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EFFICACY AND SAFETY PROFILE OF INTRAVENOUS LABETALOL IN THE MANAGEMENT OF SEVERE HYPERTENSION IN PRE-ECLAMPSIA: A PROSPECTIVE EVALUATION IN A NIGERIAN TERTIARY HOSPITAL

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ABSTRACT

Severe hypertension in pre-eclampsia remains a leading cause of maternal and perinatal morbidity and mortality worldwide, particularly in low-resource settings where access to timely and effective treatment can be challenging. Rapid blood pressure control is essential to prevent complications, and intravenous Labetalol, a combined alpha- and beta-adrenergic blocker, is widely recommended for emergency management in pregnancy. However, there is limited evidence on its efficacy and safety among populations in sub-Saharan Africa. This prospective cohort study was conducted at a tertiary hospital in Nigeria to evaluate the effectiveness and tolerability of intravenous Labetalol in women with pre-eclampsia complicated by severe hypertension, defined as systolic blood pressure of 160 mmHg or higher and/or diastolic blood pressure of 110 mmHg or higher, beyond 28 weeks of gestation. A total of 38 women received escalating bolus doses of intravenous Labetalol ranging from 20 mg up to a maximum cumulative dose of 300 mg until target blood pressure levels (130–150 mmHg systolic and 80–100 mmHg diastolic) were achieved. The study

found that 84.2% of participants attained adequate blood pressure control, with a median time to control of 20 minutes and a median of 2 doses required. Notably, 31.6% of women achieved control with a single dose. No episodes of hypotension were recorded, though some participants experienced mild adverse effects including maternal tachycardia (7.9%) and dizziness (13.2%). Neonatal bradycardia was observed in 10.5% of cases, but there were no early neonatal deaths. These findings suggest that intravenous Labetalol is both effective and well-tolerated for acute management of severe hypertension in pre-eclamptic women in this setting. Given the potential for neonatal bradycardia, close monitoring of newborns is recommended. This study supports the continued use of intravenous Labetalol as a first-line treatment for severe hypertension in pre-eclampsia within resource-limited tertiary maternity care facilities.

Keywords: Pre-eclampsia, Severe hypertension, Labetalol, Antihypertensive therapy, Maternal safety, Neonatal outcomes, Nigeria

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INTRODUCTION

Hypertensive disorders of pregnancy rank among the leading causes of maternal morbidity and mortality worldwide, accounting for approximately 14% of maternal deaths each year.[1,2] These disorders include a spectrum of conditions such as gestational hypertension, chronic hypertension, and notably pre-eclampsia—a complex multisystem disorder defined by new-onset hypertension and proteinuria after 20 weeks of gestation.[1,3] Pre-eclampsia complicates an estimated 2–8% of pregnancies globally and poses significant risks to both mother and fetus, substantially contributing to adverse perinatal outcomes such as preterm birth, fetal growth restriction, and stillbirth.[4]

Severe hypertension within the context of pre-eclampsia, generally characterized by a systolic blood pressure of 160 mmHg or higher, or a diastolic blood pressure of 110 mmHg or higher, affects a significant number of women with pre-eclampsia.[5] This severe elevation in blood pressure is associated with a high risk of life-threatening maternal complications including stroke, eclampsia (seizures), acute kidney injury, placental abruption, and coagulation disorders, which often lead to poor fetal outcomes, including intrauterine hypoxia, growth restriction, premature delivery, and increased perinatal mortality.[6]

In sub-Saharan Africa, the burden of maternal mortality due to hypertensive disorders remains disproportionately high. Nigeria alone accounts for over one-fifth of global maternal deaths, with hypertensive disorders contributing significantly to this alarming figure.[7] Persistent high mortality rates in the region reflect systemic challenges such as delayed diagnosis, late presentation to care, inadequate monitoring, and limited availability of effective and timely antihypertensive therapies. These issues are compounded by resource limitations common in tertiary referral centres, impacting the overall quality of emergency obstetric care.[8]

Labetalol, a combined selective alpha-1 and non-selective beta-adrenergic blocker, has become a preferred agent for rapid blood pressure control in severe hypertensive crises during pregnancy. Its dual mechanism of action allows for effective vasodilation while reducing the risk of reflex tachycardia, resulting in a smooth and controlled reduction of blood pressure.[9] International clinical guidelines recommend intravenous labetalol as the first-line treatment for severe hypertension in pregnancy due to its proven efficacy and a more favourable safety profile for both mother and fetus compared to other agents such as hydralazine and nifedipine.[10,11]

Despite these endorsements, there remains limited clinical data evaluating the effectiveness and safety of intravenous labetalol specifically within African populations, especially in high-burden, resource-limited tertiary emergency obstetric settings. Genetic, socio-economic, and health system factors may influence drug response and clinical outcomes, highlighting the need for evidence generated in local contexts.

This study was therefore conducted to assess the efficacy and safety profile of intravenous labetalol for emergency blood pressure control among women presenting with severe pre-eclampsia at a tertiary referral centre in Nigeria. The findings aim to inform clinical practice, optimize treatment protocols, and ultimately improve maternal and perinatal outcomes in similar resource-constrained environments facing high maternal mortality from hypertensive disorders.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, observational study conducted at the Department of Obstetrics and Gynaecology, at a tertiary healthcare institution in Nigeria.

Study population

The study population for the research was 38 eligible participants. Eligible participants were consenting pregnant women with a diagnosis of pre-eclampsia and severe hypertension (SBP ≥160 mmHg and/or DBP ≥110 mmHg) at a gestational age of 28 weeks or more, with singleton pregnancies. Women with eclampsia, chronic renal or cardiovascular disease, asthma, known Labetalol hypersensitivity, or intrauterine foetal demise were excluded.

Intervention

Each participant received intravenous Labetalol administered as escalating bolus doses over 2-minute intervals, starting at 20

mg. If target blood pressure was not achieved within 10 minutes, sequential doses of 40 mg, and up to three doses of 80 mg were given at 10-minute intervals. The total maximum dose was capped at 300 mg.

The target therapeutic endpoint was a systolic BP of 130–150 mmHg and a diastolic BP of 80–100 mmHg. Failure to achieve this target despite maximal dosing was classified as persistent severe hypertension (PSH), requiring alternate antihypertensive intervention.

Outcome Measures

Primary efficacy outcomes included the time (in minutes) from first dose to achievement of target blood pressure, the number of doses required, and the proportion of women who achieved BP control with Labetalol alone.

Maternal safety was assessed by monitoring adverse drug effects such as hypotension (SBP <100 mmHg), tachycardia, headache, nausea, vomiting, dizziness, and oliguria. Neonatal outcomes included birth weight, Apgar scores at 1 and 5 minutes, neonatal heart rate abnormalities, admission to the Special Care Baby Unit (SCBU), and early neonatal death (within 7 days).

Statistical Analysis

Data were analyzed using SPSS version 23.0. Continuous variables were presented as medians with interquartile ranges (IQR). Categorical variables were reported as frequencies and percentages.

Ethical Consideration

Ethical approval was obtained from the Health Research Ethics Committee (HREC) of the institution. Verbal informed consent was secured from all participants prior to enrolment. Confidentiality of personal health information was maintained throughout the study. Participation was entirely voluntary, and refusal to participate had no effect on the care received. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

Results

Majority of respondents were aged 30–34 years (11, 28.9%), followed by 25–29 years (9, 23.7%) and 17–24 years (7, 18.4%). Ethnically, Hausa constituted nearly half (18, 47.4%), while Fulani and others accounted for 10.5% and 42.1%, respectively. Education levels varied, with most having secondary (13, 34.2%) or tertiary education (10, 26.3%), and 15.8% having no formal education. Regarding parity, multiparous women predominated (15, 39.5%), followed by nulliparous (10, 26.3%) and grand multiparous (9, 23.7%). Most participants were at ≥37 weeks gestation (25, 65.8%), and 63.2% were booked for antenatal care.

Table 1: Obstetric history of respondents

Variable	Frequency (n=38)	Percentage (%)
Parity		
Nulliparous	10	26.3
Primiparous	4	10.5

Multiparous	15	39.5
Grand multiparous	9	23.7
Gestational age		
28 – <37 weeks	13	34.2
≥37 weeks	25	65.8
Booking status		
Booked	24	63.2
Unbooked	14	36.8

Table 1 shows that multiparous women constituted the largest group (15, 39.5%), followed by nulliparous (10, 26.3%) and grand multiparous women (9, 23.7%), while primiparous women were least represented (4, 10.5%). Most respondents were in late pregnancy at or beyond 37 weeks gestation (25, 65.8%), with the remainder between 28 and <37 weeks (13, 34.2%). Majority were booked for antenatal care (24, 63.2%), whereas 36.8% (14) were unbooked.

Table 2: Median Blood Pressure and Treatment Requirements for Control

Variable	Median (IQR)
Blood pressure (mmHg)	
Systolic blood pressure	171.0 (162.0 – 187.0)
Diastolic blood pressure	115.0 (109.0 – 127.0)
Requirements to control blood pressure	
Time (minutes)	20.0 (10.0 – 30.0)
Number of doses	2.0 (1.0 – 3.0)

Table 2 shows that respondents presented with a median systolic blood pressure of 171.0 mmHg (IQR: 162.0–187.0) and diastolic blood pressure of 115.0 mmHg (IQR: 109.0–127.0). Blood pressure was controlled within a median time of 20.0 minutes (IQR: 10.0–30.0) using a median of 2.0 doses (IQR: 1.0–3.0) of intravenous Labetalol.

Table 3: Doses Required for Blood Pressure Control and Overall Success Rate

Variable	Frequency (n = 38)	Percentage (%)
Overall Success Rate		
Controlled	32	84.2
Labetalol failure	6	15.8
No of doses required to achieve BP control (n=32)		
1	12	37.5
2 – 3	18	56.3
≥ 4	2	6.2

Table 3 shows that blood pressure control was achieved in 32 patients (84.2%), and there was labetalol failure in 6 (15.8%). Among those controlled, 37.5% (12) required a single dose, 56.3% (18) needed 2 to 3 doses, and 6.2% (2) required four or more doses to achieve control.

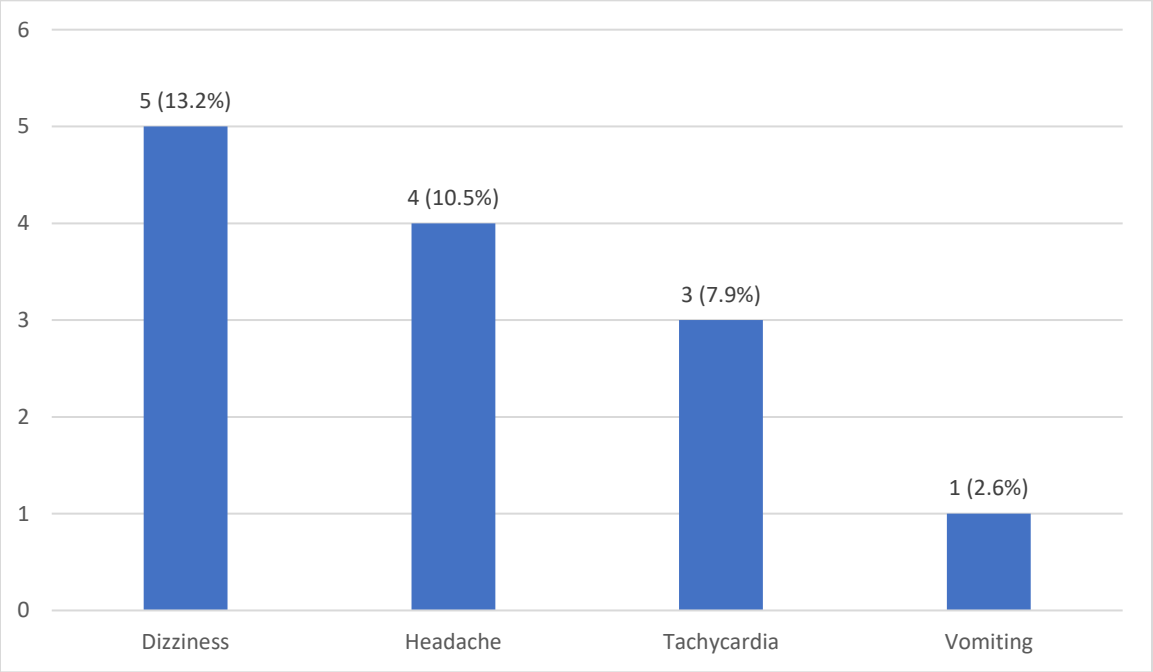

Figure 1: Maternal complications related to labetalol administration

Figure 1 shows several maternal side effects. Dizziness was the most frequently reported complication, occurring in 5 (13.2%) of the women. This was followed by headache,

which was experienced by 4 (10.5%) women. Tachycardia was reported by 3 (7.9%) women, and vomiting was the least common side effect, noted in 1 (2.6%) case.

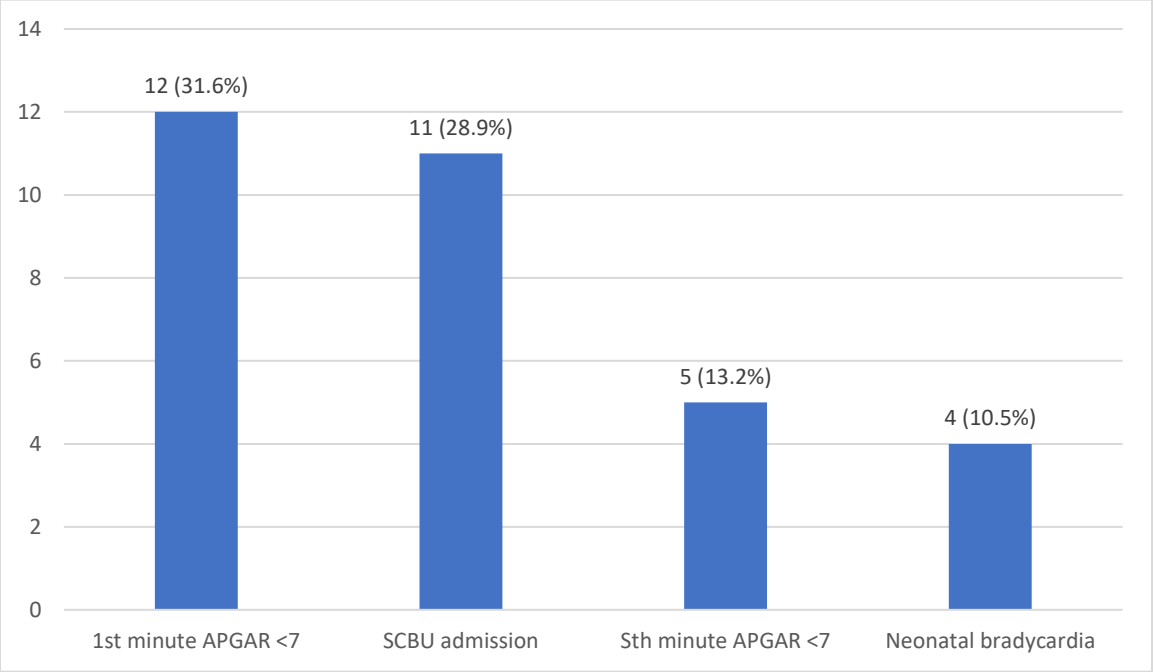

Figure 2: Neonatal outcome among women treated with labetalol

Figure 2 shows that the most common adverse outcome was a 1st minute APGAR score of less than 7, which was recorded for 12 (31.6%) neonates. Admission to the Special Care Baby Unit (SCBU) was required for 11 (28.9%) neonates. A 5th minute APGAR score of less than 7 was observed in 5 (13.2%) neonates, and neonatal bradycardia occurred in 4 (10.5%) of the infants.

DISCUSSION

This study found that intravenous Labetalol achieved rapid blood pressure control, with a median time of 20 minutes and a success rate of 84.2%. These findings are shorter than findings from similar studies.[12,13] who found control was achieved in 40 - 73 minutes. The shorter response time in our cohort may be attributed to earlier intervention, standardized dosing protocols, or better patient monitoring practices. Additionally, variations in disease severity, timing of presentation, and health system efficiency across study locations could have contributed to the differences. The prompt response observed also aligns with the pharmacologic

profile of Labetalol as a combined alpha- and beta-adrenergic blocker, which facilitates rapid vasodilation without significant reflex tachycardia. Clinically, rapid reduction of blood pressure in severe pre-eclampsia is crucial to prevent life-threatening complications such as cerebrovascular accidents, eclampsia, and multi-organ failure. Given this evidence, intravenous Labetalol should remain the first-line agent in emergency obstetric hypertension protocols, especially in settings where timely intervention can significantly improve maternal outcomes.

In our cohort, 31.6% of women achieved blood pressure control with a single 20 mg dose. This proportion is similar to findings from a similar study[14] which observed that about 45% of patients responded to the initial Labetalol dose. Conversely, another study reported higher initial dose failure rates, which may be attributed to differences in patient populations, such as more advanced disease severity or delays in treatment initiation.[15] Our favourable response rate could be explained by early diagnosis and prompt initiation of treatment. From a health systems perspective, achieving control with lower doses reduces drug exposure, minimizes adverse effects, decreases the intensity of monitoring required, and lowers treatment costs—critical considerations in resource-limited, high-volume obstetric units. Therefore, we recommend strengthening early blood pressure surveillance and implementing protocol-driven dose escalation to optimize resource use and clinical outcomes.

Maternal side effects were minimal, including tiredness (13.2%), headache (10.5%), and tachycardia (7.9%). This safety profile aligns with previous research which found Labetalol to be better tolerated than other medications for severe hypertension, such as nifedipine and hydralazine.[16,17] The absence of hypotension is particularly important, as excessive blood pressure lowering can reduce uteroplacental perfusion, risking foetal hypoxia. Our findings support the safety of intravenous Labetalol when administered with careful dose titration and monitoring. We recommend routine cardiovascular assessment prior to administration and continuous monitoring post-dose to maintain this favourable safety profile.

Neonatal bradycardia was observed in 10.5% of neonates in this study, comparable to rates in a previous study which noted increased bradycardia risk with beta-blocker exposure in utero.[18] The transplacental passage of

Labetalol likely explains this effect on foetal cardiac conduction. Despite this, no neonatal deaths occurred, and Apgar scores improved significantly by the fifth minute.

Although definitive causality is difficult to establish in pre-eclamptic pregnancies complicated by multiple risk factors, this finding underscores the need for vigilant neonatal monitoring when Labetalol is used during labour. We recommend routine foetal heart rate surveillance and prompt paediatric evaluation postpartum to ensure early detection and management of potential bradycardia or other complications.

CONCLUSION

Intravenous Labetalol proved to be an effective and safe antihypertensive agent for the emergency management of severe hypertension in pre-eclampsia within this Nigerian tertiary hospital context. Its rapid action, minimal adverse events, and favourable neonatal outcomes make it an essential tool for frontline obstetric care.

The absence of maternal hypotension and the low requirement for multiple doses offer practical advantages for busy maternity units. The incidence of neonatal bradycardia, though relatively low, highlights the importance of appropriate neonatal surveillance.

We recommend the inclusion of intravenous Labetalol in national and institutional treatment guidelines for pre-eclampsia in Nigeria and similar settings. Further multicentre studies could explore predictors of treatment response and refine dosing algorithms tailored to African obstetric populations.

RECOMMENDATIONS

Use of Intravenous Labetalol as First-Line Treatment

Intravenous Labetalol should be maintained as the first-line agent for the emergency management of severe hypertension in pre-eclampsia, given its rapid efficacy and favourable safety profile. To optimize outcomes, healthcare providers must be trained on the importance of timely administration and adherence to standardized treatment protocols. Early and prompt intervention can significantly reduce maternal complications and improve survival, especially in resource-constrained settings.

Early Blood Pressure Surveillance and Dose Optimization

Routine and early blood pressure monitoring during antenatal care and labour is essential to identify women at risk of severe

hypertension promptly. Implementing protocol-driven dose escalation allows clinicians to achieve blood pressure control efficiently while minimizing drug exposure and the risk of adverse effects. This approach also reduces the need for intensive monitoring and lowers treatment costs, which is critical in high-volume obstetric units with limited resources.

Maternal Monitoring and Safety

Before administering intravenous Labetalol, a thorough cardiovascular assessment should be performed to identify any contraindications or predisposing factors for adverse reactions. Continuous monitoring of maternal vital signs during and after dosing is recommended to promptly detect any side effects such as tachycardia or dizziness and to prevent complications like hypotension that could compromise uteroplacental blood flow. Maintaining vigilance ensures patient safety and supports positive maternal outcomes.

Neonatal Monitoring and Care

Given the observed incidence of neonatal bradycardia associated with Labetalol use, routine fetal heart rate surveillance during labour is imperative. Postpartum, newborns should be closely monitored for cardiac function, with immediate paediatric evaluation available to manage any episodes of bradycardia or related complications. Training neonatal care teams to recognize and respond to these risks will further enhance neonatal safety in settings where Labetalol is used for maternal hypertension.

Limitations and Mitigation

This study was limited by a relatively small sample size, which may restrict the generalizability of its findings to broader populations. Conducting the research in a single tertiary hospital further limits the applicability of results across different healthcare settings and regions with varying resources and patient demographics. Additionally, the observational design does not allow definitive conclusions regarding causality, particularly in neonatal outcomes, which can be influenced by multiple factors inherent in pre-eclamptic pregnancies. Variability in disease severity and timing of presentation among participants could also have impacted the observed results.

To mitigate these limitations, future studies should include larger, multi-centre randomized controlled trials that capture a wider range of populations and clinical environments. Standardizing data collection procedures and treatment protocols will reduce variability and enhance the reliability

of findings. Detailed recording of baseline clinical characteristics will enable better adjustment for confounding factors during analysis. Close collaboration with neonatal care providers can improve the detection, documentation, and management of potential neonatal adverse effects associated with maternal Labetalol use.

Implications for future research

Future research should focus on larger, multi-centre trials to confirm the efficacy and safety of intravenous Labetalol in diverse populations across sub-Saharan Africa. Investigations into long-term maternal and neonatal outcomes, as well as optimal dosing strategies tailored to different severity levels of pre-eclampsia, are needed. Additionally, exploring the mechanisms and risk factors for neonatal bradycardia could improve monitoring protocols and enhance neonatal safety.

Conflict of Interest

The authors declare no conflict of interest.

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