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Original Research Article

A prospective comparative interventional study of intravenous labetalol and oral nifedipine in the management of severe preeclampsia at a tertiary care hospital

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ABSTRACT

Background: Severe preeclampsia is an obstetric emergency requiring prompt blood pressure control to prevent maternal and perinatal morbidity. Intravenous labetalol and oral nifedipine are both recommended first-line agents, yet comparative data from Indian tertiary care settings remain limited.
Methods: A hospital-based prospective non-randomized comparative interventional study was conducted at the Department of Obstetrics and Gynecology, Government Medical College, Akola, Maharashtra. One hundred and fifty women with severe preeclampsia were allocated equally to intravenous labetalol (Group A, n=75) or oral nifedipine (Group B, n=75) per treating-unit protocol from November 2022 to October 2023. Blood pressure was recorded at baseline, 30 minutes, 1 hour, 2 hours, 6 hours and 24 hours. Maternal complications and perinatal outcomes were compared.
Results: Both agents produced progressive, clinically meaningful reductions in systolic and diastolic blood pressure. Systolic blood pressure was lower in the nifedipine group at several time points, but baseline systolic pressure also differed between groups, requiring cautious interpretation. Maternal complication rates were comparable (no complication: labetalol 74.7% vs. nifedipine 72.0%; p=0.287). Birth-weight distribution was similar. Five-minute Apgar scores and NICU admission rates differed significantly in favour of nifedipine (p=0.043 each), though absolute event numbers were small.
Conclusions: Intravenous labetalol and oral nifedipine were both effective first-line options for acute blood pressure control in severe preeclampsia. Oral nifedipine offers practical advantages when IV access is limited. IV labetalol remains valuable when titratable parenteral therapy is preferred. Prompt protocol-based treatment is more important than rigid preference for either drug.

Keywords: Acute severe hypertension, Labetalol, Nifedipine, Maternal outcome, Perinatal outcome, Pregnancy, Severe preeclampsia

INTRODUCTION

Hypertensive disorders complicate approximately 5–10% of all pregnancies worldwide and contribute to nearly 14% of maternal deaths globally.[1] Preeclampsia, defined by new-onset hypertension after 20 weeks of gestation with proteinuria and/or end-organ dysfunction, affects 2–8% of pregnancies and constitutes a significant cause of maternal intensive-care admission and perinatal mortality.[2,3] In India, hypertensive disorders account for 15–18% of maternal deaths, with a disproportionately high burden in tertiary-care referral hospitals due to late presentations.[4] Severe preeclampsia is defined by systolic blood pressure ≥160 mmHg and/or diastolic blood pressure ≥110 mmHg

and requires immediate antihypertensive therapy to prevent catastrophic complications including eclampsia, stroke, HELLP syndrome, placental abruption and maternal organ failure.[5] Conversely, overly rapid blood pressure reduction can compromise uteroplacental perfusion and fetal oxygenation, necessitating controlled, titratable therapy.

Intravenous labetalol, a combined α- and β-adrenergic blocker and oral immediate-release nifedipine, a calcium-channel blocker, are currently recommended as first-line agents for acute severe hypertension in pregnancy by WHO, ACOG and FIGO.[1,5] Labetalol offers rapid IV-titratable dosing; nifedipine offers oral convenience, low cost and usability without IV access.[6,7] However, institutional practice varies and comparative data from routine Indian obstetric settings remain limited.

The present study was therefore undertaken to compare the efficacy, safety and practical feasibility of intravenous labetalol versus oral nifedipine in the acute management of severe preeclampsia at a tertiary care hospital in Maharashtra, India.

METHODS

A hospital-based prospective non-randomized comparative interventional study was conducted at the Department of Obstetrics and Gynecology, Government Medical College, Akola, Maharashtra, India, from November 2022 to October 2023. Ethical approval was obtained from the Institutional Ethics Committee and written informed consent was taken from all participants.

Women with severe preeclampsia (systolic BP ≥160 mmHg and/or diastolic BP ≥110 mmHg, gestational age >20 weeks) requiring urgent antihypertensive therapy were included. Exclusion criteria were: eclampsia at presentation, known hypersensitivity to either drug, cardiac conduction disorders, asthma, multiple gestation, chronic hypertension on medication and pre-existing renal or hepatic failure.

A total of 150 women were enrolled. Allocation to treatment was determined by the treating-unit protocol: Group A received intravenous labetalol beginning at 20 mg, followed by 40 mg then 80 mg at defined intervals; Group B received oral nifedipine 10 mg with repeat doses at defined intervals guided by blood pressure response. Seventy-five women were allocated to each group.

Blood pressure was recorded at baseline, 30 minutes, 1 hour, 2 hours, 6 hours, 12 hours and 24 hours. Urine output was monitored hourly. The primary outcome was achievement of target blood pressure (≤150/100 mmHg) within 24 hours. Secondary outcomes included maternal complications (oliguria, imminent eclampsia, HELLP features) and perinatal outcomes (birth weight, 5-minute Apgar score, fetal heart-rate abnormalities, NICU admission). Statistical analysis was performed using SPSS version 21.0; independent-samples t-test was used for continuous variables and chi-square or Fisher's exact test for categorical variables. A p value <0.05 was considered statistically significant.

RESULTS

One hundred and fifty women with severe preeclampsia were enrolled, with 75 allocated to each treatment group. Baseline demographic, clinical and biochemical characteristics are shown in Table 1. Maternal age, gestational age distribution, parity, maternal weight and height, proteinuria, retinopathy, renal function and liver enzymes were comparable between groups (p>0.05 for all). Two significant baseline differences were noted: haemoglobin distribution differed (p=0.033), with more women in the 8–10.9 g/dl range in the nifedipine group; and pedal oedema distribution differed (p=0.041), with Grade II oedema more frequent in the labetalol group. Baseline systolic blood pressure was also higher in the labetalol group (168.6±7.1 vs. 164.9±8.4 mmHg; p=0.005). These baseline imbalances were considered during interpretation of outcomes.

Blood pressure response

Both labetalol and nifedipine produced progressive and clinically meaningful reductions in systolic and diastolic blood pressure from baseline to 6 hours, with both groups achieving target-range control by 1 hour (Table 2). Mean systolic blood pressure was lower in the nifedipine group at baseline and at 1 hour, 2 hours and 6 hours (p<0.05 at each). Because baseline systolic pressure also differed between groups, this apparent advantage should be interpreted cautiously rather than as definitive superiority. Diastolic blood pressure control was comparable between groups, with no significant difference at 30 minutes, 1 hour or 6 hours. Mean urine output at 24 hours was similar (labetalol 56.0±18.2 ml/h vs. nifedipine 59.8±19.9 ml/h; p=0.225).

Maternal and perinatal outcomes

Maternal complications and perinatal outcomes are summarised in Table 3. Overall, 73.3% of women experienced no maternal complication during the observation period. The distribution of maternal outcomes did not differ significantly between groups (p=0.287): oliguria was the most common morbidity, occurring in 14.7% in the labetalol group and 21.3% in the nifedipine group; imminent eclampsia was more frequent in the labetalol group (6.7% vs. 1.3%), while HELLP features were similar (4.0% vs. 5.3%). None of these individual differences were statistically significant.

Birth-weight distribution was comparable between groups (p=0.926), with approximately 43% of neonates weighing below 2.5 kg in both arms. Five-minute Apgar scores differed significantly: moderate depression (Apgar 4–6) was recorded in 4 neonates (5.3%) in the labetalol group

and none in the nifedipine group (p=0.043). NICU admission was required for 4 neonates (5.3%) in the labetalol group and none in the nifedipine group (p=0.043). Given the small absolute number of neonatal events and the non-randomized study design, these findings should be interpreted as signals requiring confirmation in larger randomized studies. Late fetal heart-rate decelerations were observed in 19 cases (12.7%) overall, consistent with uteroplacental insufficiency in severe preeclampsia.

Table 1: Baseline characteristics by treatment group (n=150).

Parameter	Labetalol (n=75)	Nifedipine (n=75)	P value
Mean age (in years)	28.6±6.4	28.2±6.2	0.601
Gestational age 34–36 weeks, N (%)	41 (54.7%)	44 (58.7%)	0.127
Gestational age ≥37 weeks, N (%)	30 (40.0%)	31 (41.3%)	
Primigravidae, N (%)	18 (24.0%)	27 (36.0%)	0.120
Weight >70 kg, N (%)	42 (56.0%)	38 (50.7%)	0.814
Proteinuria 2+, N (%)	41 (54.7%)	41 (54.7%)	0.767
Baseline SBP (mmHg, mean±SD)	168.6±7.1	164.9±8.4	0.005
Baseline DBP (mmHg, mean±SD)	109.7±6.6	107.7±5.3	0.043
Haemoglobin 8–10.9 g/dL, N (%)	35 (46.7%)	49 (65.3%)	0.033

Table 2: Mean systolic and diastolic blood pressure from baseline to 6 hours by treatment group (n=150).

Time point	Labetalol SBP (mmHg)	Nifedipine SBP (mmHg)	P value	Labetalol DBP (mmHg)	Nifedipine DBP (mmHg)	P value
Baseline	168.6±7.1	164.9±8.4	0.005	109.7±6.6	107.7±5.3	0.043
30 min	159.3±12.1	155.9±13.7	0.110	100.7±10.0	100.9±10.0	0.871
1 hour	140.2±8.9	135.2±8.8	0.001	90.0±0.0	90.0±0.0	—
2 hours	130.3±8.6	126.1±7.5	0.002	81.6±3.7	80.3±1.6	0.005
6 hours	123.2±7.4	120.5±3.2	0.005	80.0±0.0	80.0±0.0	—

Table 3: Maternal and perinatal outcomes by treatment group (n=150).

Outcome	Labetalol (n=75)	Nifedipine (n=75)	P value
Maternal outcomes			
No complication, N (%)	56 (74.7%)	54 (72.0%)	0.287
Oliguria, N (%)	11 (14.7%)	16 (21.3%)	
Imminent eclampsia, N (%)	5 (6.7%)	1 (1.3%)	
HELLP features, N (%)	3 (4.0%)	4 (5.3%)	
Mean urine output (ml/h)	56.0±18.2	59.8±19.9	0.225
Perinatal outcomes			
Birth weight <2.5 kg, N (%)	31 (41.3%)	34 (45.3%)	0.926
Birth weight ≥2.5 kg, N (%)	44 (58.7%)	41 (54.7%)	
Apgar 7–10 at 5 min, N (%)	71 (94.7%)	75 (100.0%)	0.043
Apgar 4–6 at 5 min, N (%)	4 (5.3%)	0 (0.0%)	
NICU admission, N (%)	4 (5.3%)	0 (0.0%)	0.043
Late FHR decelerations, n (%)	19 (12.7%)*	—	—

*Late FHR decelerations reported for the cohort overall, by-group breakdown not presented separately. FHR=fetal heart rate; HELLP=haemolysis, elevated liver enzymes, low platelets; NICU=neonatal intensive care unit.

DISCUSSION

This prospective comparative interventional study evaluated intravenous labetalol and oral nifedipine for acute blood pressure control in 150 women with severe preeclampsia at a tertiary care hospital in Maharashtra. Both agents produced sustained and clinically meaningful blood pressure reduction over 24 hours. These findings are consistent with current evidence supporting both drugs as acceptable first-line options.[1,5] Systolic blood pressure was lower in the nifedipine group at several time points, a finding observed in several Indian trials including Shekhar et al and Zulfeen et al who also reported faster time to target BP and fewer doses required with oral nifedipine.[10,11] However, in the present study, baseline systolic pressure also differed between groups, precluding a definitive conclusion of nifedipine's superiority. This caution is shared by Raheem et al who found no statistically significant difference in median time to target between the two agents.[9] Diastolic blood pressure control

and urine output at 24 hours were comparable between groups, supporting equivalent renal safety of both regimens.[8] Maternal complication rates did not differ significantly, with approximately three-quarters of women in each group experiencing no complication. This aligns with the broader evidence base, including the large multicentre trial by Easterling et al and the Cochrane review by Abalos et al, both of which concluded that neither drug has a meaningful maternal safety advantage over the other.[12,14] Oliguria was the most common complication overall, driven by the underlying renal endotheliosis and vasospasm of severe preeclampsia rather than by drug-specific effects.

A notable observation in the present cohort is that imminent eclampsia occurred numerically more often in the labetalol arm (6.7% vs 1.3%), while oliguria was more frequent in the nifedipine arm (21.3% vs 14.7%); neither difference reached statistical significance and both likely reflect random variation in a non-randomized sample of 75 per group rather than true pharmacological differences. These findings underscore the principle that no antihypertensive drug prevents eclampsia or reverses established preeclamptic organ injury: magnesium sulphate, fetal surveillance and timely delivery planning remain essential components of care irrespective of which first-line agent is selected.

The perinatal findings warrant careful interpretation. Birth weight did not differ between groups, consistent with the established understanding that fetal growth restriction is determined by placental disease rather than antihypertensive agent.[10,12,14] The significantly better 5-minute Apgar scores and lower NICU admission in the nifedipine group (p=0.043) represent an important signal. Some earlier studies, including Nivethana et al, reported higher NICU admissions in the nifedipine group, attributing this to a higher proportion of preterm deliveries.[15] In our study, the pattern was reversed, with all four NICU admissions occurring in the labetalol arm. Because the absolute event numbers were small and the study was not randomized, this finding does not establish neonatal superiority but warrants evaluation in a larger randomized trial.

A key practical consideration is that oral nifedipine does not require intravenous access, is inexpensive and widely available and can be administered even in resource-limited or peripheral settings before referral. These advantages make it particularly valuable in the Indian healthcare context where delays in IV cannulation may occur in high-volume units. Intravenous labetalol remains the preferred option when oral therapy is not possible, when titratable IV dosing is desirable or when nifedipine is contraindicated. From a public-health perspective, training peripheral health-centre staff to administer oral nifedipine as a first-line pre-referral intervention could meaningfully reduce the duration of exposure to severe hypertension during transport, a period during which eclampsia and stroke risk remain high.

The present study has several limitations that should be considered when interpreting the findings. First, allocation to treatment was based on the treating-unit protocol rather than concealed individual randomization, which introduces a risk of selection bias and limits causal inference; the observed baseline differences in haemoglobin distribution and pedal oedema reflect this non-randomized design. Second, the study was not blinded: clinicians and patients were aware of whether an intravenous or oral drug was being administered, which may have influenced monitoring intensity, fluid management decisions or the reporting of minor adverse effects, although blood pressure values and major outcomes are relatively objective endpoints.

Third, blood pressure was recorded at fixed intervals (30 minutes, 1 hour, 2 hours, 6 hours) rather than as a continuous measure of exact time-to-target; this approach may have obscured small early differences in speed of response that some trials reporting minute-by-minute endpoints have detected. Fourth, the study was conducted at a single tertiary-care government hospital, which limits generalisability to private hospitals, primary-care centres or settings with different case-mixes and resource profiles. Fifth, neonatal adverse effects potentially attributable to drug-specific mechanisms, such as hypoglycaemia or bradycardia following transplacental beta-blockade with labetalol, were not systematically documented; their inclusion would have strengthened the safety comparison. Sixth, long-term neonatal and neurodevelopmental outcomes were not assessed, which is a common limitation in acute obstetric drug trials. Future multicentre randomized trials with continuous BP monitoring, detailed adverse-effect recording and neonatal follow-up would address these gaps.[10,11,13]

CONCLUSION

Intravenous labetalol and oral nifedipine were both effective for acute blood pressure control in severe preeclampsia. Maternal complication rates were comparable. Perinatal outcome signals favouring nifedipine require confirmation in larger randomized studies. Oral nifedipine should be confidently incorporated into emergency protocols, particularly in resource-limited settings, while IV labetalol remains valuable where parenteral titration is preferred. Prompt protocol-based treatment remains the most important determinant of maternal and perinatal outcomes.

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