

ASSESSING THE DRUG UTILIZATION PATTERN IN ANTENATAL WOMEN ATTENDING OUT PATIENT DEPARTMENT OF A TERTIARY CARE HOSPITAL.

¹*Dr. Jyothi R., ²Dr. Basavaraj Bhandare and ³Dr. Satyanarayana V.

¹Postgraduate, Department of Pharmacology, Rajarajeswari Medical College & Hospital, Bangalore.

²Professor & HOD, Department of Pharmacology, Rajarajeswari Medical College & Hospital, Bangalore.

³Professor, Department of Pharmacology, Rajarajeswari Medical College & Hospital, Bangalore.

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*Correspondence for Author

Dr. Jyothi R.

Postgraduate, Department
of Pharmacology,
Rajarajeswari Medical
College & Hospital,
Bangalore.

ABSTRACT

Background: The state of pregnancy requires that all medications should be prescribed with specific caution. The physiological state of pregnancy has an effect on the pharmacokinetics of drugs administered, with attendant risk on the developing foetus. Therefore categorization of drugs according to their pregnancy risk should be taken into consideration before a drug is prescribed for pregnant women. **Objectives:** To assess the drug utilization pattern in antenatal women attending out patient Department of Obstetrics and Gynaecology. **Methods:** Prospective, Observational cross sectional study was conducted on 300 patients in Department of Obstetrics and Gynaecology OPD at Rajarajeswari Medical College and Hospital after taking Informed Consent. **Results:** Out of 300 women, 42.33% were

22-24 years of age. The average number of drugs per pregnant woman was found to be 3.96. The most frequently prescribed drugs were calcium, oral iron, folic acid preparations, antibiotics and analgesics. Within the prescriptions the percentage of the drugs according to the categories was: Category A (68.23%), Category B drugs (23.27%), Category C drugs (4.62%), Category D drugs (4.03%), and Category X drugs 0.00% (none). **Conclusion:** Calcium, iron and Folic acid were the most frequently prescribed drugs. The study concludes that most of the drugs prescribed are safer.

KEY WORDS: Pregnancy, Drug Utilization.

INTRODUCTION

Pregnancy is a time of profound physiological changes in a woman's body. These unique changes challenge clinicians managing disease states during pregnancy in the selection of medications best suited to treat their patients.^[1]

Antenatal care is organized medical service including examination and advising a pregnant woman with the objective that every wanted pregnancy culminates in the delivery of a healthy baby without impairing the health of the mother. The maternal mortality in India ranges from 100/1,00,000 in Kerala to 1200 to 1500/ 1,00,000 in the Northern States with an average of 400/1,00,000. About 30% of the babies are of low birth weight and perinatal mortality is in the range of 70-80/1,000. Main causes for such unfavorable outcomes continue to be infections, haemorrhage, anemia and pre-eclampsia which can be prevented by optimum antenatal care.^[2] Hence timely treatment of these conditions can reduce the perinatal morbidity and mortality.

All drugs used during the first (first 12 weeks), second (13th to 24th week) and third (24th week onwards) trimester of pregnancy were further classified into category-A, category-B, category-C, category-D and category-X, according to the classification for drug use during pregnancy, introduced by the US Food and Drug Administration (FDA) in 1979.^[3]

The category-A includes drugs that have shown no risk to the foetus after adequate, well-controlled studies in pregnant women. For drugs in the category B, animal studies have revealed no evidence of harm to the foetus or any adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the foetus. The category C includes the drugs, which have shown an adverse effect in animal studies and there are no adequate and well-controlled studies in pregnant women. For drugs in the category D, there is positive evidence of human foetal risk, but the benefits from use in pregnant women may be acceptable despite the risk. However, drugs with classification X are "contraindicated in pregnancy".^[3]

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.^[4]

It has been documented that congenital abnormalities caused by human teratogenic drugs accounts for less than 1% of total congenital abnormalities.^[5] Moreover in India, due to easy availability of drugs coupled with inadequate health services, increased proportions of drugs are used as self medication (for common complains and infective conditions), as compared to the prescribed drugs.^[6]

Drug utilization studies (Pharmacoepidemiology) 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.^[7]

Hence, the present study was conducted to assess the drug utilization pattern in antenatal women attending OPD of Obstetrics and Gynaecology Department.

MATERIALS AND METHODS

After taking clearance from Institutional Ethics Committee a Prospective, observational cross sectional study was conducted on 300 patients in Department of Obstetrics and Gynaecology OPD at Rajarajeswari Medical College and Hospital. Informed consent was taken.

Data was collected from case records of antenatal women in the proforma designed for the study including.

- Patient's demographic details,
- Pregnancy duration,
- Chief complaints/ Provisional diagnosis and
- Complete prescription,
- Trimester wise drug use pattern, and
- Percentage of drugs prescribed as fixed dose combination

Sample size- 300

Inclusion criteria

- The new cases of antenatal patients were included.

Exclusion criteria

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

The collected data was analyzed as per WHO criteria of Drug Prescription and the socioeconomic data was analyzed as per Kuppuswamy's Classification.

Prescribing indicators (as per WHO)

1. Average number of medicines
2. Percentage of patients receiving injectables
3. Percentage of patients receiving antibiotics

Patient indicators

1. Demographic data of antenatal women
2. Obstetric history.
3. Drug count
4. Drugs use based on trimester of pregnancy

STATISTICAL METHOD

The data collected was analyzed statistically using descriptive statistics. Wherever necessary, the results are depicted in the form of percentages and graphs.

RESULTS

At the end of the study a total of three hundred prescriptions were studied. The age of patients ranged from 18-36 years. Majority of the patients in the study were in the age group 22-24 years (42.33%) (**Table-1**). Patients obstetric history showed that 45% were primigravida, while 55% were multigravida. Out of the total women in the study 28% were in their first trimesters, 33% in their second trimesters and 39% in their third trimesters.

TABLE 1: DISTRIBUTION OF AGE IN PATIENTS.

Age in years	No of patients	Percentage
19-21	55	18.33
22-24	127	42.33
25-27	64	21.33
28-30	37	12.33
31-33	15	5
34-36	2	0.66

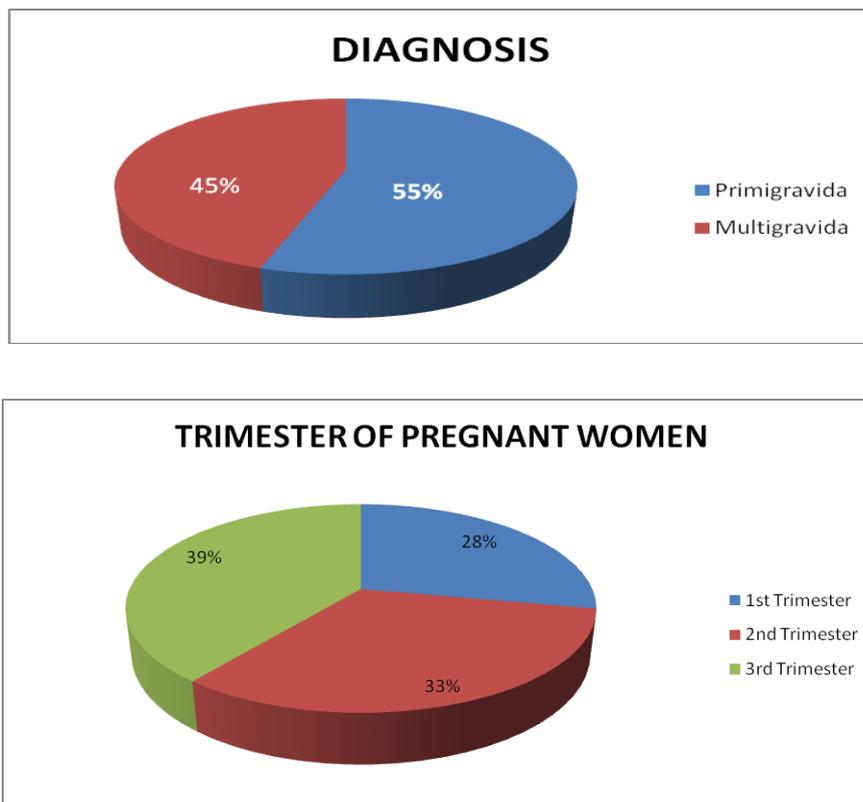


FIG 1: OBSTETRIC HISTORY.

According to Kuppuswamy Classification In this study 49% women belong to lower middle class followed by 38% women to lower class and 13% women belongs to upper-middle class.

TABLE 2: DISTRIBUTION OF PATIENTS BASED ON SOCIO-ECONOMIC STATUS (KUPPUSWAMY CLASSIFICATION).

Socio-economic status	No of patients	Percentage
Lower	114	38
Lower –middle	147	49
Upper- middle	39	13
Upper	0	0

Most common complaints of women coming to antenatal OPD were vomiting 96(32%) and anaemia 65 (21.66%) followed by gestational hypertension 23(7.66%), diabetes 16(5.33%) and upper respiratory tract infections 12(4%). Majority of women were coming for routine antenatal check-ups.

TABLE 3: PATIENTS WITH ANTENATAL COMPLICATIONS.

Antenatal complications	No of patients	Percentage
Anaemia	65	21.66
Gestational Hypertension	23	7.66
Hyperemesis gravidarum	96	32
Diabetes	16	5.33
URTI	12	4

Based on the WHO core prescribing indicators, out of the total number of drugs prescribed the average drug per prescription was 3.96. Percentage encounter with antibiotics and Injectables were 26.33% and 16.33% respectively.

TABLE 4: WHO PRESCRIBING INDICATORS.

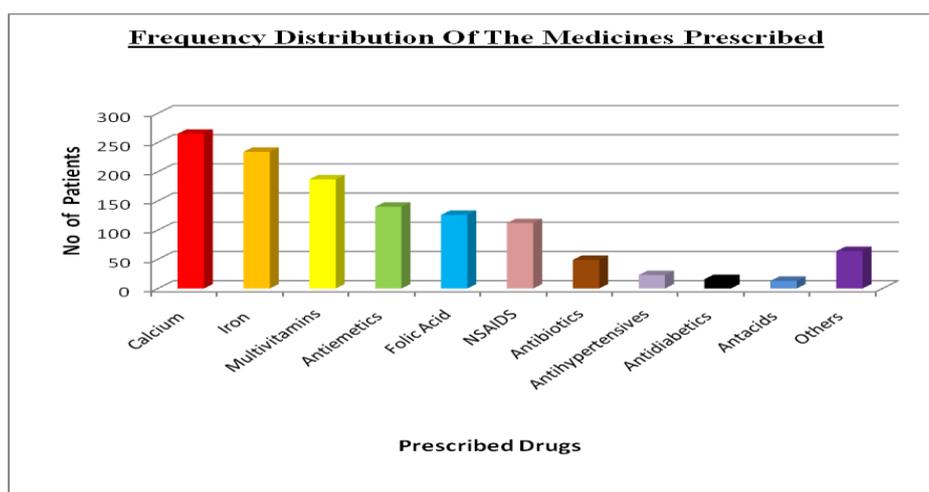
PRESCRIPTION INDICATORS	VALUE OBTAINED	WHO STANDARD
Average number of drugs per Pregnant women	3.96	1.6 -1.8
Percentage encountered with injections	26.33%	13.4 -24.1
Percentage encountered with antibiotics	16.33%	20- 26.8

The most frequently prescribed drugs were calcium, oral iron, multivitamins, antiemetics and folic acid preparations. Prescription pattern among the patients observed was like Calcium (88.3%), Iron (78%) and Multivitamins (62.3%) followed by Antiemetics (46.7%), Folic Acid (42%), NSAIDS (37.3%), Antibiotics (16.33%), Antihypertensives (7.66%), Antidiabetics (5.3%), Antacids (4.3%), and others (21.3%).

Most common antibiotic prescribed was Cephalosporins, Amoxicillin. Most common antacid prescribed was Ranitidine hydrochloride. Paracetamol and Diclofenac Sodium was the most frequently prescribed analgesic. Promethazine was most commonly used antiemetic. Prescribed antihypertensives were Alpha methyl dopa and Labetalol. Most frequently prescribed antidiabetics were Insulin, and Glyburide.

TABLE 5: FREQUENCY DISTRIBUTION OF THE MEDICINES PRESCRIBED.

Prescribed Medicines	Total	Percentage
Calcium	265	88.3
Iron	234	78
Multivitamins	187	62.3
Antiemetics	140	46.7
Folic Acid	126	42
NSAIDS	112	37.3
Antibiotics	49	16.33
Antihypertensives	23	7.66
Antidiabetics	16	5.3
Antacids	13	4.3
Others	64	21.3



Within the prescriptions the percentage of the drugs according to the categories was: Category A drugs in which adequate clinical studies have shown no risk to foetus in any trimester were 68.23%, mainly Folic acid, Ferrous Sulphate, calcium and multivitamins. Category B drugs in which Animal studies have not shown adverse effect on the foetus and there are inadequate clinical studies were 23.27%, mainly Amoxycillin, Ampicillin/Cloxacillin, Metronidazole, Azithromycin, Paracetamol, and Diclofenac Sodium. Category C drugs in which animal studies have shown adverse effects, and no adequate clinical studies, may be useful in pregnancy in spite of potential risks were 4.62%, mainly Fluoroquinolones, Ranitidine, and Antidiabetics. Category D drugs in which there is evidence of risk to human foetus, but potential benefits may be acceptable despite potential risks were 4.03%, mainly Antihypertensives and Category X drugs in which animal/human studies show foetal abnormalities, but risks involved clearly outweigh benefits were 0.00% (none). Prescribing of Category X drugs during pregnancy were not seen, Category B and C drugs were common and category A drugs were maximum as shown in TABLE 6.

TABLE 6: FDA DRUG RISK CATEGORY WISE PRESCRIPTION PATTERN.

CATEGORY	PERCENTAGE OF DRUGS
Category A	68.23%
Category B	23.27%
Category C	4.62%
Category D	4.03%
Category X	NIL

DISCUSSION

Rational drug use in pregnancy requires the balancing of benefits and potential risks associated with the use of the drug. The benefits of rational drug use during pregnancy are not only restricted to the recovery of maternal health, but are also helpful in the development of the foetus. By appropriate treatment of conditions like diabetes mellitus and infectious diseases of genital organs, embryopathies, preterm births and abortions could be prevented.^[8]

In our study, 42.33% of pregnant women are in the age group of 22-24 years who majorly visited the hospital compared to other age groups and socio-economic status comparison shows that majority are lower-middle class (49%). This was synonymous with the study conducted in Kadapa by P. Pallavi Priya et al.^[9]

We observed majority of pregnant women (39%) visited the hospital during their first trimester at their first visit for antenatal care, which was in contrast to the study by Rasmisharma et al.^[8] in which 67.9% of women visited during their third trimester followed by second and first trimester. Pregnant women with multigravida (55%) visited more than primigravida (45%). This was synonymous with the study conducted by Abubakar K et al.^[10]

In this study the average number of drugs per prescription was (3.96) which was higher than the range of the standard set by WHO (1.6-1.8) but percentage of patients prescribed with injection was 26.33%, which is higher compared to the range of the standard set by WHO. Calcium (88.3%), ferrous sulphate (78%), multivitamins(62.3%) and Folic acid(42%) were the most frequently prescribed drugs, along with Antibiotics (19.86%) and Analgesics (15.61%) which was in accordance with earlier studies done in other countries like Ethiopia.^[2] India.^[8,11-12,] Finland.^[13] and Australia.^[14]

As per FDA category in our study majority of drugs were from category A (68.23%) followed by category B (23.27%), category C (4.62%) and category D (4.03%). No drugs were prescribed from category X. Similar pattern of category distribution was reported from

Ahmedabad by Harsh Joshi et al.^[15] In a retrospective study in Finland, it was found that 20.4% of women purchased at least one drug classified as potentially harmful during pregnancy and 3.4% purchased at least one drug classified as clearly harmful.^[16] In a study by Bratislava and Nitra, it was reported that a vast majority of prescribed drugs during pregnancy, belonged to category C.^[17] So from the above data we can say that the prescription habit in our set up was quite safe.

CONCLUSION

Iron, calcium and folic acid were the most frequently prescribed drugs. Overall drug use pattern is rational. Nearly all the drugs were prescribed from essential drugs list. Majority of the drugs were prescribed as per FDA category A, the safest category during pregnancy. Hence we can conclude that polypharmacy was not practiced as the average number of drugs per prescription was comparable with a standard set by WHO.

Our study can help in evaluating the existing drug use pattern and in planning appropriate interventions to ensure rational drug therapy.

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