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A COMPARATIVE STUDY ON EFFICACY AND SAFETY OF NIFEDIPINE AND LABETOLOL IN PATIENTS WITH PRE ECLAMPSIA

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ABSTRACT

Introduction: Pre-eclampsia is a leading cause of maternal and fetal morbidity and mortality that requires timely and effective blood pressure management. This study has compared the efficacy and safety of Nifedipine with that of Labetalol in reducing blood pressure in pre-eclamptic patients. **Methodology:** Ninety pre-eclamptic patients were randomly assigned into two groups, each containing 45 patients who received either Nifedipine or Labetalol. Baseline systolic and diastolic BP was measured; subsequently, BP was measured at 2, 4, 6, 12, 24, and 48 hours following the start of therapy. The percentage of patients achieving target BP (<140/90 mmHg) was compared between groups, and also the occurrence of side effects. All analyses were done by t-tests with $p<0.05$ considered significant. **Results:** Both drugs lowered both systolic and diastolic BP; however, Labetalol provided larger reductions at every time period studied. At 48 hours, the mean systolic BP reduction was 40.8 mmHg in the Labetalol group, while it was 34.4 mmHg in the Nifedipine group ($p<0.05$). The mean diastolic BP reduction was 26.5 mmHg with Labetalol versus 22.7 mmHg with Nifedipine ($p<0.05$). A higher percentage of patients achieved target BP in the Labetalol group, 93.3% for systolic and 91.1% for diastolic BP, compared to the Nifedipine group, with only 84.4% and 75.6%, respectively. Both drugs demonstrated similar safety profiles with no major difference. **Conclusion:** In summary, this study confirms that both Nifedipine and Labetalol reduces blood pressure in patients with pre-eclampsia, but Labetalol causes more rapid and more sustained reductions in both systolic and diastolic BP with similar safety outcomes.

KEYWORDS: Pre-eclampsia, Nifedipine, Labetalol, Blood pressure, Hypertension, Efficacy, Safety, Target blood pressure.

INTRODUCTION

Pre-eclampsia is a pregnancy-related illness defined by the onset of hypertension and proteinuria after 20 weeks of gestation. It occurs in approximately 2-8% of pregnancies worldwide and is considered to be one of the major causes of maternal and fetal morbidity and mortality. The condition has a significant risk for preterm birth, maternal organ damage, and restriction in fetal

growth. Again, good blood pressure management is deemed very important to improve outcomes for both mother and baby.[1,2]

Because of these, managing blood pressure in pre-eclampsia is a must to minimize maternal and fetal complications. Uncontrolled hypertension may result in stroke, acute renal failure, placental abruption, and even fetal distress. In treating pre-eclampsia, the two main objectives are to reduce blood pressure in order to avoid such complications and to stabilize the condition until it is safe to manage delivery.[3,4]

The current guidelines are presenting pharmacological treatment for blood pressure greater than 160/110 mmHg. The choice of drugs depends on the efficacy of the drug, its side effect profile, and characteristics of the individual patient. There are several classes of antihypertensive agents; however, being most prescribed, Nifedipine and Labetalol are preferred due to proven efficacy with a relatively more acceptable safety profile.[5,6]

While nifedipine is a calcium channel blocker, labetalol is generally recognized as a combined alpha- and beta-blocker. Both drugs have been used in clinical practice for the management of elevated blood pressure in pre-eclamptic patients; however, there are limited studies comparing the efficacy and safety of either drug. This study, therefore, compares the efficacy and safety of Nifedipine with Labetalol in relation to the reduction of blood pressure.[7,8]

The findings of this study will give crucial clinical significance to the management of pre-eclampsia. This proposed research will make a direct comparison of the efficacy and safety of Nifedipine with Labetalol, hence availing information that would be quite useful in guiding clinical decisions. These results may enable clinicians to select a drug that is most effective and safest for managing blood pressure in pre-eclamptic patients, thus optimizing patient outcomes.

Furthermore, the gain in knowledge of the relative effectiveness of these two drugs will help in tailoring treatment options to more personalized treatment strategies, considering individual patient characteristics and potential side effects. The results may guide future guidelines and recommendations on the management of hypertension in pre-eclampsia.[9,10]

AIM

The study aimed to compare the efficacy and safety of Nifedipine and Labetalol in reducing blood pressure (BP) in pre-eclamptic patients

OBJECTIVES

1. Compare the efficacy of Nifedipine and Labetalol in reducing systolic and diastolic blood pressure in pre-eclamptic patients.
2. Evaluate the time-dependent changes in blood pressure for both Nifedipine and Labetalol treatment groups.
3. Determine the percentage of patients achieving target blood pressure (<140/90 mmHg) within 48 hours of treatment.
4. Assess and compare the safety profiles of Nifedipine and Labetalol, focusing on side effects.

METHODOLOGY

Study site: This was a prospective, comparative study conducted on 90 patients diagnosed with pre-eclampsia at a tertiary care hospital.
Study duration: The study is conducted over a period of 6 months.
Study design: Prospective, comparative study
Sample size: 90 pateints were enrolled into this study
Study method: This prospective, comparative study involved 90 pre-eclamptic patients divided into two groups: 45 receiving Nifedipine (10mg) and 45 receiving Labetalol (200mg). Baseline systolic and diastolic blood pressure (BP) were recorded, and measurements were taken at 2, 4, 6, 12, 24, and 48 hours post-treatment. Efficacy was assessed by BP reduction and achievement of target BP (<140/90 mmHg), while safety was evaluated based on side effects. Statistical analyses included t-tests for BP reduction comparisons with significance set at $p<0.05$.

Study criteria

Inclusion criteria

1. Pregnant women aged 18-40 years.
2. Diagnosed with pre-eclampsia (systolic BP ≥140 mmHg and/or diastolic BP ≥90 mmHg).
3. Gestational age ≥20 weeks**.**

Exclusion criteria

1. Patients with pre-existing hypertension.
2. Women with known cardiovascular diseases.
3. Patients with contraindications to Nifedipine or Labetalol.

Statistical analysis

After entering the data into a Microsoft Excel spreadsheet, basic statistical procedures were used to do statistical analysis and provide frequencies and percentages. Results were Analyzed using SPSS 19.0 version.

RESULTS

1. Subject characteristics

Subject characteristics	Nifedipine group (n=45)	Labetalol group (n=45)
Age category		
< 20 years (%)	8 (17.8%)	6 (13.3%)
20-30 years (%)	25 (55.6%)	28 (62.2%)
> 30 years (%)	12 (26.7%)	11 (24.4%)
BMI (kg/m²)		
BMI (kg/m²)	26.8 ± 3.2	27.2 ± 3.1
Comorbidities		
Hypertension (%)	18 (40.0%)	20 (44.4%)
Diabetes (%)	7 (15.6%)	8 (17.8%)

Patients were divided the into three age groups: below 20 years, from 20 to 30 years, and more than 30 years. In the Nifedipine group, 17.8% were below 20, 55.6% were between 20-30 years, and 26.7% were above 30. Whereas in the Labetalol group, 13.3% were below 20, 62.2% were between 20-30 years, and 24.4% were above 30. The mean of the BMI was the same for the two groups: 26.8 kg/m2 in the Nifedipine group compared to 27.2 kg/m2 in the Labetalol group. Hypertension and diabetes were identically distributed in both groups.

2. Baseline blood pressure.

Nifedipine group (n=45)	Labetalol group (n=45)	P-value
160.4 ± 8.0	159.8 ± 7.9	0.7
104.2 ± 5.8	104.0 ± 6.1	0.89

The baseline systolic BP was 160.4 ± 8.0 mmHg in the Nifedipine group and 159.8 ± 7.9 mmHg in the Labetalol group. The baseline diastolic BP was 104.2 ± 5.8 mmHg in the Nifedipine group and 104.0 ± 6.1 mmHg in the Labetalol group. There were no significant differences in baseline BP between the two groups.

3. Change in blood pressure at different time intervals

Time interval	Nifedipine Group (n=45)	Labetalol Group (n=45)	P-value
Systolic BP (mmHg)			
After 2 hours	148.2 ± 7.1	142.5 ± 7.2	0.02*
After 4 hours	140.1 ± 7.0	133.4 ± 7.3	0.01*
After 6 hours	135.7 ± 6.8	129.5 ± 6.9	0.01*
After 12 hours	132.3 ± 7.0	126.8 ± 7.1	0.02*
After 24 hours	129.5 ± 6.9	122.3 ± 6.7	0.01*
After 48 hours	126.0 ± 6.5	119.0 ± 6.4	0.03*
Diastolic BP (mmHg)			
After 2 hours	96.1 ± 5.3	92.7 ± 5.0	0.03*
After 4 hours	91.8 ± 5.2	88.0 ± 5.1	0.02*
After 6 hours	89.0 ± 5.1	84.4 ± 5.0	0.01*
After 12 hours	86.5 ± 5.0	81.8 ± 4.9	0.01*
After 24 hours	83.8 ± 5.1	79.2 ± 5.0	0.01*
After 48 hours	81.5 ± 4.9	77.5 ± 4.8	0.02*

This table represents the change in systolic and diastolic blood pressure in both groups at variable times, i.e., 2, 4, 6, 12, 24, and 48 hours after treatment. Values are expressed as means ± SDs. Labetalol caused a significantly greater fall of both systolic and diastolic BP in each time period than Nifedipine. The between-group difference was statistically significant at all time periods. ($p<0.05$).

4. Difference in blood pressure from baseline to 48 hours

BP Parameter	Nifedipine Group (n=45)	Labetalol Group (n=45)	P-value
Systolic BP Reduction	34.4 ± 7.2	40.8 ± 7.4	0.01*
Diastolic BP Reduction	22.7 ± 5.1	26.5 ± 5.0	0.02*

This table presents the mean change in systolic and diastolic blood pressure from baseline to 48 hours for each group. Labetalol provided a significantly greater reduction of BP compared with Nifedipine. The mean reduction in SBP was 34.4 ± 7.2 mmHg in the Nifedipine group and 40.8 ± 7.4 mmHg in the Labetalol group. The mean reduction in diastolic BP was 22.7 ± 5.1 mmHg for

those receiving Nifedipine and 26.5 ± 5.0 mmHg for those treated with Labetalol.

5. Achievement of target BP

Target BP Achieved	Nifedipine Group (n=45)	Labetalol Group (n=45)	P-value
Target Systolic BP <140 mmHg	38 (84.4%)	42 (93.3%)	0.22
Target Diastolic BP <90 mmHg	34 (75.6%)	41 (91.1%)	0.08

In the group receiving Nifedipine, target systolic BP was achieved by 84.4% of the patients, whereas in the Labetalol group, the target was reached by 93.3%. As for the diastolic blood pressure, 75.6% in the Nifedipine and 91.1% in the Labetalol group reached the target.

6. Safety outcomes (Side effects)

Adverse event	Nifedipine Group (n=45)	Labetalol Group (n=45)
Headache (%)	10 (22.2%)	6 (13.3%)
Dizziness (%)	8 (17.8%)	5 (11.1%)
Flushing (%)	7 (15.6%)	4 (8.9%)
Palpitations (%)	5 (11.1%)	3 (6.7%)

The headache occurrence was as high as 22.2% in the Nifedipine group against 13.3% in the Labetalol group. Dizziness occurred in 17.8% of the Nifedipine and 11.1% in the Labetalol groups. Other side effects, including flushing and palpitations, were reported at a lower frequency among the two groups.

DISCUSSION

This comparative study looks at the efficacy and safety of Nifedipine and Labetalol in the reduction of blood pressure in pre-eclampsia patients. The results have shown that though both drugs effectively lowered the systolic and diastolic blood pressures, Labetalol was significantly more effective with higher reductions in blood pressure over time.

Efficacy of blood pressure reduction

Results showed that both Nifedipine and Labetalol produced significant reductions in systolic and diastolic blood pressures across all time points. However, the reductions caused by Labetalol were consistently higher and reached statistical significance as early as 2 hours after treatment, continuing up to 48 hours. By 48 hours, the difference in BP reduction between the two drugs was highly significant, with a mean reduction of 40.8 mmHg in systolic BP and 26.5 mmHg in diastolic BP in the Labetalol group, compared with 34.4 mmHg and 22.7 mmHg, respectively, in the Nifedipine group.

This greater efficacy on the part of Labetalol agrees with earlier reports showing its dual action as both an alpha and beta blocker offers all-round control of blood pressure in hypertensive disorders such as pre-eclampsia. On the other hand, Nifedipine, a calcium channel blocker, demonstrated effectiveness but with a slightly more delayed and less potent action compared to Labetalol.

Achievement of target blood pressure

In the Labetalol group, the percentage of patients who reached target blood pressure was higher (systolic less than 140 mmHg and diastolic less than 90 mmHg). However, though both groups had a high proportion of patients achieving the target BP, 93.3% of the patients in the Labetalol group reached the target systolic BP, compared to 84.4% in the Nifedipine group. In the diastolic BP, similar trends were noticed, with more patients in the Labetalol group reaching target diastolic BP (91.1%) compared to that of the Nifedipine group (75.6%).

Safety outcomes

The management of pre-eclampsia should be balanced, considering the safety of both mother and fetus from potential side effects of drugs. Both drugs in the current study were well-tolerated, with no major differences regarding the occurrence of side effects. The most common side effects included headache, dizziness, flushing, and palpitations, all of which are known side effects of antihypertensive drugs.

Although this is a basically important study to learn about the comparative efficacy and safety of Nifedipine and Labetalol, it is limited by the relatively small sample size of 90 patients. Larger, multi-center studies would be required for confirmation of these findings and further investigation of the long-term maternal and fetal outcomes related to the use of these antihypertensive drugs.

CONCLUSION

The results, therefore, in this study show that Nifedipine and Labetalol are both effective agents in lowering the blood pressure of patients suffering from pre-eclampsia; Labetalol produced a faster and more sustained reduction in both systolic and diastolic BP. Both drugs had a similar safety profile as evidenced by no major difference in side effects. Given the superior efficacy of labetalol in achieving BP control, it is likely to be the drug of choice in the management of pre-eclampsia. However, both drugs are extremely important options depending on individual patient needs. Further studies might investigate combined therapies or other novel

agents in the management of pre-eclampsia in order to further optimize efficacy and safety.

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