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ORIGINAL ARTICLE

Comparative Effectiveness of Nifedipine and Labetalol for The Management of Pregnancy-Induced Hypertension: An Observational Study

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ABSTRACT
To assess the effectiveness of commonly used antihypertensive medications, specifically Nifedipine and Labetalol, and their combination in managing pregnancy-induced hypertension (PIH) among pregnant women. Pregnancy-induced hypertension (PIH), also referred to as gestational hypertension, is a prevalent medical condition affecting a considerable number of pregnant women globally. Given its impact on maternal and fetal well-being, effective management of PIH is imperative. While Nifedipine and Labetalol are frequently employed antihypertensive medications in pregnant women, there is a paucity of evidence comparing their effectiveness in addressing PIH. This prospective observational study included 94 pregnant women diagnosed with PIH, categorized into three treatment groups: Labetalol (n=54), Nifedipine (n=33), and a combination of Nifedipine and Labetalol (n=7). Blood pressure measurements were recorded before treatment initiation and at three subsequent follow-up visits. The changes in blood pressure at each follow-up were analyzed, and the Chi-squared test was employed to assess group differences. All three treatment groups exhibited significant reductions in blood pressure throughout the study period (p<0.001). Notably, the combination therapy of Nifedipine and Labetalol demonstrated the most substantial reduction in blood pressure during the first and second follow-ups. The Chi-squared test results underscored significant differences between the treatment groups concerning blood pressure reduction (p<0.001). This study offers preliminary evidence supporting the efficacy of Labetalol, Nifedipine, and a combination of Nifedipine and Labetalol in controlling pregnancy-induced hypertension among pregnant women. The combination therapy appears to exert the most pronounced impact on blood pressure reduction. Nevertheless, further research with enhanced study designs, larger sample sizes, and extended follow-up periods is imperative to validate and consolidate these findings.
Keywords: *Pre-eclampsia, Pregnancy induced hypertension, blood pressure, Nifedipine, Labetatol*

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INTRODUCTION

Pre-eclampsia, also known as Pregnancy-Induced Hypertension (PIH), is a primary contributor to maternal and neonatal morbidity and mortality, predominantly in developing countries. This condition is typically diagnosed in late pregnancy, characterized by elevated blood pressure, proteinuria, and/or edema. Disease prevention requires understanding its prevalence, etiology, and pathogenesis [1]. The World Health Organization reports that at least one woman dies every seven minutes due to complications arising from PIH disorders. Pregnancies complicated by hypertensive disorders present an increased risk of adverse fetal, neonatal, and maternal outcomes. Pregnancy-induced hypertension affects approximately 10% of pregnancies, while pre-eclampsia complicates 2-8% of pregnancies. Eclampsia

incidence varies between 1/100 and 1/1700 in resource-poor countries, while it occurs in about 1/2000 deliveries in resource-rich countries [2]. Severe pre-eclampsia in pregnancy is defined by a systolic blood pressure ≥160 mmHg or diastolic blood pressure ≥110 mmHg, or both. Eclampsia, a severe form of PIH, occurs in approximately one in 1,600 pregnancies and typically develops near the end of pregnancy [3]. Risk factors for PIH include multiple pregnancies, history of chronic hypertension, gestational diabetes, fetal malformation, obesity, extreme maternal age (under 20 or over 40 years), history of PIH in previous pregnancies, chronic diseases like renal disease, diabetes mellitus, cardiac disease, unrecognized chronic hypertension, positive family history of PIH indicating genetic susceptibility, psychological stress, alcohol use, rheumatic arthritis, extreme underweight and overweight, asthma, and low socioeconomic status [4]. PIH reduces placental perfusion, potentially resulting in feto-placental hypoxia [5,6]. Fetal hypoxia may lead to antenatal hypoxic-ischemic states in the intestine or its mucosa. Furthermore, PIH-induced utero-placental ischemia can trigger the production of inflammatory cytokines [7]. To minimize the occurrence of fetal abnormalities and complications, appropriate drug prescribing patterns should be followed. Labetalol is the most prescribed medication for PIH. However, nifedipine, a newly prescribed antihypertensive agent, has the advantage of reducing preterm labor risk. This study aims to compare the effectiveness of nifedipine and labetalol in managing hypertensive emergencies during pregnancy and enhancing pregnancy quality of life by preventing PIH-related complications.

MATERIAL AND METHODS

This prospective observational study was conducted at AC Subba Reddy Govt General Hospital, Nellore through 6 months period by reviewing 94 prescriptions. Patient data was collected through patient data collection form after getting prior informed consent from the patient. Pregnant women who were prescribed with drugs of study, Nifedipine and Labetalol as antihypertensive therapy and who are in the age group of 18-35 years were selected for the study. Patients with history and current comorbidities were excluded. After collection of the demographic data the patients were monitored for their blood pressure once in 2 months and the effect of drugs on the control of blood pressure was assessed through the questionnaires.

Statistical analysis:

The values were analyzed using IBM SPSS software and were expressed as mean ± SD. The relationship between variables was determined using Chi squared analysis were $P<0.001$ were considered significant.

RESULTS

The current study was conducted among 150 patients, most prevalent complication of pregnancy is hypertension which was observed in 94 patients and followed by DM (30 patients), epilepsy (6 patients), Anemia (20 patients). Out of 150 patients enrolled for study, 94 were PIH patients, 20 patients were at the age of 18-20 years, 45 patients were at the age of 21-25 years, 22 patients were at the age of 26-30 years.

Table 1: Data of blood pressure through 3 follow ups

Drug Name	No of Patients	BP before treatment (mm Hg) Syst/Dias	BP on first follow up (mm Hg) Syst/Dias	BP on Second follow up (mm Hg) Syst/Dias	BP on Third follow up (mm Hg) Syst/Dias
Labetalol	54	147.4±9.1/ 108.1±5.9	138.7±4.7/ 107.6±6.5	134.5±5.4/ 103.2±3.9	127.3±7.5/ 93.3±3.1
Nifedipine	33	158.3±10.4/ 118.8±4.3	137.9±5.4/ 111.5±7.7	130.2±6.4/ 99.0±5.5	121.6±4.2/ 89.3±1.4
Nifedipine + Labetalol	7	175.9±11.3/ 128.2±4.8	148.0±3/ 116.8±9.1	121.9±6.9/ 98.4±7.4	120.6±1.1/ 82.9±5.3

The table 1 shows the change in blood pressure (BP) for three different groups of patients who were treated with different drugs, over the course of three follow-up visits. The first group of 54 patients was treated with Labetalol, and their systolic BP decreased from an average of 147.4 mm Hg before treatment to 127.3 mm Hg after the third follow-up. The diastolic BP also decreased from an average of 108.1 mm Hg before treatment to 93.3 mm Hg after the third follow-up.

The second group of 33 patients was treated with Nifedipine, and their systolic BP decreased from an average of 158.3 mm Hg before treatment to 121.6 mm Hg after the third follow-up. The diastolic BP also decreased from an average of 118.8 mm Hg before treatment to 89.3 mm Hg after the third follow-up. The third group of 7 patients was treated with a combination of Nifedipine and Labetalol. Their systolic BP decreased from an average of 175.9 mm Hg before treatment to 120.6 mm Hg after the third follow-up. The diastolic BP also decreased from an average of 128.2 mm Hg before treatment to 82.9 mm Hg after the third follow-up. Overall, the results suggest that all three drugs were effective in reducing blood pressure over the course of the three follow-up visits. However, the combination of Nifedipine and Labetalol appeared to be the most effective, as it resulted in the largest decrease in both systolic and diastolic blood pressure. It is important to note that the sample size for the third group was very small, so further research is needed to confirm these results.

Table 2: Changes in the blood pressure through the follow ups

Drug Name	**Change in Blood Pressure Syst/Dias**			**Chi Squared test P value**
	First follow up	**Second follow up**	**Third follow up**	
Labetalol	7.9±1.9/ 1.0±0.8	4.3±0.8/ 3.2±1.1	2.1±0.6/ 8.3±1.6	0.001
Nifedipine	18.3±2.7/ 4.8±1.0	9.3±1.0/ 12.1±1.4	8.9±2.7/ 8.3±1.5	0.001
Nifedipine+Labetalol	27.5±3.8/ 8.3±1.9	27.4±5.2/ 16.3±2.2	0.8±0.4/ 17.2±2.1	0.001
Chi Squared test P value	0.001	0.001	0.034	

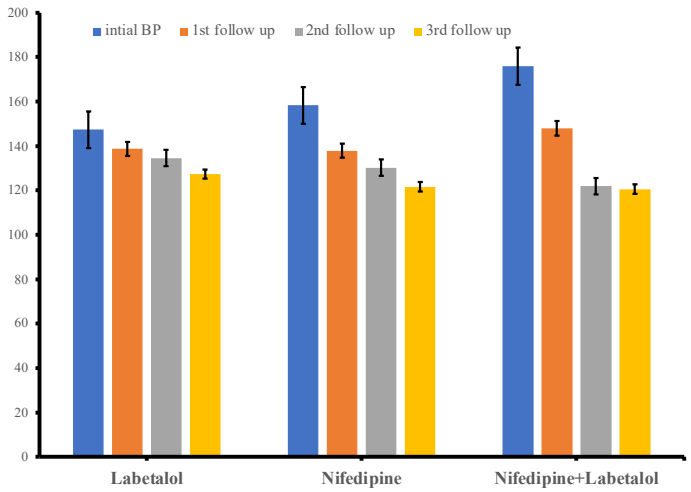

Figure 1: Changes in the blood pressure during the follow ups

For the first group of patients who were treated with Labetalol, the systolic blood pressure decreased by 7.9±1.9 mm Hg after the first follow-up, 4.3±0.8 mm Hg after the second follow-up, and 2.1±0.6 mm Hg after the third follow-up. The diastolic blood pressure also decreased over the three follow-up visits. The Chi-Squared test showed that the changes in blood pressure were significant ($P<0.001$) for all three follow-up visits. For the second group of patients who were treated with Nifedipine, the systolic blood pressure decreased by 18.3±2.7 mm Hg after the first follow-up, 9.3±1.0 mm Hg after the second follow-up, and 8.9±2.7 mm Hg after the third follow-up. The diastolic blood pressure also decreased over the three follow-up visits. The Chi-Squared test showed that the changes in blood pressure were significant ($P<0.001$) for all three follow-up visits. For the third group of patients who were treated with a combination of Nifedipine and Labetalol, the systolic blood pressure decreased by 27.5±3.8 mm Hg after the first follow-up, 27.4±5.2 mm Hg after the second follow-up, and 0.8±0.4 mm Hg after the third follow-up. The diastolic blood pressure also decreased over the first two follow-up visits, but did not change significantly after the third follow-up. The Chi-Squared test showed that the changes in blood pressure were significant ($P<0.001$) for the first two follow-up visits, but not for the third follow-up.

DISCUSSION

The present study compared the effectiveness of Labetalol, Nifedipine, and a combination of Nifedipine and Labetalol in managing pregnancy-induced hypertension. The results showed that all three treatments were effective in reducing blood pressure throughout the follow-ups, with Nifedipine + Labetalol having the greatest reduction in systolic and diastolic blood pressure compared to the other two groups. All three treatment groups showed significant reductions in blood pressure over the course of the study, as indicated by the p-values less than 0.05. However, the degree of blood pressure reduction and the rate at which the reduction occurred varied among the groups. These findings are consistent with previously published research. A study by Raheem et al. [8] found that both Labetalol and Nifedipine were effective in managing pregnancy-induced hypertension, with Labetalol being more effective in reducing diastolic blood pressure. In our study, Labetalol was also effective in reducing both systolic and diastolic blood pressure. Another study by Firoz et al. [9] compared the efficacy of Nifedipine and Labetalol in the management of pregnancy-induced hypertension and found that Nifedipine was more effective in lowering blood pressure than Labetalol. In our study, Nifedipine also demonstrated a significant reduction in blood pressure. Based on the Chi-squared test results, all three treatment groups were significantly different from each other in terms of their impact on blood pressure reduction. The combination therapy of Nifedipine and Labetalol was the most effective in reducing blood pressure, particularly during the first and second follow-ups. This suggests that using a combination of drugs may have a synergistic effect in controlling pregnancy-induced hypertension. However, it is essential to note that the number of patients in the combination therapy group (n=7) was significantly smaller than the other groups, which may have an impact on the generalizability of the results. Further research with larger sample sizes is needed to confirm the findings of this study. The study included a relatively small number of participants, particularly in the combination therapy group (Nifedipine + Labetalol) which is one major limitation. This limitation may affect the generalizability and robustness of the findings, as well as the statistical power of the study. The study did not mention random assignment of participants to the treatment groups. If participants were not randomly assigned, it could potentially introduce selection bias and confound the results. The study did not include a control group with no intervention or a placebo treatment. The absence of a control group makes it difficult to determine the true effect of the treatments on blood pressure reduction, as other factors could have contributed to the observed changes.

CONCLUSION

This study aimed to compare the efficacy of Labetalol, Nifedipine, and a combination of Nifedipine and Labetalol in controlling pregnancy-induced hypertension in pregnant women. The results suggested that all three treatment options were effective in reducing blood pressure, with the combination therapy showing the most significant impact, particularly during the first and second follow-ups. However, several limitations, such as the small sample size, lack of randomization, and absence of a control group, should be considered when interpreting the findings. While this study provides preliminary evidence supporting the efficacy of Labetalol, Nifedipine, and a combination of Nifedipine and Labetalol in controlling pregnancy-induced hypertension, further research with improved study designs is needed to confirm these findings and determine the optimal treatment approach for this population. By addressing the limitations of the current study, future research will contribute to a more comprehensive understanding of the best strategies for managing pregnancy-induced hypertension, ultimately improving maternal and fetal outcomes.

Conflict of Interest: Authors has NO conflicts of interest.

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