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A comparative study of intravenous labetalol versus oral nifedipine in severe hypertension in pregnancy in a tertiary hospital ,Newdelhi

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Abstract:*Hypertensive disorders are the most common medical disorders encountered during pregnancy and are responsible for 15% of the maternal deaths in India.There is still controversy regarding choice of antihypertensive therapy in hypertensive emergencies in pregnancy. Currently Intravenous Hydralazine, oral Nifedipine and intravenous Labetalol are recommended for the treatment of severe hypertension in pregnancy.The objective of study was to compare the efficacy,safety, side-effects of intravenous labetalol and oral Nifedipine, mode of delivery in two groups, fetal outcome in patients receiving either Labetalol or Nifedipine in hypertensive emergency.A randomized control trial consisting of50 patientswas done over a period of one yearin Department of Obstetric and Gynaecology Dr.BabaSahebAmbedkar Hospital in Delhi. Efficacy of treatmentbasedside effects of drugs, number of doses required to attain target blood pressure,mode of delivery whether spontaneous or induced, normal or caesarean was noted in both groups. Fetal weight, maternal and neonatal outcomes were compared in each group. Our study provedboth drugs effectively control the blood pressure in severe hypertension in pregnancy. But Labetalol stood better than Nifedipine to decrease diastolic blood pressure and number of patients responding with first dose.But,further trials with larger sample size are needed to validate the results.*

Keywords:*Hypertensive disorders,Nifedipine,Labetalol*

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I. Introduction

Hypertensive disorders are the most common medical disorders encountered during pregnancy and are responsible for 15% of the maternal deaths in India.[1]According to American College of Obstetricians and Gynecologists (ACOG) hypertension in pregnancy is defined as systolic blood pressure (SBP) of 140 mm Hg or higher and Diastolic blood pressure (DBP) of 90 mmHg or higher after 20 weeks of gestation with previous normal BP.The main goal of treatment is to safeguard the mother from the development of acute complication like cerebro-vascular accidents, eclampsia, target organ damage and maternal mortality while delivering a healthy infant.[2,3]There is still controversy regarding the initiation of antihypertensive therapy in mild and moderate hypertension as well as about the choice of antihypertensive therapy in hypertensive emergencies and urgencies. National Institute for Health and Clinical Excellence guidelines 2010 recommend use of intravenous Hydralazine, oral Nifedipine and intravenous Labetalol for treatment of severe hypertension in pregnancy. Intravenous Hydralazine has been drug of choice since 1970s but a recent meta-analysis cautions against its use as the drug of first choice due to severe hypotension and other maternal and fetal complications.[4]

Different anti-hypertensive drugs available are: Methyldopa, Betablocker including Labetalol,Calcium channel blocker (Nifedipine),Hydralazine, Nitroglycerine.Sisson et al [5] studied Hydralazine versus Labetalol for management of hypertension. They concluded that Labetalol is safe and effective anti- hypertensive for management of severe hypertension. Nifedipine may more effectively control severely increased BP than does Hydralazine and Labetalol.[6]

Till date, there have not been many randomized clinical trials comparing these two agents.Hence this study was conducted to compare the efficacy safety and side-effects of labetalol and Nifedipine, mode of delivery in two groups, fetal outcome in patients receiving either Labetalol or Nifedipine.

II. Material and methods

The study was conducted for a period of one year from 2012 to 2013 in Department of Obstetric and Gynaecology Dr.BabaSahebAmbedkarHospital in Delhi. A total of 50 patients aged between 18-35 years, pregnancy of gestation age >28 weeks, with severe hypertension >/=160/110 were included in the study. Patients with heart failure,asthma,medical disorder of pregnancy excluding hypertension, allergic to either Nifedipine or Labetalol,non pregnancy related hypertension,previous caesarean sectionwere excluded from study.

All enrolled patients were randomly divided into two study groups using computer generated random numbers. Group A (N=25) were treated with intravenous Labetalol 20mg i.v. bolus; Group B (N=25) were treated with oral Nifedepine 10mg;

Blood pressures was monitored after every 20 minutes and dose of Labetalol given as escalating dose regimen (20mg, 40mg, 80mg,80mg, 80mg) every 20 minutes until target BP was achieved ,with maximum dose not exceeding 300mg in Group A; and Nifedipine was repeated as 10mg up to five doses every 30 minutes in Group B.

All patients were kept in hospital from time of admission until 48 hours after delivery to ensure BP monitoring. Patients were asked a questionnaire regarding side effects of drugs. Mode of delivery whether spontaneous or induced, normal or caesarean was noted in both groups. Fetal weight, maternal and neonatal outcomes were compared in each group.

Statistical analysis:

Statistical analysis was performed by using statistical software SPSS version 13 and Student t-test was applied . P value <0.05 wasconsidered significant.

III. Observations and results

Out of 50 patients, majority of patients belonged to age group 21 – 30 years. The mean age in group administered Nifedipine was 23.12 years and 24 years in Labetalol group . Only 3 cases (12%) in Nifedipine group and 2 cases (8%) in Labetalol group were illiterate.

In both groups majority patients were primigravida. 84% patientsinNifedipine group while 68% patients in Labetalol group. Maximum number belonged to urban area with middle income group. Majority of patients in both group presented at gestation age between 30 – 36 weeks. Overall, descriptive statistics highlights that the sample was equally distributed in both the groups. This reduces the chances of confounding cause due to the variability in covariates in the analysis.

Table 1. Shows control of blood pressure – comparision between two groups of drug

Nifedipine			
No. of patient	Diastolic Blood pressure at time of admission(mmHg)	Reduction in BP after 20 minute	Need to increase in dose or need to add other antihypertensive
19	110-119	8	11
5	120-129	2	3
0	130-139	-	0
1	140-150	-	1
Total- 25		10(40%)	15(60%)
Labetalol			
18	110-119	15	3
4	120-129	3	1
2	130-139	-	2
1	140-150	-	1
Total-25		18(72%)	7(28%)

In Nifedipine group 19 cases (76%) had a DBP in range of 110-119 mmHg of these 8 cases (32%) responded favourably but in remaining cases dose was increased or other drugs were added. Similarly in Labetalol group 18 cases (72%) had DBP in the range of 110-119 mmHg of which 15 cases (60%) responded to Labetalol.

In Labetalol group 18(72%) patients responded to first dose while in Nifedipine group 10(40%) patient responded to first dose of drug.There is a statistically significant (p=0.04).Induction rate is slightly more in Nifedipine group (64%) as a compared to Labetalol group(60%). Delivery interval after augmentation is almost equal in both groups. However this association was marginally insignificant (p=0.08).

Most the patients had normal delivery after induction 16 cases (64%) in Labetalol group 14 cases (56%) inNifedipine group while 8 cases (32%) underwent caesarean section in labetalol group and 11 cases (44%) had section in Nifedipine group.

After delivery 60% babies delivered in a Labetalol group shifted to mother and only 24% shifted to nursery while in Nifedipine group 48% babies shifted to mother side and 36%babies shifted to nursery.

Table 2: Showscomparision of side effect between two groups of drug

DRUG	Nifedipine (N=25)		Labetalol(N=25)	
Group	No. Of cases	Percentage of Cases	No. Of cases	Percentage of Cases
Headache	4	16%	2	8%
Tachycardia	7	28%	-	
Postural Hypotension	4	16%	2	8%
Drowsiness	3	12%	2	8%
Dyspnea	0		0	
Abnormal vision	0		0	
Fever	0		1	4%

Table 2 shows side effect like headache, tachycardia and postural hypotension were more in Nifedipine as compared with Labetalol.
Diastolic Blood Pressure was properly controlled in both groups (none had DBP> 110 after 2 hours of drug administration).

Table 3: Shows reduction in diastolic blood pressure pre and post drug administration after two hours

DRUG	Nifedipine		Labetalol		*P-Value
Pressure(mmHg)	No. Of cases	Percentage of Cases	No. Of cases	Percentage of Cases	
Diastolic BP reduction after 2 hr of drug					
40 mmHg	0	0%	2	8%	
30 mmHg	5	20%	4	16%	0.742
20 mmHg	13	52%	13	52%	
10 mmHg	6	24%	6	24%	
0 mmHg	1	4%	0	0	

Table 3 shows there was an equal distribution in reduction of diastolic blood pressure in both the groups.However, 40% reduction was observed in 8% of the cases receiving Labetalol while there were no such cases reported in group receiving Nifedipine. Similarly, none of the cases receiving Labetalol were reported to have no reduction in blood pressure while 1 case with no reduction was reported in the Nifedipine group (p= 0.742)

IV. Discussion

In this study mean age in group administered Nifedipine were 23.12 years and the Labetalol group as 24 years. The overall mean age was 23.56 years. Hence, age difference between the groups was non significant(p=1.0)indicating similar age distribution between the two age groups. Hansel et al. 1986 also supported this the commonly affected age group was 21-30 years in his study.

It was found that 68% of patients in Labetalol group and 84 % of patients of Nifedipine group were primigravida. Lakshmi B S et al[7] stated that it is the disease of primigravida. They believed that the disorder in some way have an immunological basis that previous exposure to foetal antigen may be protective.

In our study 17 cases (68%) in Nifedipine group were from middle income group while in Labetalol group 18 cases (72%) were from middle income group.Eastman in his study concluded that maternal death from hypertensive disorder in pregnancy was inversely related to average income per capita[8]. It is due to quality of antenatal care were less accessible to low income group. The present study isalsoinconcordance with it.

68% patients in Nifedipine group and 64% patients in Labetalol group were from gestational age 30 – 36 weeks. Most of the patients in both groups of drug presented in third trimester.

In our study 72% patients in Labetalol group showed improvement in BP within 20 minute of starting of therapy. Starting dose of injection Labetalol in severe PIH was from 20 mg intravenous and repeated at interval of 20 min.Only 28% required an increase in the dose of drug for control of blood pressure while Nifedipine group 60% patients required it.

Out of 25 cases in each group, total of 15 cases(60%) in Nifedipinerecievinggroup had to receive more than one dose to control blood pressure compared to 7(28%) patients in group receiving Labetalol (p=0.04).In similar study done by Lakshmi B S et al[7]found 44% patients achieved target BP with a single dose of labetalol whereas only 14% patients achieved target BP with the first oral dose of nifedipine (P, 0.002) .The magnitude of fall in SBP, DBP and MAP was greater in the Labetalol group compared with the nifedipine group (P,0.05).This is in comparison to our study.

In our study there was an equal distribution in reduction of diastolic blood pressure in both the groups. None of the cases receiving Labetalol were reported to have no reduction in blood pressure while 1 case with no

reduction was reported in the Nifedipinegroup(p=0.742).Symond et al 1980 reported that a more satisfactory control of blood pressure was obtained with inj.labetalol with minimum side effects[8].

In our study 64% patients in Nifedipine and 60% patients in Labetalol group had induction of labour. Qurmalawi et al reported in their study that rate of induction of labour and rate of caesarean section was less in Labetalol group. They concluded that Labetalol may have some ripening effects on cervix and Bishops score was higher in this group.[9]

In this study 44% patients in Nifedipine group,32% patients Labetalol group were delivered by caesearean section. Operative delivery rate was more with Nifedipine as compared to Labetalol. Comparable results were reported by Qurmalawi et al [8] and Symonds et al .[9]

In our study 86% babies were live born in both groups. Results were comparable to the study of Lamming et al, Labetalol had no apparent detrimental effects on fetusantenatally, during labour or postnatally[9] .NICU admission is 36% in Nifedipine group while 24% in Labetalol group in our study.Giannubilo S R et al found higher rate of intrauterine growth restriction among women treated with labetalol(38%) compared with those treated with nifedipine(15.5%) $p < 0.05$).[10]

Side effects observed like headache, tachycardia and postural hypotension are more in Nifedipine group while 2 cases (8%) in Labetalol group were having headache and other 2 cases (8%) were having postural hypotension. In a study by Raheem etal[11], nausea, vomiting and dizziness was more common in Labetalol group in comparison to Nifedipine.

Our study findings were comparable to other studies. Further trials are needed to prove the difference in efficacy of both the drugs in terms of fetal and maternal effects. Further studies are required with larger sample size to validate the results.

V. Conclusion

To conclude, both drugs effectively control the blood pressure in severe hypertension in pregnancy.Labetalol stood better than Nifedipine to decrease diastolic blood pressure and number of patients responding with first dose.Labetalol at present is more expensive, need to be administered intravenously but advantageous in severe hypertension of pregnancy while Nifedipine is cheaper but not suitable for hypertensive crisis. Further trialswith larger sample size are needed to prove the difference in efficacy of both the drugs in terms of fetal and maternal effects and to validate the results.

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