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Research Article

Comparison of Therapeutic Effect of Labetalol with Nifedipine in Control of Hypertensive Disorders of Pregnancy

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ABSTRACT

Background: Pregnancy-induced hypertension (PIH) is a major contributor to maternal and perinatal morbidity and mortality worldwide. Labetalol and nifedipine are commonly recommended first-line antihypertensive agents in pregnancy; however, evidence comparing their relative efficacy and fetomaternal outcomes remains variable.
Objectives: To compare the efficacy and safety of oral labetalol and oral nifedipine in the management of pregnancy-induced hypertension, with emphasis on blood pressure control, dose requirement, maternal outcomes, and neonatal outcomes.
Methods: A randomized prospective comparative study was conducted in a tertiary care hospital over one year. One hundred pregnant women diagnosed with PIH after 20 weeks of gestation were randomized into two groups: Group A received oral labetalol (n=50) and Group B received oral nifedipine (n=50). Blood pressure parameters, time to achieve target blood pressure (≤150/100 mmHg), number of doses required, need for additional antihypertensive therapy, maternal complications, and neonatal outcomes were recorded and analyzed using SPSS version 22.
Results: Baseline demographic and clinical characteristics were comparable between groups. Labetalol achieved significantly lower systolic blood pressure and mean arterial pressure at 30 minutes compared to nifedipine ($p<0.05$). The mean time to reach target blood pressure was significantly shorter with labetalol (28.2 ± 8.1 minutes vs. 33.4 ± 12.3 minutes; $p<0.001$). Fewer doses were required in the labetalol group ($p=0.028$). Mean blood loss during delivery and incidence of postpartum hemorrhage were significantly lower with labetalol. Neonatal birth weight was significantly higher in the labetalol group ($p=0.002$), while other neonatal outcomes were comparable.
Conclusion: Both labetalol and nifedipine are effective and safe for managing PIH. However, labetalol demonstrated superior efficacy with faster blood pressure control, fewer dose requirements, reduced intrapartum blood loss, and improved neonatal birth weight, supporting its role as a preferred first-line agent in PIH management.

Keywords*: Pregnancy-Induced Hypertension, Labetalol, Nifedipine, Maternal-Fetal Outcomes, Antihypertensive Agents.*

INTRODUCTION

Hypertensive disorders of pregnancy (HDP) are among the most common medical complications encountered during pregnancy and remain a leading cause of maternal and perinatal morbidity and mortality worldwide, particularly in developing countries. This condition, which includes gestational hypertension and pre-eclampsia, affects approximately 5–10% of all pregnancies. These conditions significantly contribute to adverse maternal outcomes such as placental abruption, eclampsia, stroke, renal and hepatic dysfunction, as well as fetal complications including intrauterine growth restriction, prematurity, low birth weight, and increased perinatal mortality.

HDP is defined as the new onset of hypertension, with systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg, occurring after 20 weeks of gestation in a previously normotensive woman, without proteinuria or systemic involvement. When hypertension is accompanied by proteinuria or evidence of end-organ dysfunction, it is classified as

pre-eclampsia, a more severe and potentially life-threatening condition. Early detection and effective management of HDP are crucial to prevent disease progression and reduce maternal and fetal complications.

The pathophysiology of HDP and pre-eclampsia is complex and not fully understood. Current evidence suggests that abnormal placentation, impaired trophoblastic invasion of spiral arteries, endothelial dysfunction, exaggerated inflammatory response, and an imbalance between angiogenic and anti-angiogenic factors play central roles. These abnormalities lead to increased systemic vascular resistance, reduced uteroplacental perfusion, and widespread vasoconstriction, resulting in hypertension and multi-organ involvement.

Antihypertensive therapy remains a cornerstone in the management of HDP, with the primary goal of reducing maternal blood pressure while preserving adequate uteroplacental blood flow. An ideal antihypertensive agent in pregnancy should be effective, rapidly acting, safe for both mother and fetus, and well tolerated. Among the various drugs available, labetalol and nifedipine are widely recommended as first-line agents for the management of hypertension in pregnancy.

Labetalol is a combined alpha- and beta-adrenergic blocker that lowers blood pressure by reducing peripheral vascular resistance without significant reduction in cardiac output or uteroplacental perfusion. It is commonly used in both oral and intravenous forms for mild to severe hypertension in pregnancy. Nifedipine, a dihydropyridine calcium channel blocker, reduces blood pressure through vasodilation by inhibiting calcium influx into vascular smooth muscle. It is effective in both acute and chronic hypertension and is favored for its oral route of administration and rapid onset of action.

Although both labetalol and nifedipine are considered safe and effective, studies have reported variable results regarding their comparative efficacy, speed of blood pressure control, side-effect profiles, and maternal-fetal outcomes. Given the significant burden of HDP and the need for evidence-based therapeutic choices, this study aims to compare the efficacy and safety of labetalol and nifedipine in the management of pregnancy-induced hypertension, with particular emphasis on blood pressure control, maternal adverse effects, and perinatal outcomes.

MATERIALS AND METHODS

Study type and setting

A comparative randomized prospective study was conducted to evaluate and compare the therapeutic efficacy of labetalol and nifedipine in the management of pregnancy-induced hypertension (HDP). The study was carried out in the Department of Obstetrics and Gynaecology at North Bengal Medical College and Hospital, Darjeeling, a tertiary care teaching hospital catering to a large referral population.

Study period

The study duration was one year, during which eligible participants were recruited from the antenatal clinic, labour room, and postnatal ward of the department.

Pregnant women diagnosed with hypertension after 20 weeks of gestation were screened for eligibility.

Study population

Inclusion criteria comprised women with blood pressure readings of ≥140/90 mmHg recorded on at least two occasions more than six hours apart, gestational age between 20 weeks and term, and willingness to participate after providing informed consent. Women with multifetal pregnancy, chronic hypertension, diabetes mellitus, cardiac disease, renal disease, thyrotoxicosis, eclampsia, intrauterine fetal demise at presentation, or those unwilling to participate were excluded from the study.

Sample size and sampling technique

The sample size was calculated using power analysis with an assumed effect size of 0.5, a significance level of 0.05, and a power of 80%. Based on these parameters, a minimum of 50 participants were required in each group, resulting in a total sample size of 100. Participants were recruited using a consecutive sampling technique until the required sample size was achieved.

Study tools and technique

After obtaining written informed consent, detailed demographic and clinical information was recorded, including age, gravidity, gestational age, obstetric history, and relevant medical history. A thorough general and obstetric examination was performed for each participant. Baseline blood pressure was measured using a mercury sphygmomanometer in the sitting position after a rest period of at least 10 minutes. Two readings were taken at least six hours apart, and the average value was recorded. Laboratory investigations including complete blood count, liver function tests, renal function tests, and urine examination for proteinuria were performed in all patients to assess disease severity and rule out end-organ involvement.

Participants were randomly allocated into two groups using a computer-generated randomization sequence, with allocation concealment ensured through sealed opaque envelopes. Group A received oral labetalol at an initial dose of 100 mg three

times daily, while Group B received oral nifedipine at an initial dose of 10 mg twice daily. Drug doses were adjusted as required based on blood pressure response and clinical condition, following standard treatment protocols.

Following initiation of therapy, blood pressure monitoring was performed every six hours for the first 48 hours and subsequently twice daily until delivery. The time taken to achieve target blood pressure (≤150/100 mmHg), number of doses required, and need for additional antihypertensive therapy were documented. Patients were monitored closely for drug-related adverse effects such as bradycardia, hypotension, dizziness, and fatigue in the labetalol group, and headache, flushing, tachycardia, and palpitations in the nifedipine group.

Fetal surveillance included daily fetal heart rate monitoring and periodic ultrasonography with Doppler studies where indicated to assess fetal growth and wellbeing. Mode of delivery was decided based on obstetric indications and maternal-fetal status. Estimated blood loss during delivery and occurrence of postpartum hemorrhage were recorded. Neonatal outcomes including birth weight, Apgar scores, need for NICU admission, and complications were documented.

All data were entered into Microsoft Excel and analyzed using IBM SPSS version 22. Continuous variables were expressed as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages. Appropriate statistical tests were applied, and a p-value of <0.05 was considered statistically significant.

Ethical Considerations

Ethical clearance for the study was obtained from the Institutional Ethics Committee of North Bengal Medical College and Hospital prior to commencement. Confidentiality of participant information was strictly maintained, and participants were informed of their right to withdraw from the study at any stage without affecting their standard of care.

RESULTS

A total of 100 pregnant women diagnosed with pregnancy-induced hypertension were included in the study, with 50 patients each in the labetalol and nifedipine groups. The baseline sociodemographic and obstetric characteristics of the two groups were comparable. Most participants belonged to the 21–25-year age group, accounting for 58% in the labetalol group and 46% in the nifedipine group, followed by the 26–30-year age group (20% and 18%, respectively). Adolescents (<20 years) constituted 16% of the labetalol group and 24% of the nifedipine group. No statistically significant difference was observed in age distribution between the groups ($p = 0.462$). Primigravida women formed the majority in both groups (60% in labetalol and 58% in nifedipine), with similar distribution of multigravida patients ($p = 0.677$). Most patients delivered at term (≥37 weeks), with 76% in the labetalol group and 74% in the nifedipine group, and no significant difference in gestational age distribution was noted ($p = 0.487$) **(Table 1).**

Baseline blood pressure parameters were comparable between the two groups prior to drug administration. The mean systolic blood pressure (SBP) was 161.5 ± 4.2 mmHg in the labetalol group and 160.4 ± 4.4 mmHg in the nifedipine group ($p = 0.689$). Similarly, baseline diastolic blood pressure (DBP) and mean arterial pressure (MAP) did not differ significantly between groups ($p = 0.709$ and $p = 0.877$, respectively). Thirty minutes after drug administration, both drugs produced a significant reduction in blood pressure; however, the reduction was more pronounced in the labetalol group. Mean SBP was significantly lower in the labetalol group compared to the nifedipine group (150.1 ± 5.8 mmHg vs. 155.3 ± 6.6 mmHg; $p = 0.048$). MAP was also significantly lower with labetalol (119.5 ± 5.5 mmHg) than nifedipine (122.1 ± 3.3 mmHg; $p = 0.033$), while DBP reduction was comparable between groups ($p = 0.897$). The mean time taken to achieve target blood pressure was significantly shorter in the labetalol group (28.2 ± 8.1 minutes) compared to the nifedipine group (33.4 ± 12.3 minutes) ($p < 0.001$) **(Table 2).**

Regarding dose requirements, a single dose was sufficient to achieve target blood pressure in 40% of patients receiving labetalol, compared to 28% in the nifedipine group. A higher proportion of patients in the nifedipine group required four or more doses (24% vs. 16%). This difference in dose requirement was statistically significant ($p = 0.028$). Additional antihypertensive therapy was required in 6% of patients in the labetalol group and 12% in the nifedipine group; however, this difference was not statistically significant ($p = 0.223$) (**Table 3**).

Fetomaternal outcomes showed comparable mode of delivery between the two groups, with spontaneous vaginal delivery being the most common (64% in labetalol vs. 62% in nifedipine; $p = 0.582$). Mean blood loss during delivery was significantly lower in the labetalol group (488.4 ± 53.2 ml) compared to the nifedipine group (521.1 ± 58.3 ml) ($p < 0.001$). Postpartum hemorrhage occurred significantly more frequently in the nifedipine group (8%) than in the labetalol group (2%) ($p = 0.031$). Maternal complications such as eclampsia, meconium-stained liquor, and stillbirth were infrequent and comparable between groups (**Table 4**).

Neonatal outcomes demonstrated a significantly higher mean birth weight in the labetalol group (2.9 ± 0.8 kg) compared to the nifedipine group (2.5 ± 0.6 kg) ($p = 0.002$). APGAR scores at 1 and 5 minutes were similar between the two groups, as were rates of fetal distress and NICU admission. Neonatal mortality was higher in the nifedipine group (6%) compared to the labetalol group (2%), though this difference did not reach statistical significance ($p = 0.054$) **(Table 4).**

Tables

Table 1. Sociodemographic parameters in patients (N=100)

Parameters	Labetalol		Nifedipine		p-value
	Frequency	%	Frequency	%	
Age group					
<20	8	16	12	24	0.462
21-25	29	58	23	46	
26-30	10	20	9	18	
31-35	3	6	6	12	
Gravida					
1	30	60	29	58	0.677
2	14	28	15	30	
3	6	12	6	12	
Gestational age (weeks)					
28-32	5	10	2	4	0.487
32-36	5	10	7	14	
36-40	34	68	35	70	
>40	6	12	6	12	

Table 2. Drug outcome parameters in patients (N=100)

Parameters	Labetalol		Nifedipine		p-value
	Mean	SD	Mean	SD	
Baseline blood pressure (mmHg)					
SBP	161.5	4.2	160.4	4.4	0.689
DBP	111.9	6.6	109.9	7.2	0.709
MAP	130.9	6.8	129.8	5.6	0.877
Blood pressure 30 mins after drug administration					
SBP	150.1	5.8	155.3	6.6	0.048*
DBP	102.1	2.2	103.4	4.1	0.897
MAP	119.5	5.5	122.1	3.3	0.033*
Time taken to reach target blood pressure (min)	28.2	8.1	33.4	12.3	<0.001*

Table 3. Number of dose required to achieve target blood pressure of patients (n=100)

Number of doses	Labetalol		Nifedipine		p-value
	Frequency	%	Frequency	%	
1	20	40	14	28	0.028*
2	10	20	12	24	
3	12	24	12	24	
4 and above	8	16	12	24	
Additional antihypertensives required					
Yes	3	6	6	12	0.223
No	47	94	44	88	

Table 4. Fetomaternal outcomes in patients (N=100)

Parameters	Labetalol		Nifedipine		p-value
	Frequency	%	Frequency	%	
Mode of delivery					
SVD	32	64	31	62	0.582
Elective LSCS	8	16	7	14	
Emergency LSCS	10	20	12	24	
Mean blood loss during delivery (ml)	488.4	53.2	521.1	58.3	<0.001*
Gestational age at delivery					
Preterm	12	24	18	26	0.051
Term	38	76	42	74	
Adverse maternal events					
Eclampsia	2	4	3	6	0.783
MSL	4	8	7	14	0.062
Stillbirth	2	4	0	0	0.671
PPH	1	2	4	8	0.031*
Adverse fetal and neonatal events					
Mean birthweight	2.9	0.8	2.5	0.6	0.002*
IUFD	0	0	0	0	-
Fetal distress	8	16	9	18	0.988

APGAR at 1 min	7.7	1.1	7.8	0.9	0.862
APGAR at 5 mins	8.8	1.2	8.3	0.9	0.767
NICU admission	11	22	12	24	0.676
Death	1	2	3	6	0.054

DISCUSSION

Pregnancy-induced hypertension (HDP) remains a significant contributor to maternal and perinatal morbidity, particularly in low- and middle-income countries. The present study compared the efficacy and safety of oral labetalol and oral nifedipine in the management of HDP and demonstrated that both drugs were effective in achieving blood pressure control; however, labetalol showed superior performance in terms of faster attainment of target blood pressure, lower dose requirement, reduced blood loss during delivery, and improved neonatal birth weight.

In the present study, baseline demographic and obstetric characteristics were comparable between the two groups, indicating that differences in outcomes were attributable primarily to the pharmacological effects of the study drugs rather than confounding factors. The majority of patients were young primigravidae presenting at term gestation, a finding consistent with observations reported by Clark et al. (2015) and Easterling et al. (2019), who highlighted the high prevalence of hypertensive disorders among young pregnant women in tertiary care settings. ,

Both labetalol and nifedipine produced significant reductions in systolic and diastolic blood pressure following administration. However, labetalol achieved a significantly greater reduction in systolic blood pressure and mean arterial pressure at 30 minutes, as well as a shorter time to reach target blood pressure. These findings contrast with several earlier studies, including Vermillion et al. (1999), Dhali et al. (2012), and Li et al. (2023), which reported faster blood pressure control with oral nifedipine compared to intravenous labetalol. , , The discrepancy may be explained by differences in study design, drug dosage, route of administration, and patient population. In the present study, both drugs were administered orally in a controlled inpatient setting, which may have favored the more stable hemodynamic profile of labetalol.

The requirement of fewer doses to achieve target blood pressure in the labetalol group further supports its sustained antihypertensive effect. Similar findings were reported by Sharma et al. (2017), who observed that a higher proportion of women achieved blood pressure control with the initial dose of labetalol compared to nifedipine. The dual alpha- and beta-adrenergic blocking action of labetalol likely contributes to a more consistent reduction in peripheral vascular resistance without reflex tachycardia, as also described by Scardo et al. (1999) and Shawkat et al. (2018). ,

An important observation in the present study was the significantly lower mean blood loss during delivery and reduced incidence of postpartum hemorrhage in the labetalol group. This finding has limited direct comparison in existing literature, as most studies have focused primarily on blood pressure outcomes. However, the reduced vasodilatory effect of labetalol compared to nifedipine may contribute to improved uterine tone and reduced bleeding, a hypothesis that warrants further investigation.

Neonatal outcomes in the present study were largely comparable between the two groups, with similar APGAR scores, rates of fetal distress, and NICU admissions. However, the significantly higher mean birth weight observed in the labetalol group suggests a potential advantage in maintaining uteroplacental perfusion. This finding contrasts with Giannubilo et al. (2012), who reported higher rates of intrauterine growth restriction with labetalol in mild hypertensive disorders. The difference may be attributable to variations in disease severity, duration of drug exposure, and gestational age at treatment initiation.

Maternal adverse events such as eclampsia and meconium-stained liquor were infrequent and comparable between groups, consistent with findings from Raheem et al. (2012), and Shi et al. (2015), all of whom reported similar safety profiles for both drugs. , Although neonatal mortality was numerically higher in the nifedipine group in the present study, the difference did not reach statistical significance and may be related to underlying disease severity rather than drug effect.

CONCLUSION

This study demonstrates that both labetalol and nifedipine are effective and safe in the management of pregnancy-induced hypertension. However, labetalol showed superior efficacy by achieving faster blood pressure control, requiring fewer doses, and being associated with lower intrapartum blood loss and higher neonatal birth weight. Maternal and neonatal adverse outcomes were comparable between the two groups, confirming the overall safety of both agents. These findings suggest that labetalol may be a preferable first-line antihypertensive in pregnancy-induced hypertension, particularly in settings where rapid and sustained blood pressure control is essential to optimize maternal and perinatal outcomes.

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