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A STUDY OF THE PRESCRIPTION PATTERN OF ANTIHYPERTENSIVE DRUGS IN PREGNANCY INDUCED HYPERTENSION IN A TERTIARY CARE TEACHING HOSPITAL IN ASSAM

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ABSTRACT: Worldwide, hypertension represents one of the most common complications of pregnancy. Hypertensive disorders continue to occur globally, complicating 5-20% of pregnancies. Its incidence varies from 2 to 8% of pregnancies in developed countries reaching 10% or more in developing countries. Hypertension in pregnancy is defined as systolic blood pressure (sBP) ≥ 140 mmHg and/or diastolic blood pressure (dBP) ≥ 90 mmHg, or by $\uparrow$ in sBP ≥ 30 mmHg, or in dBP ≥ 15 mmHg from preconception or first trimester blood pressure confirmed by two measurements 6 hours apart. It is associated with high rates of perinatal morbidity and mortality and is the third most common cause of maternal death worldwide. The present study was designed to analyze the physicians prescribing pattern of various antihypertensives, a drug utilization study of both qualitative and quantitative variants, also describing physician's compliance with existing guidelines. The greatest challenge in treating hypertension in pregnancy is to reduce the blood pressure to assure the safety of mother and at the same time not to compromise uteroplacental perfusion or cause harmful effects on the fetus.

INTRODUCTION: Hypertensive disorders of pregnancy (HDP), comprising conditions such as gestational hypertension, preeclampsia, and eclampsia, represent a significant global health concern, contributing to maternal and fetal morbidity and mortality¹. Pre-eclampsia is a complex and enigmatic disorder that manifests during pregnancy and is characterized by hypertension and proteinuria. It affects approximately 6-8% of pregnancies worldwide and poses significant risks to maternal and fetal health.

Hypertension in pregnancy is defined as systolic blood pressure (sBP) ≥ 140 mmHg and/or diastolic blood pressure (dBP) ≥ 90 mmHg, or by $\uparrow$ in sBP ≥ 30 mmHg, or in dBP ≥ 15 mmHg from preconception or first trimester blood pressure confirmed by two measuring 6 hours apart². It's interesting to note that 7% of patients with pre-eclampsia in one pregnancy run the risk of suffering it again in subsequent pregnancies³.

Addressing the problems associated with preeclampsia is crucial for improving maternal healthcare in India, where the prevalence of the illness is estimated to be around 8-10% among pregnant women⁴. The exact pathogenesis of pre-eclampsia remains elusive, but emerging evidence suggests a failure in the placental development process, specifically the transformation of spiral

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arteries. This compromised placentation leads to a stressed and under-perfused placenta, triggering a cascade of events that contribute to the characteristic clinical features of pre-eclampsia⁵. Hypertension in pregnancy is of following major types

Chronic Hypertension: Blood pressure (BP) $\geq$ 140/90 mmHg is diagnosed before pregnancy, in first 20 weeks of gestation or persists 42 days after delivery.

Gestational Hypertension: Blood pressure $\geq$ 140/90 mmHg established after 20 weeks of gestation and not associated with proteinuria.

Preeclampsia Eclampsia: Hypertension, proteinuria ($\geq$ 0.3 g/24 hours) and edema after 20th week of gestation. Eclampsia is defined as appearance of generalized convulsions associated with signs of preeclampsia, or their occurrence within 7 days of parturition and not caused by epilepsy or other convulsive disorder².

A number of drugs in various combinations are generally used for effective long-term management of hypertension. Therefore, drug utilization studies, which evaluate, analyze the medical, social and economic outcomes of the drug therapy, are more meaningful and observe the prescribing attitude of physicians with the aim to provide drugs rationally⁶. The World Health Organization (WHO) in 1997 defined drug utilization as the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences⁷.

The present study was designed to analyze the physicians prescribing pattern of various antihypertensives, a drug utilization study of both qualitative and quantitative variants, also describing physician's compliance with existing guidelines. The greatest challenge in treating hypertension in pregnancy is to reduce the blood pressure to assure the safety of mother and at the same time not to compromise uteroplacental perfusion or cause harmful effects on the fetus⁸.

MATERIALS AND METHODS: A prospective observational study was conducted by Department of Pharmacology in collaboration with the

Department of Obstetrics & Gynaecology in Gauhati Medical College and Hospital, Guwahati, after taking permission from the Institutional Ethics Committee (MC No: 190/2007/Pt-II/March.2024/15). The Case record sheets of the patients diagnosed for pregnancy induced hypertension or gestational hypertension admitted to the obstetrics ward were reviewed for 6 months. The information regarding total number of drugs prescribed, with dosage, frequency and duration were recorded and from this the core indicators like prescribing indicators and complementary indicators were evaluated.

Selection Criteria:

Inclusion Criteria: All admitted women in delivery ward of O & G department of GMCH with gestational age greater than 28 weeks.

Exclusion Criteria:

1. Patients who are a known case of chronic hypertension.
2. Patients who are not willing to give consent.

Prescribing Indicators⁹:

(a) Average number of drugs per patient was calculated by dividing the total number of different drug products prescribed by the number of patients surveyed.

(b) Percentage of drugs prescribed by generic name was determined by dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, multiplied by 100.

(c) Percentage of drugs prescribed from essential drug list (NLEM 2022) was determined by dividing the number of products prescribed from essential drug list by the total number of drugs prescribed, multiplied by 100.

Complementary Indicators: Effect of the drug on the fetus (Low birth Weight, IUGR, death or defect, were also recorded) the prescribed drugs also reviewed for their category and safety.

Definition of Risk Factors¹⁰:

Category A: Controlled studies in women fail to demonstrate a risk to the fetus in any trimester and the possibility of fetal harm remains remote.

Category B: Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the 1st trimester (and there is no evidence of a risk in later trimesters).

Category C: Either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal or other) and there are no controlled studies in women and animals are not available. Drugs should be given only if the potential benefits justify the potential risk to the fetus.

Category D: There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g. if the drug is needed in a life threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

Category X: Studies in animals or human beings have demonstrated fetal abnormalities or there is

evidence of fetal risk based on human experience or both, and the risk of the use of these drugs in pregnant women clearly outweighs any possible benefits.

RESULTS: Among prescriptions collected 3% were with eclampsia, 22% were with oligohydramnios and around 31% with anemia.

TABLE 1: DEMOGRAPHIC DISTRIBUTION OF THE PATIENTS

Age group (years)	Number of patients	Percentage
18-20	16	10.7%
21-25	43	28.7%
26-30	44	29.3%
31-35	45	30%
36-40	2	1.3%

TABLE 2: GRAVIDITY WISE DISTRIBUTION OF PATIENTS

Gravida	Number of patients	Percentage
Primi	76	50.7%
Second	47	31.3%
Third	17	11.3%
Fourth	10	6.7%

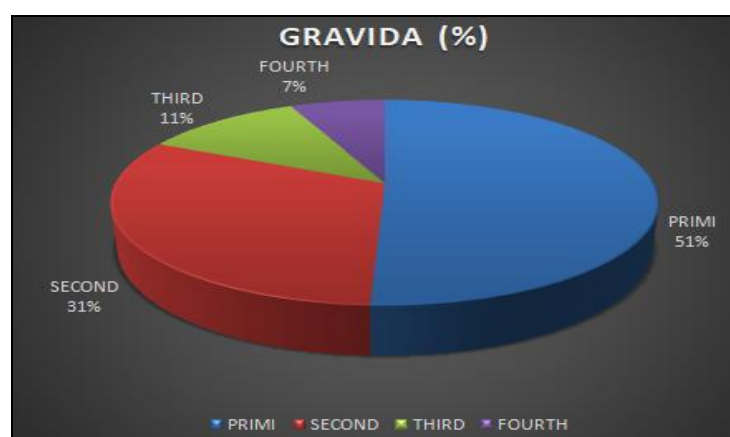


FIG. 1: GRAVIDITY WISE DISTRIBUTION OF PATIENTS

TABLE 3: BLOOD PRESSURE RANGE OF PATIENTS BEFORE ADMINISTRATION OF DRUGS

BP range	BP (mm of Hg) systolic/diastolic	Number of patients	Percentage
Mild	140-160/90-110	96	64%
Severe	>160/110	54	36%

TABLE 4: MATERNAL COMPLICATIONS

Maternal complications	Number of patients	Percentage
Eclampsia	5	3.3%
Oligohydramnios	33	22%
Anaemia	46	30.7%
LVSD	1	0.7%
Hypothyroidism	10	6.7%
Bronchial Asthma	1	0.7%

*LVSD: Left ventricular systolic dysfunction. *Remaining 35% patients didn't present with any other maternal complications other than preeclampsia.

TABLE 5: NEONATAL OUTCOMES

Neonatal outcome	Number of patients	Percentage
Low birth weight/preterm labour	34	22.6%
Fetal distress	62	41.3%
IUGR	12	8%

*Remaining 28% babies didn't go through the above complications.

TABLE 6: PRESCRIBING PATTERN OF ANTIHYPERTENSIVE DRUGS IN HOSPITAL

Drug therapy	Number of patients	Percentage
Single Drug	128	85.3%
Two Drugs	22	14.7%

TABLE 7: NAME OF ANTIHYPERTENSIVES USED AND THEIR FREQUENCY

Name of drug used	Frequency	Category of drug
Labetalol	68	45.3%
Nifedipine	45	30%
Amlodipine	37	24.7%

TABLE 8: MODE OF DELIVERY OF THE PIH PATIENTS

Mode of delivery	Number of patients	Percentage
Cesarean Section	124	82.7%
Vaginal Delivery	26	17.3%

TABLE 9: DETAILS OF DRUG USE INDICATORS

Indicators	Data
Core indicators	
Average drugs prescribed per prescription	6.2
Average number of antihypertensives per prescription	1.3
Prescriptions by generic name	65%
On essential list	88%
Facility indicators	
Availability of EDL	YES
Key drugs available	YES

DISCUSSION: Rational prescribing of drugs is crucial in pregnancy as it involves risk to the mother as well as the fetus. Since, pregnancy induced hypertension (PIH) is one of the most common complications of pregnancy, we planned this study to look into the prescribing pattern in PIH patients. The most commonly prescribed antihypertensives were Labetalol, Nifedipine and Amlodipine, all of which belongs to Category C. Single drug therapy was given to majority of patients. The incidence of PIH was highest among primigravida (50.7 %) in our study this co-relates with study by Tanuja *et al* (2010) ¹¹. Fetal complications like premature babies, IUGR and fetal distress were noticed among the PIH patients.

CONCLUSION: The present study concluded that the incidence of hypertensive disorders in pregnancy was high for primigravida and in an age group of 31-35 years. Labetalol was the commonest prescribed antihypertensive as monotherapy. Further studies with larger sample size can be

conducted to study the prescription pattern of antihypertensives in PIH patients as well as to study any co-relation of complications with the use of drugs.

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CONFLICT OF INTEREST: Declared none

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