazam	1	0.16

Figure 11: Percentage distribution of monotherapy.

Hematinics were the most commonly prescribed class of monotherapy constituting 25.43% of the total number of drugs prescribed, this was followed by GI drugs (16.69%), Antibiotics (13.10%), Vitamin and mineral supplements (12.01%), others (10.76%) and Antiemetics (7.33%).

Among the Hematinic agents the prescribing of the Iron (13.42%) was followed by Folic acid (12.01%).

Table 4: Drug utilization pattern based oncombination therapy.

| Drugs	Frequency	Percentage (%)
Cefuroxime + clavulanic acid	11	12.09
Ceftriaxone + sulbactam	20	21.98
Cefoperazone + sulbactam	1	1.10
Amoxicillin + clavulanic acid	1	1.10
Lactobacillus + niacinamide + pyridoxine + Folic acid	3	3.30
L- arginine + proanthocyanodin	2	2.20
Folic acid+iron+iodine+vitamin d+dha	7	7.69
Calcium + vitamin d3	17	18.68
Iron + folic acid	11	12.09
Asparagus racemosus, withania somnifera, Trigonella foenum graeceum, glycyrrhizaglabra and allium sativum.	4	4.40
Clindamycin + clotrimazole	4	4.40
Ambroxol+ guaifenesin+ levosalbutamol	2	2.20
Formoterol + budesonide	1	1.10
Insulinisophane/nph+humaninsulin/ Soluble insulin	7	7.69
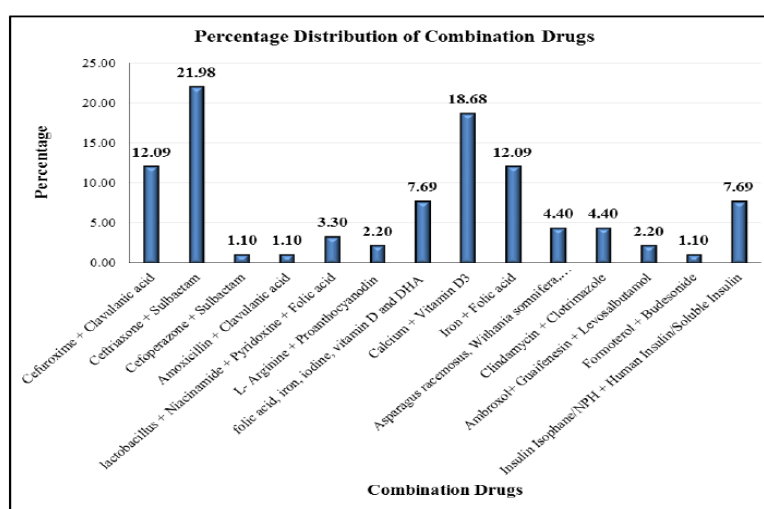
Figure 12: Percentage distribution of combination therapy.

The Ceftriaxone + Sulbactam (21.98%) were the most commonly prescribed combination therapy followed by Calcium + Vitamin D3 (18.68%), Iron + Folic acid (12.09%) and Cefuroxime + Clavulanic acid (12.09%) respectively.

Evaluation of rationality based on who prescribing indicators

Table 5: Who prescribing indicators.

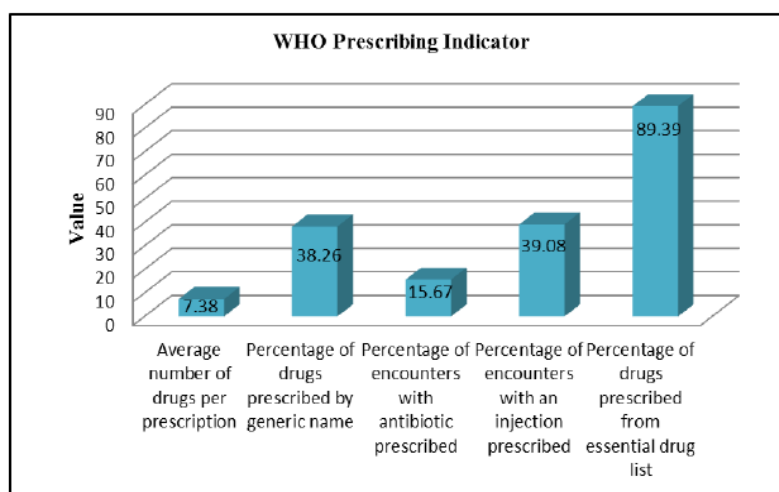| Indicator	Percentage (%)
Average number of drugs perPrescription	7.38
Percentage of drugs prescribedby generic name	38.26
Percentage of encounters withantibiotic prescribed	15.67
Percentage of encounters withan injection prescribed	39.08
Percentage of drugs prescribedfrom essential drug list.	89.39

Figure 13: Distribution based on who Prescribing Indicators.

The total number of drugs prescribed in the study was 735 drugs. Average number of drugs per prescription was 7.38%. Percentage of patients with an injection prescribed was 39.08%, percentage of patients prescribed with an antibiotic was 15.67%, percentage of patients prescribed with generic name was 38.26% and Percentage of drugs prescribed from Kerala essential medicine list was 89.39%.

Classification of drugs based on USFDA pregnancy risk category

Table 6: Risk classification of medicines based on us FDA pregnancy risk category

Us FDA pregnancy risk category	Number of prescribed Drugs	Percentage(%)
A	183	24.90
B	369	50.20
C	134	18.23
D	0	0.00

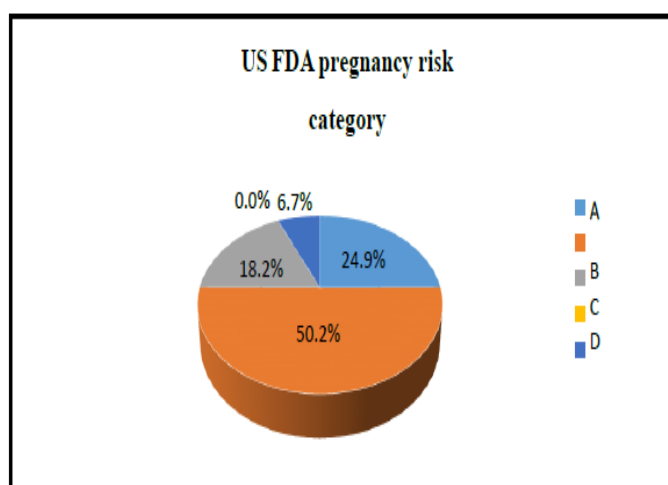| X	49	6.67
Total number of Prescribed drugs	735	100

Figure 14: Classification of medicines based on us FDA pregnancy risk category.

50.2% of drugs prescribed belong to B category; this was followed by A category (24.9%), C category (18.2%), and X category (6.7%) respectively.

Assessment of relationship between materna body mass index and mode of delivery

Table 7: Distribution of BMI categories based on mode of delivery.

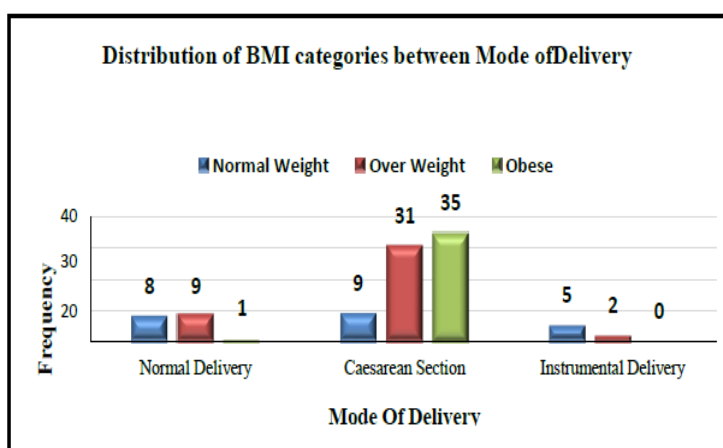| Bmi categories	Mode of delivery		
	Normal delivery	Caesarean Section	Instrumental Delivery
Normal weight	8 (36.36%)	9 (40.91 %)	5 (22.73 %)
Over weight	9 (21.43 %)	31 (73.81 %)	2 (4.76 %)
Obese	1 (2.78 %)	35 (97.22 %)	0 (0 %)
Total	18	75	7

Figure 15: Distribution of BMI category based on mode of delivery.

There are 42 pregnant women with 'Over weight', from that 73.81 % respondents had Caesarean Section delivery.

Table 8: Comparison of maternal body mass index and their mode of delivery.

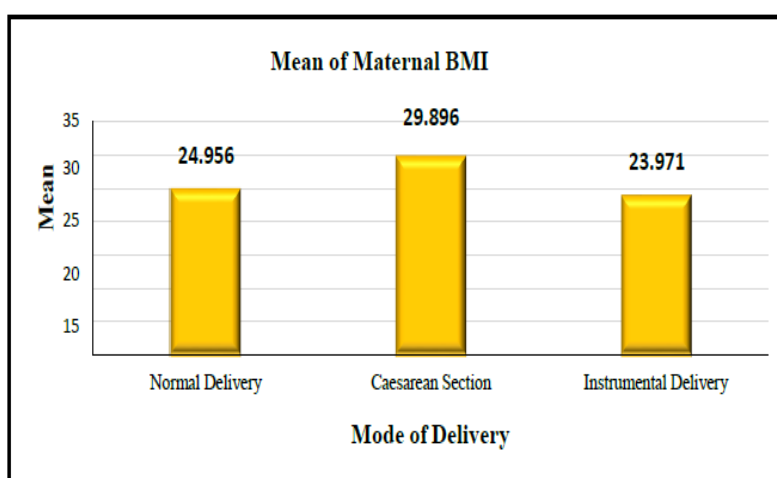| Mode of Delivery	N	Mean	Std. Deviation	F value	p value
Normal Delivery	18	24.956	3.156		
Caesarean Section	75	29.896	3.843	19.166*	< 0.001
Instrumental Delivery	7	23.971	2.615		

*Significant at 0.05 level

Figure 16: Comparison of maternal body mass index and their mode of delivery.

The mean value of maternal body mass index for mode of delivery 'Normal Delivery', 'Caesarean Section' and 'Instrumental Delivery' are obtained as 24.956, 29.896 and 23.971 respectively. It can be observed that maternal body mass index is comparativelyhigher for the respondents who had 'Caesarean Section' mode of delivery.

DISCUSSION

A prospective study was conducted to assess the drug utilization pattern with 100 pregnant women from obstetrics and gynecology department of a tertiary care hospital in Trivandrum. The study revealed that most women belonged to the age group of 25-35 years (91%) similar to the findings by Thacker et al. Majority of the women were primi gravida and 40% of them were undergraduate. All were educated above or up to high school. Women in third trimester composed of 95% of the subjects, with only 2% and 3% from the first and second trimester respectively. This is similar to the findings by Abubakar K et al, owing largely to admission for labour.

Majority of the women were found to have comorbidities (55%). Hypothyroidism was the most reported comorbidity (28%), followed by Diabetes Mellitus (12%) and Hypertension (7%). Most women were found to be over weight (42%) or were obese (36%).

On assessing drug utilization pattern in these pregnant women, the most commonly prescribed drug was found to be Vitamin and Mineral Supplements (96%) which includes Calcium and Vitamin D3. This is followed by Antibiotics (94%), GI drugs (94%) and Hematinics (92%) which were prescribed in majority of the women. This is similar to the findings from the study conducted by Vafaeerokh et al.

The study also revealed that most of the medications prescribed were monotherapy drugs than combination drugs. Out of all monotherapy drugs, Hematinics was found to be the most prescribed monotherapy (25.43%) which include Iron and Folic acid. This can be attributed to the need for supplements during pregnancy. This is followed by GI drugs (16.69%). The most prescribed combination drug was found to be Ceftriaxone + Sulbactam (21.98%), followed by Calcium + Vitamin D3 (18.68%).

The study also analyzed the WHO prescribing indicators with the drugs which depicted the average number of drugs prescribed to be 7.38. This is higher than the WHO standard of 1.6 - 1.8. The percentage of antibiotics and injections prescribed were found to be 15.67% and 39.08% respectively. Only 38.26% drugs were prescribed in generic name, which is low compared to the WHO standard of 100%. Most drugs (89.39%) were found to be taken from the Kerala Essential Drug List 2019-2020.

On classification of drugs into USFDA pregnancy risk categories, most drugs were found to be from category B (50.2%) followed by category A (24.9%). This is similar to the findings from Bharathi et al. Category C drugs formed 18.23% of the drugs. No drugs were found from category D. Use of category X drugs (6.67%), Oxytocin and Misoprostol, was to induce labour and thus its use was justified.

From the data collected, we observed a prevalence of cesarean section in women with higher body mass index. Thus we assessed the relationship between maternal body mass index and modes of delivery in our study The results generated showed a statistically significant difference in modes of delivery with Body Mass Index (P<0.001, F=19.166). This showed that the majority of pregnant women with a BMI >=25 (66%) were found to have undergone

cesarean section compared to normal and instrumental delivery. This indicates that higher maternal body mass index is associated with increased likelihood of Caesarean section. This is in accordance to findings from Inigo Melchor, Angeliki et al,

CONCLUSION

Drug use has become prevalent in pregnancy for the treatment of conditions caused by or unrelated to pregnancy. The effect of these drugs on maternal and fetal health is of great concern. According to a study by Sachdeva et al, more than 90% pregnant women take prescription and over the counter medications.

The study showed that an average of 7.38 drugs were prescribed to pregnant women. The most commonly prescribed drugs are Vitamin and Mineral supplements, followed by Antibiotics and Gastrointestinal drugs. Pantoprazole was the most commonly prescribed monotherapy drug and Ceftriaxone + Sulbactam was found to be the combination most prescribed.

Hypothyroidism was reported to be the most common comorbidity. Most drugs were found to be from USFDA pregnancy risk category B. Most of the drugs were prescribed for a specific indication. Though this classification was replaced by Pregnancy and Lactation Labeling Rule (PLLR), risk categories can provide a rough outline of the level of drug related teratogenic risks in pregnancy and thus is used in this study.

Less than half of the drugs were prescribed in generic name. The percentage of antibiotics prescribed exceeded the WHO proposed value.89.39% drugs were prescribed from the Kerala Essential Drug List (2019-2020).

The study found that there was a significantly higher rate of Cesarean section in overweight pregnant women.

In conclusion, the management of conditions in pregnant women in the Obstetrics and Gynecology department of a Tertiary Hospital in Kerala complied with rational prescribing practices to a high extent. Periodic studies, dissemination of updated guidelines to prescribers, medication counselling can help to improve the safety of drug use and ensure rational drug use and prescribing in pregnancy.

ACKNOWLEDGEMENT

We bow in gratitude before the Almighty God for the wisdom and perseverance that has been bestowed upon us during this research project, and indeed, throughout our life.

The success and final outcome of this project required a lot of guidance and assistance from many people and we are extremely privileged to have got this all along the completion of our project. All that we have done is only due to such supervision and assistance and we would not forget to thank them.

We are also thankful to Dr. Shaiju David Alfi, Managing Director, The Dale View College of Pharmacy and Research Centre, Thiruvananthapuram for giving us good support and facilities, in spite of his busy schedule.

We would like to express our sincere gratitude and heartfelt indebtedness to Dr. P Manoj Kumar, Principal, The Dale View College of Pharmacy and Research Centre, Thiruvananthapuram, for his valuable guidance, constant encouragement and creative suggestions during the course of this project and the preparation of this project.

We humbly owe our gratitude and sincere regards to our respected teacher and Head of the Department, Mrs. Senthila S, Associate Professor, Department of Pharmaceutics, The Dale View College of Pharmacy and Research Centre, Thiruvananthapuram, for constant inspiration and encouragement to conduct the study.

Words are not enough to express our deep gratitude to our esteemed clinical guide Dr. Beena S, MBBS, DGO, Consultant Gynecologist in SK Hospital, Thiruvananthapuram, for his keen interest, timely help and valuable suggestion from very beginning till the completion of the study.

We take this opportunity to express our sincere thanks and gratitude to the unstinting and eminent project guide Mr. Arun J L, Associate Professor and Co-guide Ms. Lilly M Assistant Professor, Department of Pharmacy Practice, The Dale View College of Pharmacy and Research Centre, Thiruvananthapuram.

We extend our special thanks to Mrs. Kavitha K V, Dr. Aneeta Toms, Mrs. Safna N Fazil and to all the staff members of The Pharmacy Practice Department for their valuable help and encouragement which lead to the successful completion of this project.

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