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A prospective study to assess the clinical risk factors and the drug utilization pattern in female patients with gestational hypertension

Mathew George
bijuvij075@gmail.com
Pushpagiri College of Pharmacy,
Thiruvalla, Kerala

Lincy Joseph
sonysarovaram@gmail.com
Pushpagiri College of Pharmacy,
Thiruvalla, Kerala

Naveena Susan Symon <u>naveenatom20@gmail.com</u> Pushpagiri College of Pharmacy, Thiruvalla, Kerala

ABSTRACT

Hypertension in pregnancy is a pregnancy-specific, multisystem disorder characterized by the development of edema, elevated blood pressure and proteinuria after 20 weeks of gestation. The hypertensive disease occurs in 5% to 10% of all pregnancies and is a major cause of maternal and perinatal morbidity and mortality. A prospective observational study was performed to assess the risk factors that potentiate gestational hypertension and also to evaluate the drug utilization pattern in patients diagnosed with gestational hypertension. 72 patients who were admitted with gestational hypertension in the Gynaecology department of Pushpagiri Medical College Hospital were enrolled for this study. A standardized data collection form was prepared and necessary data were collected which includes the demographic details, obstetric history, past medical history, past medication history, current medication etc. The risk factors, complications associated with gestational hypertension and drug utilization pattern were analyzed. Pre-existing hypertension and diabetes mellitus are found to be the most common risk factors of gestational hypertension in this study. Most commonly prescribed anti-hypertensive drug was Labetalol and found to be safe. The antihypertensive drug therapy was found to be significant. From the study, it was found out that the overall drug utilizes an action pattern in gestational hypertension patients was in accordance with the specific hypertensive treatment guidelines.

Keywords— Gestational hypertension, Drug utilization, Antihypertensives, Pregnancy, Maternal complications, Fetal outcomes

1. INTRODUCTION

Hypertension in pregnancy is a pregnancy-specific, multisystem disorder characterized by the development of edema, elevated blood pressure and proteinuria after 20 weeks of gestation. In normotensive women, blood pressure in early pregnancy decreases up to 20 weeks of gestation and gradually increases to normal or higher than pre-pregnancy levels before delivery. 2

The hypertensive disease occurs in 5% to 10% of all pregnancies and is a major cause of maternal and perinatal morbidity and mortality. From 15% to 24% of maternal deaths in developed countries are attributed to hypertensive disorders in pregnancy.³ Though the exact cause of hypertensive disorders in pregnancy is not understood, it is believed to be a disorder of the blood vessel lining. Abnormalities of the placenta also described as a causative factor. It also arises due to a combination of genetic and environmental factors.⁴ The early prediction and detection of hypertensive disorders in pregnancy are important for its monitoring and management to reduce maternal and fetal mortality.⁵ Factors considered to place a pregnancy at high risk include previous severe preeclampsia, renal disease, autoimmune disease, diabetes, and chronic hypertension. During pregnancy, maternal risk factors which may lead to PIH including nulliparity, previous history of PIH, more than 5 years since the last gestation, multiple pregnancies, maternal blood pressure of 130/90 mmHg or more in the first trimester of pregnancy, urinary tract infection and periodontal disease. The antihypertensives indicated for maternal benefits, it may prolong the pregnancy and improves fetal maturity. But in severe hypertension, since the uteroplacental blood flow reduces, women are delivered soon after their blood pressure is controlled. This results in a quick reduction in maternal blood flow that adversely affects the fetal health.⁶ For a blood pressure $\leq 140/90$ mm Hg, drug therapy is not generally recommended. Severe hypertension should be treated with antihypertensive drugs such as methyl dopa and labetalol as the first-line choice of drugs. Nifedipine is suggested as a second-line drug. Angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARB) are associated with adverse fetal outcomes and hence contraindicated in pregnancy. Majority of the hypertensive individuals cannot be controlled by single drug therapy and may require two or more antihypertensive agents selected from various drug classes⁴. The effective management of hypertensive disorders in pregnancy can be achieved by the use of a number of drugs in various combinations. But the usage of such drugs should be in accordance with the guidelines for treatment of hypertension and rationality, effectiveness and tolerance of the drug use should be evaluated. To reduce the blood pressure in order to assure the safety of the mother and the fetus is the

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greatest challenge in the treatment of pregnancy-induced hypertension. In pregnancy, drug therapy presents a special concern due to the threat of potential teratogenic effects of the drug and physiologic adjustments in the mother, in response to pregnancy.⁸

This is a prospective observational study performed with an aim to assess the risk factors that potentiate gestational hypertension and also to evaluate the drug utilization pattern in patients diagnosed with gestational hypertension. 72 patients who were admitted with gestational hypertension in the Gynaecology department of Pushpagiri Medical College Hospital were enrolled for this study.

2. OBJECTIVES

- To evaluate the clinical risk factors that leads to the development of gestational hypertension.
- To assess the foetal and maternal outcomes associated with gestational hypertension.
- To assess the effective utilization of various drugs on the disease.
- To evaluate the complications.

3. MATERIALS AND METHODS

Study Design: Prospective Observational study

Study Population: Patients diagnosed with Gestational hypertension

Study Site: The Obstetrics and Gynaecology department of Pushpagiri Medical College Hospital, Thiruvalla.

Inclusion Criteria:

Hypertensive pregnant female patients having blood pressure $\ge 140/90$ mmHg of gestational age above 20 weeks, those who give consent voluntarily to participate in the study, both IP and OP patients were included in the study.

Exclusion Criteria: Patients who were not willing to give consent, patients having congenital fetal abnormalities.

Study Period: 6 months

A sample size of the study: 72

Methods of data collection: The study was carried out after taking approval from the Institution Ethics Committee. The informed consent of patients was taken prior to the study. A standardized data collection form was prepared and necessary data were collected which includes the demographic details, obstetric history, past medical history, past medication history, current medication etc. The risk assessment was done by evaluating the parameters such as age distribution, gravidity, admission, gestational time, past medical, and medication history and obstetric history. For assessing the complications, mode of delivery, blood pressure values, birth weight were analyzed. During the second visit, parameters were checked again and assessed the outcome. The data for assessing the drug utilization pattern was collected from their medical records and evaluated using WHO prescribing indicators and complementary indicators. All information regarding the study were collected from the case records and discussions conducted with the inpatients and bystanders during the ward rounds, with the support of the physician.

Ethical Considerations: The approval from Institutional Ethics Committee was obtained before the commencement of the study. (IEC Enrollment No: PCP/E1/01A/06/2018). Informed consent was obtained from all patients who met the inclusion criteria, were enrolled for the study.

4. RESULTS AND DISCUSSION

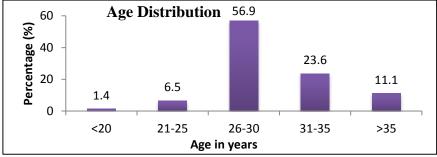


Fig. 1: Distribution of patients based on age group

Majority of the patients in this study belong to the age group of 26 to 30 (56.9%).

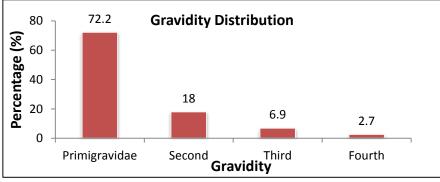


Fig. 2: Distribution of patients based on gravidity

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Majority of the patients in this study were found to be primigravidae (72.2%). The study conducted by **Anujeet Kaur** et al ⁴ produced similar results.

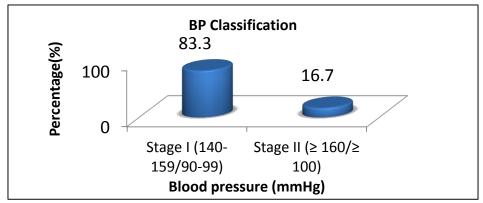


Fig. 3: Distribution of patients based on blood pressure range

Among the study population, the majority of patients (83.3%) were diagnosed with stage I hypertension (140-159/90-99 mmHg) before drug administration.

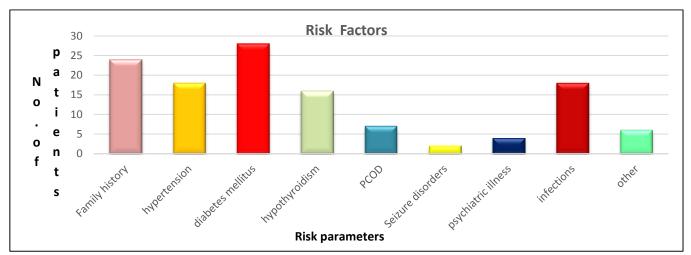


Fig. 4: Risk factors for gestational hypertension

Majority of the patients in the study had co-morbidity of pre-existing diabetes mellitus. Other prominent co-morbidities were pre-existing hypertension (25%), hypothyroidism (22.2%), PCOD (9.7%), seizures (2.8%), psychiatric illness (5.6%), infections (6.9%) and obesity (5.5%).

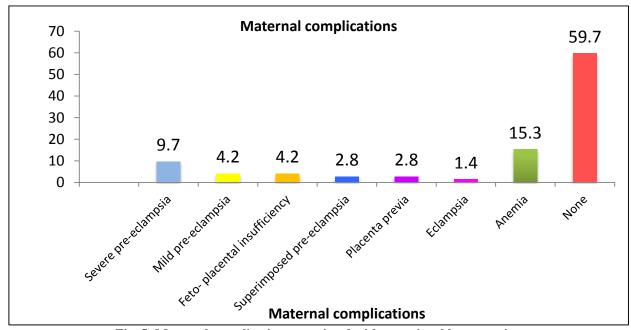


Fig. 5: Maternal complications associated with gestational hypertension

A most reported maternal complication associated with gestational hypertension is anemia (15.3%).

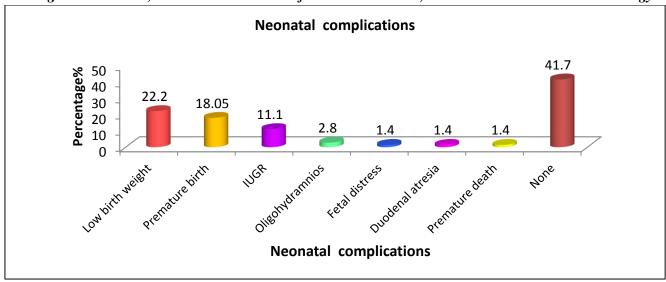


Fig. 6: Neonatal complications associated with gestational hypertension

Among the complications reported, low birth weight appeared to be the major complication (22.2%).

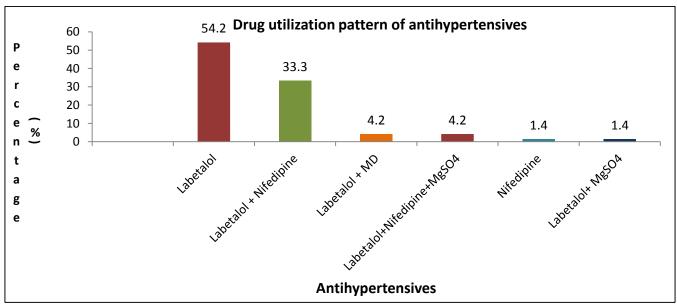


Fig. 7: Drug utilization pattern of antihypertensive agents

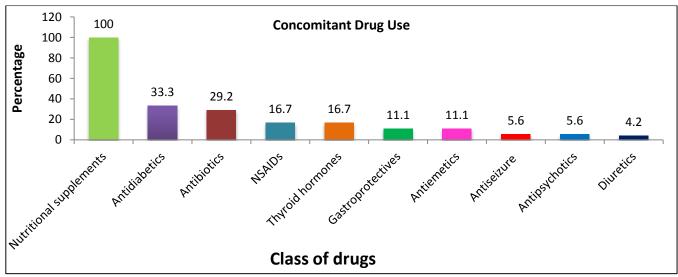


Fig. 8: Concomitant drug use in pregnancy

In the study, the most commonly prescribed anti-hypertensive drug is Labetalol (54.2%) followed by a combination of Labetalol with Nifedipine (33.3%). Labetalol is given in doses of 100-200mg. Other classes of drugs prescribed are nutritional supplements, hypoglycemic, antibiotics, NSAIDs, thyroid preparations, gastroprotective, antiemetics, antipsychotics, antiseizure drugs, and diuretics. Nutritional supplements are received by all patients (100%) enrolled in this study.

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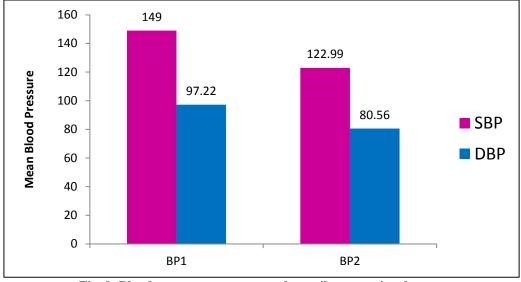


Fig. 9: Blood pressure management by antihypertensive therapy

Blood pressure of the gestational hypertensive patients attained normal range after antihypertensive drug administration. The antihypertensive drug therapy was found to be significant. Most of the drugs were used appropriately and was in accordance with standard guidelines.

5. CONCLUSION

From the study, it is found that gestational hypertension is one of the most common disorders observed in pregnancy. Patients of the age group 25-30 are found to be more in number diagnosed with gestational hypertension. Pre-existing hypertension and diabetes mellitus are found to be the most common risk factors of gestational hypertension in this study. Preeclampsia and anemia are the most encountered maternal complications. Low birth weight and premature birth were found to be the most common neonatal complication. The most prescribed anti-hypertensive drug is Labetalol and was found to be safe. The antihypertensive drug therapy was found to be significant. Most of the drugs were used appropriately and was in accordance with standard guidelines. None of the contraindicated antihypertensive drugs were prescribed to a single patient. None of the drugs prescribed were in the teratogenic category. The outcomes can be improved with proper diagnosis and management that can be achieved through regular health screenings. Proper antenatal check-up and follow up are crucial for the prevention and management of hypertensive complications.

6. ACKNOWLEDGMENT

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