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A randomised prospective comparison of labetalol and Nifedipine in the management of severe pre-eclampsia

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Abstract
Background: The incidence of hypertensive disorders ranges from 2-8% of all pregnancies and contributes to 9% of maternal mortality in Asia and 12% in India [2, 3]. Approximately 70% of hypertensive disorders are due to gestational hypertension-preeclampsia [4]. The present study for the treatment of severe pre-eclampsia was undertaken to determine, the efficacy of Labetalol which is a selective alpha-1 adrenergic blocker and non – selective beta adrenergic blocker used as first line of drug these days. Along with Labetalol in comparison with an age old drug Nifedipine a calcium channel blocker was used.
Method: This is a prospective study conducted in the Department of Obstetrics and Gynecology, Vinoba Behave civil Hospital, Silvassa from September 2020 to May 2021 to evaluate the efficacy of Labetalol & Nifedipine in control of blood pressure in women with acute hypertensive crisis and to observe maternal and perinatal outcome in acute hypertensive crisis during pregnancy with Nifedipine and Labetalol 40 pregnancy induced hypertensive patients of acute hypertensive crisis were studied and categorized into 20 patients treated with Nifedipine drug and 20 patients treated with Labetalol drug.
Results: Nifedipine & Labetalol are equally efficacious in controlling hypertension in females with severe pre-eclampsia. Nifedipine was seen to be a better drug with faster effects than Labetalol in controlling hypertension.
Conclusion: Nifedipine is the preferred drug in case of severe pre-eclampsia to control blood pressure as it is more efficacious and can be used in the peripheral centers due to cost effectiveness and its ease of administration and storage.

Keywords: Severe pre-eclampsia, Nifedipine, labetalol, blood pressure

Introduction
Hypertensive disorders of pregnancy are responsible for increased number of hospital admissions, labour inductions, maternal and fetal morbidity and mortality, also complicating pregnancy and form part of a deadly triad, along with hemorrhage and sepsis [1]. It contributes greatly to the maternal morbidity and mortality [1].
The risk may evolve over days or just few hours and may present as worsening blood pressure that may culminate into hypertensive emergencies. Placental abruption and fetal distress are common with severe preeclampsia along with maternal complications like hypertensive encephalopathy and cerebrovascular accidents [5].
Overall, 10% to 15% of direct maternal deaths are associated with preeclampsia and eclampsia [6]. Where maternal mortality is high, most of deaths are attributable to eclampsia, rather than preeclampsia [6]. It has been estimated by the WHO that worldwide approximately 45,000 women will die each year from hypertensive disorders of pregnancy [2].
Cerebral hemorrhage is the commonest cause of maternal death in pre-eclampsia and eclampsia, hence treatment is mandatory.
Until better evidence is available, the best choice of drug for an individual woman probably depends on the experience and familiarity of her clinician with a particular drug and on what is known about adverse maternal and fetal side effects [7].
The mode of administration and rapidity of the action forms the basis for selection of anti-hypertensive therapy in hypertensive emergencies. The Society of Obstetricians and Gynecologists of Canada recommend that, blood pressure should be lowered to <160 mmHg systolic and <110 mmHg diastolic. Initial antihypertensive therapy should be with Labetalol, Nifedipine capsules or Hydralazine. Nifedipine and $MgSO_4$ can be used at the same time [8].
Parenteral Reserpine was routinely used for this purpose in most hospitals in India; however the use of Reserpine has become obsolete due to its erratic efficacy and side effects.

Parenteral Diazoxide and Sodium nitroprusside have never been popular for use in pregnancy.
Parenteral Hydralazine widely used in the west is not easily available in India.
The present study for the treatment of severe pre-eclampsia was undertaken to determine, the efficacy of Labetalol which is a selective alpha-1 adrenergic blocker and non – selective beta adrenergic blocker used as first line of drug these days.
Along with Labetalol in comparison with an age old drug Nifedipine a calcium channel blocker was used.

Inclusion & Exclusion Criteria
Inclusion criteria
1. Pregnant women completed 20 weeks of gestation (primigravida and multigravida) of blood pressure more than or equal to 160/110mmHg in acute uncontrolled hypertension.
2. Period of gestation accurately known by last menstrual period.
3. Singleton pregnancy.
4. Twins plus PIH.

Exclusion criteria
1. Heart disease.
2. Diabetes Mellitus.

Materials and methodology
The study was conducted in VINOBA BHAVE hospital, Silvassa to evaluate the efficacy of Labetalol & Nifedipine in control of blood pressure in women with acute hypertensive crisis.
In this study all the cases of pregnancy induced hypertension patients of acute hypertensive crisis admitted under OBGY department about 40 cases was studied. During the period from September 2020 to May 2021. Patients of acute hypertensive crisis was divided in two groups Group A -20 patients of acute hypertensive crisis treated with Nifedipine Group B-20 patients of acute hypertensive crisis treated with Labetalol.
Case selection will be done in the criteria of history, clinical examination.
Soon after the admission clinical data will be recorded according to the Performa.
The diagnosis will be mainly based on clinical examination.

Results
In the present study, 67.5% female were primigravida in the study, whereas 32.5% were multigravida.
We used Nifedipine orally & IV Labetalol in 40 patients of severe pre-eclampsia.
In the present study, we observed maternal and perinatal outcome in acute hypertensive crisis during pregnancy with Nifedipine & Labetalol, & their use for control of blood pressure in patients with acute hypertensive crisis during pregnancy, thus we found that, Nifedipine & Labetalol are equally efficacious in controlling hypertension in females with severe preeclampsia. Nifedipine was seen to be a better drug with faster effects than Labetalol in controlling hypertension.

1. Age distribution
The current study shows pertaining to Labetalol patients, the maximum number women fell in age group of 15-20 yrs,i.e 2, In age group of 21-25 yrs were 9, In age group of 26-30 yrs were 5, In age group of 31-40 were only 4. Similarly patients administered with Nifedipine, in age group of 15-20yrs were 3, in 21- 25 yrs had maximum number of patients as 12, in age group of 26-30yrs were only 5 and no patients belonging in age group of 31-40yrs.

2. Types of Parity
In my current study, of severe pre eclamptic women, 67.5% women were primigravida and whereas 32.5% were multigravida.
The p-value obtained was <0.0001, which indicates that difference in the Mean Diastolic blood pressure before and after the treatment started was very significant in Labetalol group as well as Nifedipine group.

3. Mean diastolic blood pressure
There was a significant difference in the time taken, to reduce the blood pressure to the target level.
On an average the target Mean Diastolic blood pressure in the Nifedipine group and Labetalol group, after the treatment given was achieved at the earliest, till the end of 25 minutes (P <0.05, statistically significant).
At the end of 30 minutes onwards was seen, that both the drugs statistical status of intergroup differences of changes in Mean Diastolic blood pressure after treatment started, was not significant. (P > 0.05).

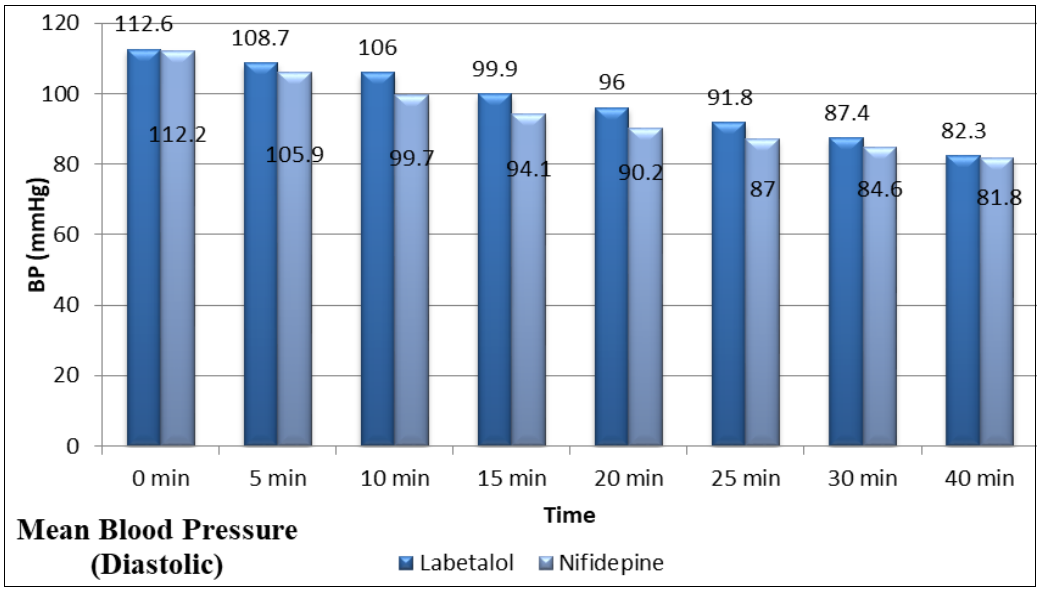

Fig 1: Mean Blood Pressure (Diastolic)

4. Pulse rate

Statistical status of intergroup differences of changes in Mean Pulse rate after the treatment started, the P-value obtained was > 0.05, not significant in both Nifedipine and Labetalol group

The P-value obtained was <0.05, which indicates that difference in the Mean Fetal Heart rate before and after the treatment started was not significant in Nifedipine group as well as Labetalol group.

5. Fetal heart rate

Statistical status of intergroup differences of changes in Mean Fetal heart rate after the treatment started, (the P-value obtained was > 0.05), not significant in both Nifedipine and Labetalol group.

6. Fundoscopic findings

It's evident in this study that patients on Nifedipine had fundoscopic changes is following grades, In Grade of 0 had 11(55%) patients, Grade 1 had 2(10%) patients, Grade 2 had 3(15%) patients, Grade 3 had 4(20%) patients and Grade 4 and grade 5 zero patients were there. Similarly in patients given Labetalol were in grade 0 had 14(70%) patients, Grade 1 had 2 (10%) patients, grade 2 had 3(15%) patients, Grade 3 had 1 (5%) patients, Grade 4 and Grade 5 category were zero patients.

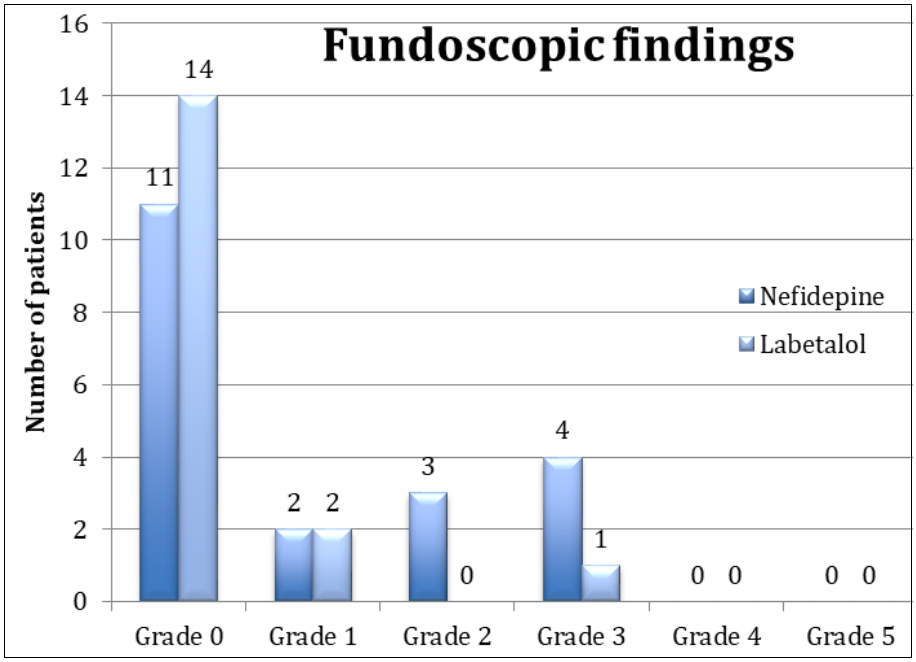

Fig 2: Fundoscopic findings

7. Complications

Table 1: Complications

Complications	Nifedipine group	Labetalol group	Total
Abruptio	3	1	4
HELLP	1	2	3
Eclampsia	4	1	5
Total	8	4	12

Table 2: Complications

Complications	Nifedipine group	Labetalol group	Total
Present	8	4	12
Absent	12	16	28
Total	20	20	40

8. Hemoglobin

In our study, it is seen that the Hb percentage was more than 10mg/dl was seen in 11 (55%) in Nifedipine group whereas, 8 (40%) in Labetalol group.

7 (35%) patients were found out from the Nifedipine group to have Hb of less than 7, as opposed to 11 (55%) in the Labetalol group.

Similarly, only 2 (10%) & 1 (5%) patients were found out to have Hb less than 7 in the Nifedipine & Labetalol group respectively.

9. Mean Platelet Counts

As evident from the table, that the platelet levels less than 2.5 cu/mm in 3 (15%) in Nifedipine group whereas, 2 (10%) in Labetalol group.

7 (35%) patients were found out from the Nifedipine group to have platelet levels of 2.5 to 2.7 cu/mm, opposed to 10 (50%) in the Labetalol group.

Similarly, 10 (50%) & 8 (40%) patients were found out to have platelet levels in the range of 2.7 to 2.8 in the Nifedipine & Labetalol group respectively. This finding was statistically significant

10. Mean urea levels

The mean blood urea values at baseline i.e pre-treatment and post-treatment of the groups.

The standard deviations were found out to be 1.41 for Nifedipine & 6.5 for Labetalol group.

The Intergroup difference was not statistically significant.

11. Mean Uric acid Levels

The mean serum uric acid values baseline pre-treatment and post treatment of the groups.

The standard deviations were found out to be 0.212 for Nifedipine & 0.212 for Labetalol group, same.

The Intergroup difference was not statistically significant.

12. Mean SGOT Levels

The mean of SGOT values baseline i.e. pre-treatment and post treatment of the groups.

The standard deviations were found out to be 3.88 for Nifedipine & 4.59 for Labetalol group.

The Intergroup difference was not statistically significant

13. Mean SGOT Levels

The SGPT mean baseline i.e. pre-treatment and post-treatment of the groups.

The standard deviations were found out to be 2.82 for Nifedipine & 3.88 for Labetalol group.

The Intergroup difference was not statistically significant.

14. Mean LDH Levels

The LDH mean baseline values pre-treatment and post treatment of the groups.

The standard deviations were found out to be 35.5 for Nifedipine & 49.49 for Labetalol group.

The Intergroup difference was not statistically significant

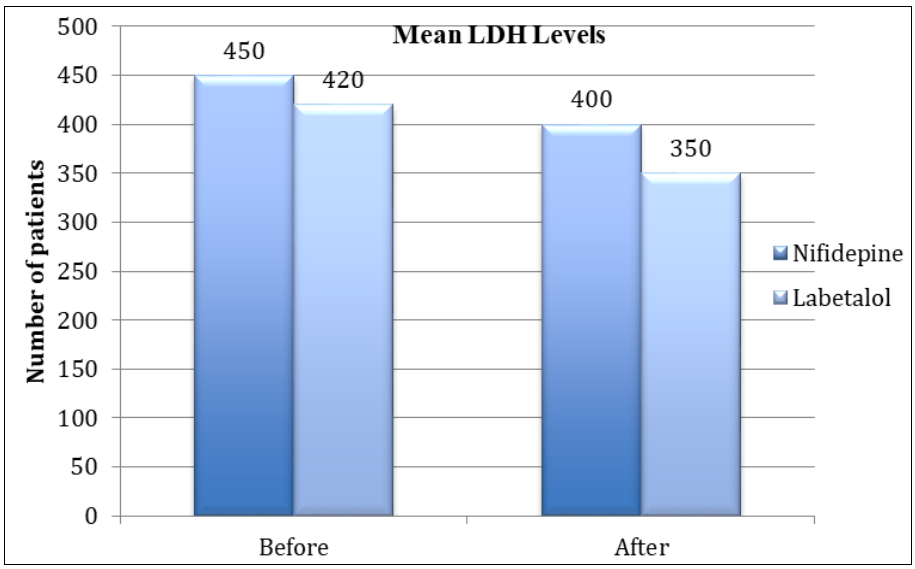

Fig 3: Mean LDH Levels

15. Mean Apgar levels

In our study, it was seen that the APGAR score more than 6 in around 18 (90%) babies in Nifedipine group whereas, 19 (95%) babies in Labetalol group.

2 (10%) babies were found out from the Nifedipine group to have Apgar score in between 3 to 6, as opposed to 1 (5%) baby in the Labetalol group.

On the contrary, no baby was found out to have an Apgar of less than 3 in the Nifedipine & Labetalol group.

Conclusion

In the present study, both oral Nifedipine and IV Labetalol were ultimately effective in reaching the therapeutic goal, but Nifedipine achieved the target blood pressure more rapidly and with fewer doses than Labetalol.

Both drugs demonstrated a similar adverse effects profile.

Nifedipine is also cheaper, easier to store, easier to administer as it is given orally, whereas IV Labetalol is more expensive, needs to be stored at a lower temperature and needs slow IV administration.

Thus the present study concludes that Nifedipine is the preferred drug in case of severe pre-eclampsia to control blood pressure as it is more efficacious and can be used in the peripheral centers due to cost effectiveness and its ease of administration and storage.

Inj Labetalol still has a role in hypertensive emergencies in pregnancy, as it can be used in an unconscious or drowsy patient.

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