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Original Research

A comparative study to evaluate the efficacy of Oral Labetalol and Oral Nifedipine in hypertensive disorders of pregnancy

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***ABSTRACT*:**

Background: Hypertensive disorders of pregnancy affect one of every ten pregnant women, and are one of the leading causes of maternal and perinatal mortality and morbidity. The present study was conducted to compare oral labetalol and oral nifedipine in hypertensive disorders of pregnancy. **Materials & Methods:** The present study was conducted on 120 pregnant women. Preterm or term pregnant women with severe preeclampsia/ eclampsia and BP ≥160/100 mm Hg were included in the study. Patients were divided into 2 groups of 60 each. Group I patients were given oral labetalol and group II were given oral 10 mg Nifedipine. **Results:** Primi was seen in 36 in group I and 34 in group II, G2 12 in group I and 10 in group II, G3 8 in group I and 10 in group II and G4 4 in group and 6 in group II. The difference was non- significant (P> 0.05). In group I, SBP was 172.4 mm Hg in group I and 164.2 mm Hg in group II, DBP was 112.6 mm Hg in group I and 110.8 mm Hg in group II. The difference was significant (P< 0.05). Neonatal outcome was better in nifedipine but difference was non significant. **Conclusion:** Authors found oral Nifedipine better in terms of lowering blood pressure in pregnant ladies. However difference was non- significant.

Key words: Blood pressure, Nifedipine, labetalol.

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INTRODUCTION

Hypertensive disorders of pregnancy affect one of every ten pregnant women, and are one of the leading causes of maternal and perinatal mortality and morbidity.[1] Hypertensive disorders of pregnancy, an umbrella term that includes preexisting and gestational hypertension, preeclampsia, and eclampsia, complicate up to 10% of pregnancies and represent a significant cause of maternal and perinatal morbidity and mortality. It has effects both on expectant mother and fetus. The impact due to hypertensive disorders in pregnancy on maternal and neonatal mortality and morbidity is very high in India and other developing countries.[2]

The hypertensive disorders of pregnancy constitute the most widely studied, discussed and analysed condition, because of the fact that they adversely affect both the mother and fetus. They predispose to progression to severe forms of pre-eclampsia, eclampsia, HELLP syndrome, abruption placenta, haemorrhage, disseminated intravascular coagulation, acute renal failure and death, acute or chronic uteroplacental insufficiency resulting in ante or intrapartum anoxia that may lead to, intrauterine growth restriction.[3]

Most of the authorities recommend labetalol, hydralazine and nifedipine as first line alternatives for the treatment of severe hypertension during pregnancy. Nifedipine has the advantage of being cost effective, rapid onset of action, long duration of action and can be administered orally, however it is known to cause sudden maternal hypotension and fetal distress caused by placental hypo perfusion, palpitation and transient neuromuscular weakness when used concomitant with magnesium sulphate. Intravenous Labetalol is considered to control severe hypertension in pregnancy. Both intravenous labetalol and nifedipine have been compared directly with many other antihypertensive agents for hypertensive crises during pregnancy.[4]

Most of these trials suffer from small sample size or methodological shortcomings, thus precluding any definite conclusion regarding comparative efficacy and safety of these two drugs.

Thus present study was conducted to compare efficacy of oral labetalol and oral nifedipine in management of hypertensive disorders of pregnancy.

MATERIALS & METHODS

The present Prospective Observational study was conducted in the department of Obstetrics & Gynaecology, Rajshree Medical Research Institute, Bareilly, Uttar Pradesh. The study protocol was approved from institutional ethical committee. Written consent was obtained prior to the study. A total number of 120 patients who were prescribed with either Labetalol or Nifedipine were selected and included in the study. Preterm or term pregnant women with severe preeclampsia/ eclampsia and BP ≥160/100 mm Hg were included in the study.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 60 each. Group I patients were given oral labetalol and group II were given oral 10 mg Nifedipine.

Maternal blood pressure was recorded at every fifteen minutes interval till first 30 minutes after achieving target blood pressure equal to or less than 140/90 mmhg, then every 30 minutes for next 2 hours followed by hourly for next 24 hours. Continuous maternal vital parameters and fetal heart sounds via fetal Doppler was taken at the beginning and after every 30 minutes after achieving target blood pressure equal to or less than 140/90 mmHg. Finally, the documented data was analyzed using Microsoft excel version and statistical methods (t test) to find p value to compare the two treatment groups.

RESULTS

Table 1 Distribution of patients

Gravida	Group I	Group II	P value
Primi	36	34	0.51
G2	12	10	
G3	8	10	
G4	4	6	

Table 1 shows that primi was seen in 36 in group I and 34 in group II, G2 12 in group I and 10 in group II, G3 8 in group I and 10 in group II and G4 4 in group and 6 in group II. The difference was non- significant (P> 0.05).

Table 2 Gestational age in both groups

Gestational age (Weeks)	Group I	Group II	P value
36-37	8	10	0.05
37-38	20	18	
38-39	22	20	
>39	10	12	

Table 2 shows that gestational age in group I patients was 36-37 weeks seen 8 in group I and 10 in group II, 37-38 weeks seen 20 in group I and 18 in group II, 38-39 weeks 22 in group I and 20 in group II and >39 weeks 10 in group I and 12 in group II. The difference was significant (P< 0.01).

Graph I Gestational age

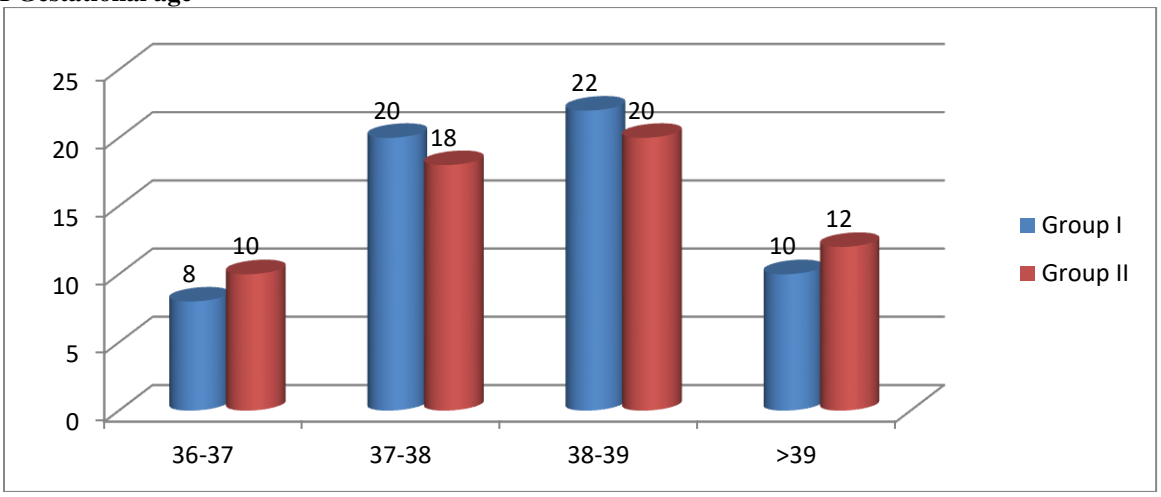

Table 3: Comparison of blood pressure in both groups

Blood pressure	Group I	Group II	P value
SBP (mm Hg)	172.4	164.2	0.05
DBP (mmHg)	112.6	110.8	0.02

Table 3 shows that in group I, SBP was 172.4 mm Hg in group I and 164.2 mm Hg in group II, DBP was 112.6 mmHg in group I and 110.8 mm Hg in group II. The difference was significant (P< 0.05).

Table 4: Comparison of efficacy of labetalol and nifedipine

Drug name	Nifedipine (n=60)	Labetalol (n=60)
Duration in days	6	8.5
Duration in Hours	130	180
mean±SD (d)	6±2.63	8.5±3.83
mean±SD (h)	128±60.12	178±76.8

SD: Standard Deviation,*n-Sample Size.

Table 5: Neonatal outcome

Outcome of pregnancy	Labetalol	Nifedipine	P value
	Frequency	Frequency	
Alive	52	54	0.25 (Non significant)
Dead	8	6	
Total	60	60	

DISCUSSION

Antihypertensive agents are mainly used to prevent and treat severe hypertension. The antihypertensive agents have a role in controlling hypertension and there by maternal and fetal complications can be avoided.[5] The commonly used antihypertensive drugs in pregnancy induced hypertension are Methyldopa, Labetalol, other beta blockers (Acebutolol, Metoprolol, Pindolol and Propranolol) and calcium channel blockers Nifedipine. There are few studies evaluating the efficacy of antihypertensive agents in pregnancy. The efficacy of the drug in controlling the high blood pressure is important in preventing complications both to women and fetus.[6] The present study was conducted to compare oral labetalol and oral nifedipine in hypertensive disorders of pregnancy.

In this study, primi was seen in 36 in group I and 34 in group II, G2 12 in group I and 10 in group II, G3 8 in group I and 10 in group II and G4 4 in group and 6 in group II. The difference was non- significant (P> 0.05). Shekhar et al[7] determined the efficacy and safety of oral nifedipine for treatment of severe hypertension of pregnancy compared with intravenous labetalol. The pooled analysis of seven trials (four from developing countries) consisting of 363 woman–infant pairs showed that oral nifedipine was associated with less risk of persistent hypertension and reported maternal side effects. However, on sensitivity analysis the outcome 'persistent hypertension' was no longer significant.

We observed that in group I, SBP was 172.4 mm Hg in group I and 164.2 mm Hg in group II, DBP was 112.6 mmHg in group I and 110.8 mm Hg in group II. The difference was significant (P< 0.05). Results showed that gestational age in group I patients was 36-37 weeks seen 8 in group I and 10 in group II, 37-38 weeks seen 20 in group I and 18 in group II, 38-39 weeks 22 in group I and 20 in group II and >39 weeks 10 in group I and 12 in group II. The difference was significant (P< 0.01).

Gavit et al[8] compared oral Nifedipine and intravenous Labetalol in control of acute hypertension in severe pre-eclampsia and eclampsia. In this study, 40 sample size treated with intravenous Labetalol and other 40 sample size treated with oral Nifedipine. The maternal and perinatal outcome in two groups sample size with oral Nifedipine and intravenous Labetalol compared and found that nevertheless these results do establish oral Nifedipine as an alternative to IV Labetalol in lowering BP in acute severe hypertension. In the present study oral Nifedipine as an alternative to IV Labetalol in lowering BP in acute severe hypertension. In summary oral Nifedipine may be preferable as it has a convenient dosing pattern orally.

Five trials (323 woman–infant pairs) were included for analyses of intrauterine fetal death and four trials were included for the analysis of neonatal mortality. The analyses did not show a significant difference of risk for intrauterine death between nifedipine and labetalol (RR 0.66, 95% CI 0.35–1.27); however, the risk of neonatal death was significantly reduced with nifedipine compared with labetalol. There was no heterogeneity amongst trials. Sensitivity analysis did not change the significance of the results.[9]

The most extensively used antihypertensive drugs in pregnancy are β adrenoceptor antagonists, Nifedipine, methyldopa and Labetalol. These drugs are used alone or in combinations in routine obstetric practice in our country. Each of these drugs have different mode of action. Nifedipine is vasodilator and calcium channel blocker.

Methyl dopa is centrally acting antihypertensive. Labetalol is both α and β blocker. There were few clinical studies in which these drugs were compared in the same setting, when used orally with respect to their antihypertensive efficacy, side effects, maternal and neonatal outcome both in mild and severe PIH.[10]

A recent prospective study conducted by Patela NK et al.[11] to evaluate the comparative effectiveness and safety of nifedipine, methyldopa and labetalol monotherapy in patients with Pregnancy induced hypertension (PIH) concluded that Labetalol was more effective than methyldopa and nifedipine in controlling blood pressure in patients with Pregnancy induced hypertension (PIH) in contrary to results of our study.

The limitations of our study are Study population is heterogenous which includes both proteinuric and non-proteinuric pregnant women with high blood pressure and Blood pressure considered is the highest single reading recorded among all four hourly measurements for the entire day.

CONCLUSION

Authors found oral nifedipine better in terms of lowering blood pressure in pregnant ladies.

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