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RESEARCH ARTICLE

DRUG UTILIZATION STUDY IN PREGNANCY INDUCED HYPERTENSION IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Introduction: Pregnancy induced hypertension(PIH) is one of the most common complications of pregnancy worldwide.It is associated with both maternal mortality and morbidity as well as perinatal mortality. Though a number of drugs are available to treat PIH, differences in benefit-risk ratio of these drugs stresses the need for surveying the use of these drugs. ***Methods:*** The present study is a retrospective observational study performed on the basis of case record sheets of patients admitted with PIH. ***Results:*** Out of the total prescriptions studied the most commonly prescribed antihypertensive was Methyldopa, followed by Labetalol. Nifedipine, Amlodipine, and Magnesium sulphate were the other drugs prescribed. Majority drugs prescribed were from category B and C. Single drug therapy was prescribed in 79.87 % patients. ***Conclusion:*** Methyldopa was the commonly prescribed antihypertensive. None of the prescribed drugs were from teratogenic category D and X.

Keywords: Pregnancy induced hypertension, Drug utilization study, Antihypertensive

INTRODUCTION

Worldwide, hypertension represents one of the most common complications of pregnancy. Hypertension disorder 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. [1, 2] Hypertension in pregnancy is defined as systolic blood pressure (sBP) ≥ 140 mmHg and/or diastolic blood pressure (dBP) ≥ 90 mmHg, or by ↑ in sBP ≥ 30 mmHg, or in dBP ≥15 mmHg from preconception or first trimester blood pressure confirmed by two measuring 6 hours apart. [3]

It is associated with high rates of perinatal morbidity and mortality and is the third most common cause of maternal death worldwide. Pre-eclampsia decreases utero-placental perfusion, which puts the foetus at high risk for problems such as preterm birth and perinatal mortality. It may also lead to maternal hypertension and multisystemic organ dysfunction and damage, including eclampsia. [4, 5]

A number of drugs in various combinations are generally used for effective long –term management of hypertension in pregnancy. There is need to survey the pattern of usage of antihypertensives drugs, to see if the current usage is rational, effective and tolerated and in concordance with current guidelines for treatment of hypertension.[6] The greatest challenge in treating hypertension in pregnancy is to reduce the blood pressure to assure the safety of mother and at same time not to compromise uteroplacental perfusion or cause harmful effects on the foetus.10The ideal therapy of hypertension in pregnancy should be potent, rapidly acting and without any adverse maternal or foetal effect.[7]

The present study aims to investigate the drug utilization pattern of antihypertensive drugs in pregnancy induced hypertension.

METHODS

A retrospective observational study was conducted in the Department of Obstetrics & Gynaecology, College of Medicine & JNM Hospital, Kalyani after taking permission from the Institutional Ethics Committee. The Case record sheets of the patients diagnosed for pregnancy induced hypertension or gestational hypertension admitted to the obstetrics ward during the period July – December 2013 were reviewed.

The information regarding drugs prescribed, number of drugs, dosage, frequency, duration, whether generic names used were recorded and from this the core indicators like prescribing indicators and complementary indicators were evaluated.

Prescribing indicators [8]

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 was determined by dividing the number of products prescribed from essential drug list of the hospital by the total number of drugs prescribed, multiplied by 100.

Complementary Indicators

a) Effect of the drug on the foetus (Low birth Weight, Foetal distree, IUGR, death)

b) category and safety of prescribed drugs.

Definition of risk factors

These definitions are those used by the United States food and Drug Administration (FDA). [9]

Category A:

Controlled studies in women fail to demonstrate a risk to the foetus in the 1st trimester (and there is no evidence of a risk in later trimesters), and the possibility of foetal harm remains remote.

Category B:

Either animal-reproduction studies have not demonstrated a foetal 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 foetus (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 foetus.

Category D:

There is positive evidence of human foetal 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 foetal abnormalities or there is evidence of foetal risk based on human experience or both, and the risk of the use drug in pregnant women clearly outweighs any possible benefits. The drug is contraindicated in women who are, or may become pregnant.

RESULTS

A total of 154 prescriptions were collected. Among these patients, a higher number, 55.84 % belonged to stage II hypertension (B.P . ≥ 160/ ≥ 100) before administration of drugs (Table 3). Neonatal outcome of these pregnancies were noted which showed low birth weight in 18.83% cases, followed by foetal distress in 3.24% cases. (Table 4)

Out of 154 patients, 123 (i.e, 79.87%) received a single antihypertensive drug while 27 (i.e,17.53 %) received two antihypertensive drugs and 4 patients (2.59%) received three drugs.(Table 5)

Methyl dopa was the most common antihypertensive drug used as monotherapy in 54 (i.e, 35.06% cases) , followed by Labetalol in 32 (i.e, 20.77%) cases. Combination of Methyl dopa and Labetalol was the most common multidrug antihypertensive regimen used in 7.79% cases.

Average number of antihypertensives per prescription was found to be 1.22. A total of 83.76% prescriptions were found in generic name.

Table 1: Demographic distribution of the patients

Age Groups	Number of patients	Percentage
18-20	19	12.33
21-25	84	54.55
26-30	36	23.37
31-35	15	9.74

Table 2: Gravidity wise distribution of patients

Gravida	Number of patients	Percentage
Primi	79	51.29
Second	48	31.16
Third	21	13.63
Fourth	6	3.89

Table 3: Blood pressure range of patients before administration of drugs

B.P. Classification	Systolic/ Diastolic B.P.	Number of patients	Percentage
Hypertension stage I	140-159/ 90-99	68	44.16
Hypertension stage II	≥ 160/ ≥ 100	86	55.84

Table 4: Neonatal outcomes

Neonatal Outcome	Number of patients	Percentage
Low Birth Weight	29	18.83
Foetal distress	5	3.24
IUGR	3	1.94
Death	2	1.29

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Table 5: Number of antihypertensive drugs

Number of Drugs	Number of patients	Percentage
Single drug	123	79.87
Two drugs	27	17.53
Three drugs	4	2.59

Table 6: Antihypertensive drug/ combination used

Name of Drug/s	Number of patients	Percentage	Risk category
Methyl dopa	54	35.06	B
Labetalol	32	20.77	C
Nifedipine	26	16.88	C
Amlodipine	6	3.89	C
Magnesium sulfate	5	3.24	A
Methyl dopa + Labetalol	12	7.79	B+ C
Methyl dopa + Nifedipine	8	5.19	B+ C
Labetalol + Nifedipine	7	4.54	C+ C
Methyl dopa + Labetalol + Nifedipine	4	2.59	B+ C+ C

Table 7: Drug use indicators

Core Indicator	Value
Average number of drugs per prescription	4.2
Average number of antihypertensives per prescription	1.22
Prescriptions by generic name	83.76%
On Essential Drug List	64.28%
Facility Indicators	
Availability of Essential Drug List	Yes
Availability of Key drugs	100%

DISCUSSION

In our study, as described earlier, 79.87 % patients admitted with Pregnancy induced hypertension, received monotherapy antihypertensive regimen which is similar to an earlier study in Govt hospital by Ashna S Pandya et al. which showed 75.96% patients received a single antihypertensive drug. However, another study by Naveen Kumar T et al showed much less (46.94%) percentage of patients receiving monotherapy in pregnancy induced hypertension.[10,11]

Methyl dopa was found to be the most common antihypertensive prescribed, followed by Labetalol. Similarly, in earlier studies mentioned above, Methyldopa was most commonly prescribed, however in those studies Nifedipine was the second most commonly used drug.

Rational drug use in pregnancy requires balancing of benefits and the potential risks associated with the use of drugs. The majority of drugs used in this study were from Category B and C. Magnesium Sulfate, belonging to category A(safest) was used in less number of patients. However, in contrast to earlier study by Naveen Kumar T et al., drugs belonging to categories with higher risk (category D) like Atenolol or Telmisartan were not found in our present study which shows better adherence to guidelines.

The most common neonatal outcome was low birth weight baby. The co-relation of the effect of PIH on foetal weight should be evaluated by further studies. The incidence of IUGR, premature babies and foetal distress were also noticed but it cannot be co-related to PIH or drugs used in this study.

CONCLUSION

Hypertension in pregnancy is one of the most common disorders encountered in pregnancy . Methyldopa was found to be the commonest prescribed antihypertensive in monotherapy and combination, as it is safe during pregnancy. The incidence of Low birth weight babies was high which may be due to either effect of maternal hypertension or drugs which should be evaluated by further studies. None of the prescribed drugs were from teratogenic category D and X.

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