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Original Research

Assessing the effectiveness of two Antihypertensive medications in managing pregnancy-induced hypertension

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ABSTRACT:

Aim: Assessing the effectiveness of two Antihypertensive medications in managing pregnancy-induced hypertension. **Materials and method:**This study was done in the Department of Pharmacology. This research included all pregnant women who had a diastolic blood pressure (DBP) higher than 100 mm Hg on at least two separate occasions, with a time interval of 4 hours, after reaching 20 weeks of gestation.A total of 200 patients diagnosed with PIH were randomly assigned to two groups, with 100 patients in each group. Following informed written permission, Group A was administered Nimidipine 30 mg every 8 hours, whereas Group B got Nifedipine 10 mg every 8 hours in an alternating manner with equivalent distribution. The groups were also separated into two subgroups: one with diastolic blood pressure (DBP) between 100-109 mm Hg, and another with DBP over 110 mm Hg. The age, parity, pre-treatment risk factors that impact the mother and fetal outcome, non-stress test (NST), and extra medicines such as magnesium sulfate (MgSO4) and phenobarbital utilized on the patients in both groups were carefully matched. **Results:**In Group A, the highest number of instances occurred between 37-40 weeks of gestation, whereas in Group B, it was between 33-36 weeks. The diastolic blood pressure upon presentation is statistically comparable between the two groups, with a p-value of 0.31. The incidence of non-proteinuric and proteinuric conditions is similar in both groups (p=0.43). The Apgar scores at 1 and 5 minutes are statistically similar between the two groups (p>0.05). Both groups exhibit similar levels of control in terms of systolic and diastolic blood pressure. Group A had a low incidence of adverse effects, such as headache, flushing, and hypotension, affecting around 3% of participants. The perinatal outcomes in both groups were similar, with a 95% probability of babies being allowed to go home in Group A and 87% in Group B, indicating comparable results. **Conclusion:**Nimodipine is a viable substitute for Nifedipine in managing hypertension during pregnancy due to its safety, efficacy, and few adverse effects.Due to its higher cost compared to Nifedipine in countries like India, Nifedipine remains the preferred first medication.

Keywords: Diastolic blood pressure; Nifedipine; Nimodipine

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INTRODUCTION

Hypertensive disorders of pregnancy complicate about 7-10% of pregnancies [1]. Severe hypertension increases maternal mortality and morbidity due to cerebrovascular accidents, pulmonary oedema and placental abruption. Several anti-hypertensive drugs have been tried in the pregnancy considering various factors in the pregnancy. Methyldopa, Labetalol and Nifedipine (Dihydro-piridine group 2) are commonly in use at present. But in developing countries, Labetalol is not used as first line drug due to cost constraints and Methyldopa, which is an established first line drugtakes longer time to act and on the other hand Nifedipine, which is used for both acute and chronic hypertensions have long side effects like rapid drop in the pressure following medication, complications like Myocardial infarction and Congestive cardiac failure [3].

It has been banned in countries like Australia. Nimodipine (Dihydro-piridine group) is one more anti- hypertensive drug with similar mechanism of action as Nifedipine and lowers the blood pressure more gradually, hence overcomes the known side effects of Nifedipine and also helps to increase cerebral perfusion pressure [4]. Therefore, this study was conducted to compare the efficacy of Nimodipine

and Nifedipine in the control of blood pressure during pregnancy, and to assess the maternal and fetal side effects of the drugs.

MATERIALS AND METHOD

This Prospective was conducted at Department in the department of pharmacology. The study was approved by the institutional research and ethical committee. An informed and written consent was obtained by all the subjects. This study was completely in-patient based. Primary data was generated by studying patients admitted for the management of pregnancy-induced hypertension (PIH).On admission, detailed history, clinical examination and investigation related to PIH are done.All pregnant women with diastolic blood pressure (DBP) more than 100 mm Hg on at least 2 occasions 4 hours apart after 20 weeks of gestation were included in this study.Patients with heart disease including ischaemic heart disease, Haemotological disorders, Liver disease and History of intolerance / hypersensitivity to dihydropyridine groups of drugs were excluded from the study.Total of 200 patients with diagnosis of PIH were randomized into 2 groups of 100 each. After informed written consent, Group A received Nimidipine 30 mg 8th hourly and Group B received Nifedipine 10 mg 8thhourly alternatively with matching distribution. Each group was further sub-divided as DBP between 100- 109 mm Hg and above 110 mm Hg.All patients BP measurement was done at rest, in sitting or 15 degreelateral recumbency. Two consecutive readings 4 hours apart and with Korotkoffs phase-V were used to determine DBP. Aim of the treatment was to maintain the DBP between 90–100. Patients with gestational age of less than 34 weeks, and those with impending eclampsia /eclampsia were given MgSO4 as per Zuspans regimen. Decision to continue with conservative management of pregnancy or to deliver and mode of delivery was made depending on maternal and fetal indications. Patients were followed until delivery, indication for induction, mode of delivery, fetal and maternal outcome and side effects of the drug if any during the treatment were noted.Relevant statistical methods were applied depending on the type of data that were generated. Chi-Square test, Fischer exact test, Student t test (Paired), Effect size and Statistical software namely SPS S Version 21.0 was used for the analysis.

RESULTS

The age, parity, pre-treatment risk factors that affect the maternal and fetal outcome, NST, additional drugs like MgSO4 and Phenobarbitone used on the patients of both the groups were matched. The gestational age at presentation in either group is as follows.

Table 1: Gestational Age at Presentation

Gestational age at presentation in weeks	GroupA=100		GroupB=100	
	Number	%	Number	%
20-24	0	0	3	3
25-28	5	5	5	5
29-32	5	5	23	23
33-36	33	33	40	40
37-40	57	57	27	27
>40	0	0	2	2

The maximum number of cases was between 37-40 weeks of gestation in Group A and 33-36 in Group B.

Table 2: Diastolic BP at Presentation

Diastolic BP in mmHg	GroupA=100		Group=100		P value
	Number	%	Number	%	
100-109	62	62	52	52	0.31
110andabove	38	38	48	48	

Diastolic BP at presentation is statistically similar between two groups with p=0.31

Table 3: Division of patients into Non-proteinuric and Proteinuric cases

Non-proteinuric and Proteinuric cases	Group A=100		Group A=100		P -value
	Number	%	Number	%	
Non-Proteinuric	65	65	54	54	0.43
Proteinuric(Significant proteinuria≥300mg/L)	35	35	46	46	

Non-proteinuric and Proteinuric is comparable between the two groups(p=0.43)

Table 4: Mean Pattern of Blood pressure (Post-treatment)

StudyPeriod	Systolic Blood pressure mm HG		Diastolic Blood pressure mm HG	
	GroupA	GroupB	GroupA	GroupB
0hour	151.11±7.65	156.01±8.87	105.11±6.07	108.14±6.32
8hour	144.08±7.26	145.01±7.43	98.14±6.48	99.14±5.81
24hour	141.04±8.22	146.08±6.66	94.62±6.38	97.06±5.57
48hour	139.06±6.45	142.01±6.70	91.90±7.22	94.29±8.98
72hour	136.07±6.67	139.99±5.54	90.21±6.46	94.96±10.89
Studentt(0hour -72hour)	t=6.98 p<0.001	t=5.12 p<0.001	t=8.46 p<0.001	t=3.33 p<0.001
Effectsize	1.38	1.53	1.91	1.36

Table5: Comparison Apgar score between groups

Apgar Score	Apgar at 1minute		Apgar at 5minutes		P value
	GroupA	GroupB	GroupA	GroupB	
	N=100	N=100	N=100	N=100	0.32
>7.0	82(82%)	80(80%)	90(90%)	87(87%)	
7 -4	14(14%)	13(13%)	6(6%)	9(9%)	
<4.0	4(4%)	7(7%)	4(4%)	4(4%)	

Apgar score at 1 and 5 minutes are comparable between the two groups(p>0.05)

Both groups are comparable in terms of systolic and diastolic blood pressure control. Group A had minimal side effects like headache, flushing and hypotension for about 3%. Perinatal outcomes were comparable between the two groups with 95% carry home baby rate in Group A and 87% in group B, which are also comparable.

DISCUSSION

The present study compares Nifedipine, which is the commonly used anti-hypertensive with Nimodipine in terms of control of blood pressure during pregnancy and their maternal and fetal side effects and neo-natal outcome. The diastolic pressure at presentation was100-109 mm Hg in 62% of the patients in Group A and52% of the patients in Group B. Diastolic BP of 110 mm Hg and above was present in 38% of patients in Group A and 48% of patients in Group B with significant proteinuria in 35% in Group A and 46% in Group B. Ferrazzani& Associates, 1990 showed that, risk of perinatal morbidity and mortality is increased when hypertension in pregnancy is associated with proteinuria[5]. In 12% of non-proteinuric patients and 14% of proteinuric patients in Group A, BP was not under control even after 48 hours. In 9% of non-proteinuric and 21% of proteinuric patients in Group B, BP was not under control even after 48 hours. This is comparable in both the groups (p=0.43). These patients with uncontrollable BP were given MgSO4and pregnancy was terminated.In Gita Banerjee and co-author's study[6] using Nimodipine, there was more fall in MAP after 72 hours in the non-proteinuric than in the proteinuric group. This study too has found similar results. Present study using Nifedipine and Nimodipine can be compared to Katerina Fenakle at al study[7], who used Nifedipine in their study. There was adequate control of blood pressure (consistently below 160/110 mm Hg). Mean prolongation in both the groups is around 6 days, whereas in the above study, it was 15 days. The longest duration of prolongation of pregnancy was 30 days in both groups. Prolongation of pregnancy in days is statistically comparable between both the groups with p=0.32. Minimal side effects like headache and flushing were in Group A, which were tolerable. Group B did not have any side effects. Hypotension with Systolic BP < 90 mm Hg was seen in 1 patient after delivery[8]. Post-treatment complications likehypotension were seen in 3% and 3% patients had pleural effusion in Group A. Postpartum impendingeclampsia and Abruptio Placenta (Grade 0) were noticed in Group B in 3% of the cases. In majority of patients, pregnancy was prolonged for 1-3 days and it was prolonged beyond 2 weeks in 13% in Group A and15% in Group B, which were comparable to other studies 8.56% in Group A and 62% in Group B requiredinduction, majority of them for uncontrolled hypertension. Elective CS was done in 22% and 17% of patients in Group A and Group B respectively. Type of delivery was comparable between the two groups. Over 82% of new born had Apgar score of >7. Apgar score at 1 and 5 minutes were comparable between the two groups with p>0.05. Proteinuric patients in both the groups and low birth weight babies compared non-proteinuric patients. Birth weight distribution was comparable between both the two groups. 41% and 45% in Group A and B respectively were admitted to NICU which are comparable. Majority of the babies were admitted to NICU in view of preterm, intrapartum asphyxia and meconium aspiration, which correlates with many other studies[9]. 2 baby in Group A died due to intra ventricular haemorrhage. 3 babies died in Group B were preterm, 2 had necrotizing enterocolitis and the other had severe birthasphyxia.

CONCLUSION

In the treatment of hypertension in pregnancy,

Nimodipine and Nifedipine were equally effective in the control of blood pressure, both systolic anddiastolic. This control was better in the non-proteinuric patients. With effective control of blood pressure, the pregnancy could be prolonged thus enhancing fetal maturity. There was no difference in both the groups with regard to obstetric interventions, NICU admissions and birth apgar and birth weight. Hence to conclude Nimodipine is a safe effective oral drug that can be offered to an alternative to Nifedipine in the management of PIH. As it is comparatively much moreexpensive than Nifedipine, in developing countries, Nifedipine continue to be preferred first line drug.

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