GPMPJ
GLOBAL PROFESSIONALS MULTIDISCIPLINARY PRACTICES JOURNAL
EISSN: 3043-6052
Vol 2, No 4: June 2025
An open Access Peer-Reviewed Journal
Original Article

A CROSS-SECTIONAL OBSERVATIONAL STUDY ON INTRAVENOUS HYDRALAZINE FOR MANAGING SEVERE HYPERTENSION IN PRE-ECLAMPTIC WOMEN IN A TERTIARY CENTRE, NIGERIA

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ABSTRACT

Severe hypertension remains a critical threat in the management of pre-eclampsia, particularly in low-resource settings where it significantly contributes to maternal and neonatal morbidity and mortality. Hydralazine, a direct-acting vasodilator, remains widely used due to its affordability and accessibility. However, concerns persist about its safety, delayed onset, and potential maternal and neonatal side effects, including reflex tachycardia, headaches, and risks to the foetus. This study assessed the clinical effectiveness and safety of intravenous hydralazine in women with severe pre-eclampsia in a tertiary hospital in Nigeria. It focused on blood pressure control, dosage needs, and associated maternal and neonatal outcomes. A cross-sectional observational study was conducted among 38 women with severe hypertension (SBP ≥160 mmHg or DBP ≥110 mmHg) beyond 28 weeks of gestation. Each received intravenous Hydralazine. Primary outcomes included time to achieve target blood pressure (<160/110 mmHg), number of doses required, and adverse effects. Data were analysed using SPSS version 23. Hydralazine was effective in 97.4% of cases (37/38), with a median time of 60 minutes (IQR: 40–80) to achieve blood pressure control. A median of three doses (IQR: 2–4) was required. No hypotension was observed. Maternal side effects included tachycardia (26.3%) and headache (18.4%). Neonatal outcomes were concerning,

with three early neonatal deaths (7.9%), suggesting possible foetal compromise despite effective maternal blood pressure control. In conclusion, intravenous Hydralazine remains a viable option for managing severe hypertension in pre-eclampsia where resources are limited. However, its delayed action and potential adverse effects—especially on neonates—highlight the need for cautious use, close monitoring, and further comparative research to enhance treatment safety and efficacy.

Keywords: Hydralazine, Severe Hypertension, Pre-eclampsia, Cross-Sectional Study, Efficacy, Safety, Neonatal Outcomes, Nigeria.

How to cite: Obinna PE, Mark IO, Isenalumhe SA, Afekhobe JSB, Yaya OB, Ekeng O. A Cross-Sectional Observational Study on Intravenous Hydralazine for Managing Severe Hypertension in Pre-Eclamptic Women in A Tertiary Centre, Nigeria. *Global Professionals Multidisciplinary Practices Journal*. 2025, 2(4):49-62

INTRODUCTION

Severe hypertension—defined as systolic blood pressure (SBP) ≥160 mmHg or diastolic blood pressure (DBP) ≥110 mmHg—in the setting of pre-eclampsia represents a critical obstetric emergency and a significant contributor to global maternal and perinatal morbidity and mortality.[1] Estimates suggest that hypertensive disorders of pregnancy complicate up to 10% of all pregnancies worldwide, with severe hypertension occurring in approximately 1–2% of cases.[1,2] In low- and middle-income countries (LMICs), where 99% of maternal deaths occur, hypertensive complications account for 14% of all maternal deaths globally—second only to hemorrhage.[3,4] Immediate blood pressure control is essential to prevent life-threatening complications such as stroke, eclampsia, acute kidney injury, pulmonary oedema, and foetal hypoxia or demise.[5]

Hydralazine hydrochloride, a direct-acting arteriolar vasodilator, has been used for decades in the acute management of severe hypertension in pregnancy.[6] Its mechanism involves relaxation of vascular smooth muscle, leading to reduced peripheral resistance and a subsequent decrease in blood pressure.[6,7] Due to its affordability, ease of availability, and historical use, Hydralazine continues to be widely used, particularly in LMIC settings where access to newer antihypertensives may be limited.

Despite its long-standing use, Hydralazine is not without controversy. It has been

associated with a range of maternal side effects, including reflex tachycardia, headache, nausea, vomiting, and dizziness, which may mimic or exacerbate symptoms of pre-eclampsia, complicating clinical assessment.[8,9] More importantly, concerns persist regarding its potential to induce abrupt hypotension, potentially impairing uteroplacental perfusion and leading to adverse foetal outcomes such as distress, acidosis, or neonatal death.[10,11] As such, agents like Labetalol and Nifedipine have gained favour in recent years, supported by comparative trials suggesting improved tolerability and similar or superior efficacy profiles.[12,13]

Given the ongoing use of Hydralazine in many resource-limited environments, particularly in sub-Saharan Africa, it remains critical to evaluate its real-world performance. This cross-sectional observational study was conducted to describe the clinical effectiveness, dose-response patterns, and maternal and neonatal safety outcomes associated with the use of intravenous Hydralazine in the management of severe hypertension in pre-eclamptic women at a tertiary care centre in Nigeria—a region with a high burden of hypertensive disorders in pregnancy.

MATERIALS AND METHODS

Study Setting and Design

This was a hospital-based, prospective, cross-sectional observational study conducted in a tertiary healthcare facility in Nigeria. The study documented outcomes for patients who received intravenous Hydralazine as part of routine clinical management for severe hypertension in pre-eclampsia.

Study Population

The study included 38 consenting pregnant women diagnosed with pre-eclampsia complicated by severe hypertension (SBP ≥ 160 mmHg and/or DBP ≥ 110 mmHg) at a gestational age of 28 weeks or more, with singleton pregnancies, who received intravenous Hydralazine. Inclusion criteria for data documentation were: (1) consenting gravid clients with pre-eclampsia complicated by severe hypertension after 28 weeks of gestation, (2) singleton pregnancies, and (3) receipt of intravenous Hydralazine for blood pressure management. Exclusion criteria were conditions where Hydralazine would be clearly contraindicated (e.g., tachyarrhythmias).

Hydralazine Intervention

IV Hydralazine was administered per hospital protocol, starting with a 5mg bolus

over 5–10 minutes. Blood pressure and pulse were monitored every 20 minutes. If SBP remained ≥160 mmHg or DBP ≥110 mmHg, additional 5mg doses were given, up to a cumulative maximum of 30mg. The goal was to reduce SBP below 160 mmHg and DBP below 110 mmHg. Persistent hypertension after 30mg was classified as severe and managed with an alternative agent.

Data Collection and Outcome Measures

Data were prospectively collected through patient records, observations, and interviews. During Hydralazine treatment, blood pressure and pulse were monitored every 20 minutes.

Efficacy outcomes included time to BP control, total doses required, single-dose response rate, and overall success. Safety outcomes included maternal side effects (e.g., hypotension, nausea) and neonatal outcomes (e.g., distress, low Apgar scores, SCBU admission, early death).

Ethical Considerations

Ethical approval was obtained from the HREC of the tertiary care centre. Informed written consent was secured from all participants for data collection and use in research, with assurances of confidentiality and no impact on care quality for non-participation.

Statistical Analysis

Data from the 38 participants were analyzed using SPSS Version 23.0. Descriptive statistics (median, IQR, frequencies, percentages) were used to summarize the data.

RESULTS

Table 1: Sociodemographic characteristics of participants

Variable	Frequency (n=38)	Percentage (%)
Age groups (years)		
17 - 24	11	28.9
25 - 29	9	23.7
30 - 34	7	18.4
35 - 39	7	18.4
40 - 44	4	10.5

Ethnic group		
Hausa	16	42.1
Fulani	9	23.7
Igbo	2	5.3
Yoruba	1	2.6
Others	10	26.3
Educational status		
Non formal	4	10.5
Primary	11	28.9
Secondary	13	34.2
Tertiary	10	26.3

Table 1 shows that among the 38 respondents, those aged 17–24 years were the most represented, numbering 11 (28.9%), followed by 9 (23.7%) aged 25–29 years. Both the 30–34 and 35–39 age groups accounted for 7 (18.4%) participants each, while 4 (10.5%) were aged 40–44 years.

Ethnically, Hausa respondents formed the largest group, 16 (42.1%), followed by Fulani at 9 (23.7%). Others, including minority ethnicities not individually listed, comprised 10 (26.3%). Igbo and Yoruba participants were 2 (5.3%) and 1 (2.6%) respectively. Regarding educational status, 13 (34.2%) had secondary education, 11 (28.9%) had primary education, and 10 (26.3%) attained tertiary education. Only 4 (10.5%) had no formal education.

Table 2: Obstetric history of participants

Variable	Frequency (n=38)	Percentage (%)
Parity		
Nulliparous	16	42.1
Multiparous	9	23.7
Primiparous	7	18.4

Grand multiparous	6	15.8
Gestational age		
28 - < 37 weeks	10	26.3
≥37 weeks	28	73.7
Booking status		
Booked	21	55.3
Unbooked	17	44.7
Mode of delivery		
Vaginal	14	36.8
Caesarean section	24	63.2

Table 2 shows that out of the 38 participants, 16 (42.1%) were nulliparous. Multiparous women accounted for 9 (23.7%), while 7 (18.4%) were primiparous and 6 (15.8%) were grand multiparous. Most of the women, 28 (73.7%), had gestational age ≥ 37 weeks, while 10 (26.3%) were between 28 and <37 weeks. Regarding booking status, 21 (55.3%) had booked antenatal care, whereas 17 (44.7%) were unbooked. The mode of delivery was caesarean section for 24 (63.2%) participants, while 14 (36.8%) had vaginal delivery.

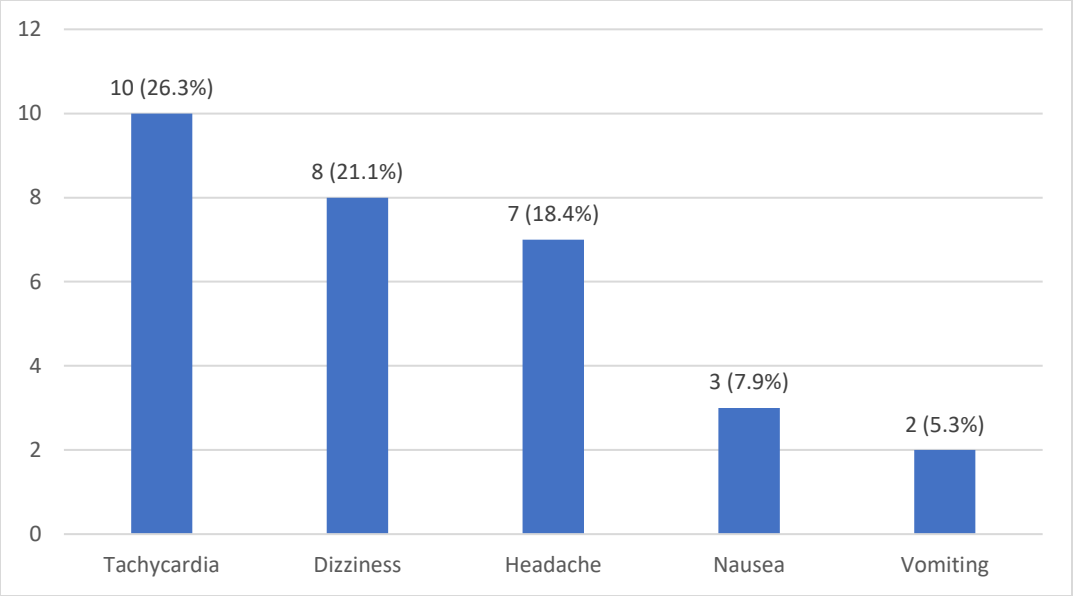

Figure 1: Complications experienced with hydralazine among respondents

Tachycardia was the most common maternal complication, observed in 10 (26.3%) of the women. Dizziness was experienced by 8 (21.1%) women, while headache was reported by 7 (18.4%) women. Nausea occurred in 3 (7.9%) women, and vomiting was the least common of the recorded side effects, affecting 2 (5.3%) women.

Table 3: Median (IQR) of blood pressure and requirements for its control

Variable	Median (IQR)
Blood pressure (mmHg)	
Systolic blood pressure	172.5 (164.0 – 199.0)
Diastolic blood pressure	119.5 (110.0 – 127.0)
Requirements to control blood pressure	
Time (minutes)	60.0 (40.0 – 80.0)
Number of doses	3.0 (2.0 – 4.0)

Table 3 shows that the median systolic blood pressure recorded was 172.5 mmHg (IQR: 164.0–199.0), while the diastolic median was 119.5 mmHg (IQR: 110.0–127.0). The time required to control blood pressure had a median of 60.0 minutes (IQR: 40.0–80.0). The median number of hydralazine doses administered was 3.0 (IQR: 2.0–4.0).

Table 4: Number of doses required for blood pressure control and overall success rate with hydralazine

Variable	Frequency (n = 38)	Percentage (%)
Number of doses required to achieve blood pressure control (n=37)		
1	7	18.9
2 – 3	16	43.2
≥ 4	14	37.8
Overall success rate		
Controlled with hydralazine	37	97.4
Hydralazine failure	1	2.6

Among the 37 patients with complete dosing data, 16 (43.2%) required 2–3 doses of hydralazine to control their blood pressure. Fourteen (37.8%) needed 4 or more doses, while 7 (18.9%) responded to just a single dose. Overall, hydralazine was successful in controlling blood pressure in 37 (97.4%) of the 38 participants. Only 1 (2.6%) experienced treatment failure.

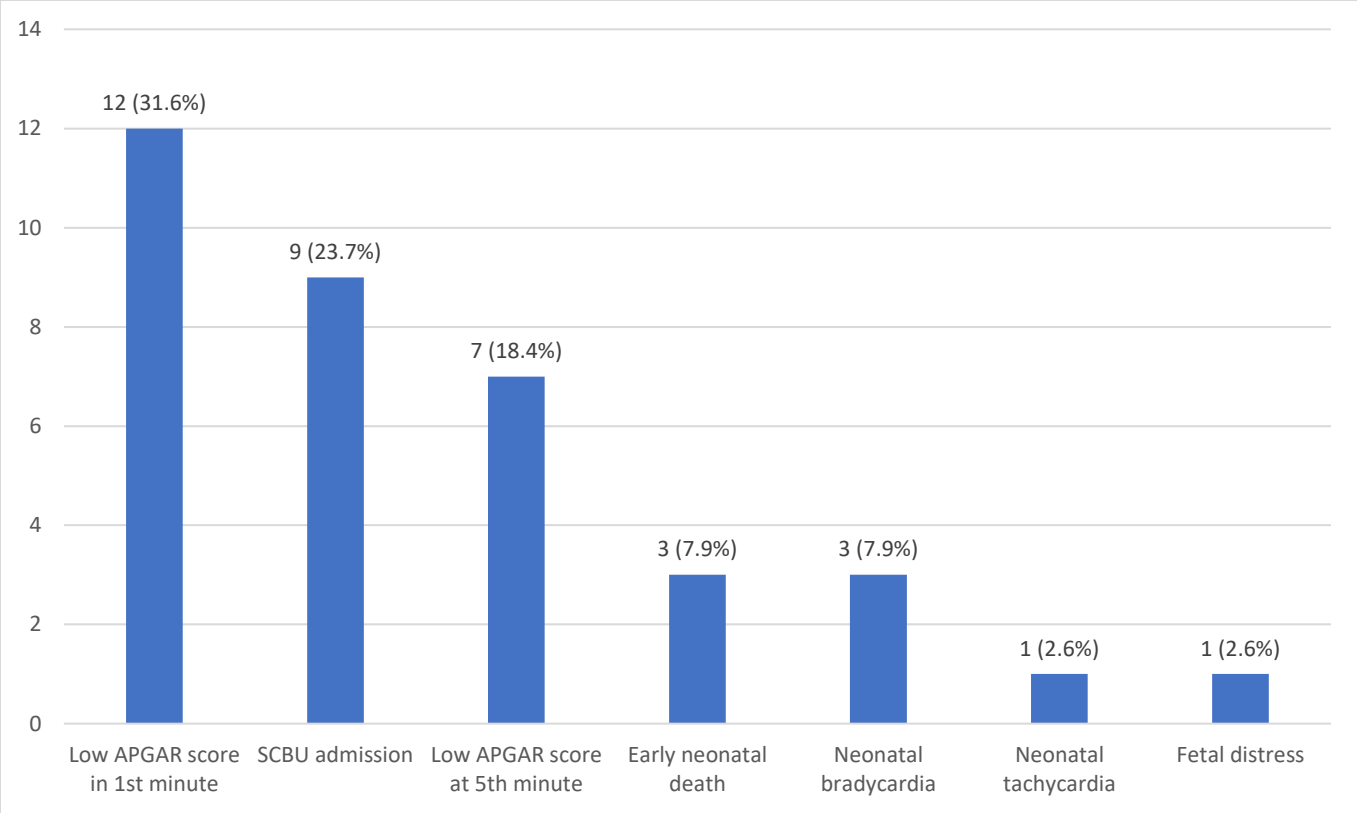

Figure 2: Foetal and neonatal complications among respondents

A low APGAR score in the 1st minute was the most frequent adverse neonatal outcome, recorded in 12 (31.6%) neonates. Special Care Baby Unit (SCBU) admission was required for 9 (23.7%) neonates. A low APGAR score at the 5th minute was observed in 7 (18.4%) neonates. Early neonatal death occurred in 3 (7.9%) cases, and neonatal bradycardia was also recorded in 3 (7.9%) neonates. Neonatal tachycardia affected 1 (2.6%) neonate, and foetal distress was also observed in 1 (2.6%) case.

DISCUSSION

Hydralazine took a median of 60 minutes to control severe hypertension in this study. This is considerably slower than the 45 minutes reported in a similar study conducted in Edo State[14] and the 40 minutes observed in research from Abuja.[15] Another study from India reported an even faster mean time of 22.4 minutes for Hydralazine.[16] This slower control time may be due to the 20-minute interval between doses, as per the observed protocol, which could inherently prolong the time to achieve blood pressure control

compared to protocols with shorter intervals or escalating doses of other agents. Additionally, the direct vasodilatory mechanism of Hydralazine requires careful, gradual titration to avoid excessive hypotension, which may also extend the time needed to reach target blood pressure in some patients. The severity and duration of hypertension before presentation in the patient population might further contribute to this effect. A longer time to control blood pressure translates to extended maternal exposure to the risks associated with severe hypertension, including cerebrovascular complications and eclampsia. Therefore, clinicians should be aware of Hydralazine's relatively slower onset of action compared to alternatives like Labetalol. This consideration is important when rapid blood pressure reduction is critical.

Despite the slower onset, Hydralazine showed a very high primary success rate of 97.4%, with only one patient failing to respond. This aligns with findings from other studies conducted in Nigeria, where success rates as high as 100% have been reported.[17,18] Hydralazine's potency as a direct-acting arteriolar vasodilator enables it to effectively counteract the intense vasospasm characteristic of pre-eclampsia, resulting in reliable blood pressure reduction once an adequate dose is administered. This dependable efficacy is a significant clinical advantage, particularly in settings where Hydralazine is the most accessible, familiar, or affordable potent parenteral antihypertensive. Therefore, it remains a viable therapeutic option for managing severe hypertension in pre-eclampsia, especially as a second-line agent or when first-line drugs are contraindicated or unavailable.

The study also confirmed Hydralazine's notable side effect profile, with maternal tachycardia occurring in 26.3% and headache in 18.4% of patients. These rates are consistent with those reported in other studies, including research in Nigerian populations, which found headaches to be significantly more common with Hydralazine compared to Labetalol.[19,20,21] These side effects arise from Hydralazine's vasodilatory action, which triggers a baroreceptor-mediated reflex sympathetic stimulation leading to tachycardia and palpitations. Cerebral vasodilation can contribute to headaches. Such side effects can be distressing and complicate clinical assessment, as headache symptoms may mimic neurological signs of worsening pre-eclampsia, such as impending eclampsia. This similarity could lead to diagnostic

challenges or unnecessary interventions. Therefore, clinicians using Hydralazine should be vigilant in monitoring and managing these common side effects and provide appropriate patient education.

A particularly concerning finding was the occurrence of three early neonatal deaths (7.9%) in the Hydralazine-exposed group, alongside one case of foetal distress. Similar studies have reported associations between Hydralazine use and adverse perinatal outcomes, including higher rates of caesarean section and low Apgar scores.[20,22] Neonatal deaths in severe pre-eclampsia are multifactorial, but Hydralazine's less predictable maternal blood pressure reductions may contribute to acute decreases in uteroplacental perfusion, especially in foetuses already compromised by intrauterine growth restriction or prematurity. The underlying severity of maternal disease also plays a crucial role. Managing pre-eclampsia aims to optimize outcomes for both mother and child; therefore, any therapy that potentially increases neonatal risk requires careful consideration. An early neonatal death rate of 7.9% in this cohort signals a significant safety concern. Continuous foetal heart rate monitoring is essential when using Hydralazine, with preparedness for rapid intervention if foetal distress occurs. Potential neonatal adverse effects must be a key factor in the risk-benefit analysis when selecting Hydralazine, particularly where alternative agents with potentially better neonatal safety profiles exist. Use should be cautious in cases with known foetal compromise.

CONCLUSION

Hydralazine demonstrated high efficacy (97.4%) in controlling severe hypertension among women with pre-eclampsia; however, this was often achieved with a relatively slower onset of action. Additionally, maternal side effects such as tachycardia (26.3%) and headache (18.4%) were common. Most notably, an early neonatal mortality rate of 7.9% was observed, raising significant concerns about perinatal safety. While causality cannot be definitively inferred from this observational study, the association underscores the importance of cautious use, especially in settings where foetal compromise is suspected.

Given its reliable antihypertensive action and availability, Hydralazine may remain a valuable option—particularly as a second-line agent or where alternatives like Labetalol are contraindicated or inaccessible. However, its use must be accompanied by close maternal and foetal monitoring, with prompt

access to emergency obstetric and neonatal care.

Limitations

This study was limited by its relatively small sample size and single-centre design, which may affect generalizability. Additionally, variations in provider practices and delay in intervention timing could have influenced treatment outcomes.

Recommendations for Future Research

Larger multicentre studies with randomized controlled designs are needed to directly compare Hydralazine with other antihypertensives, particularly in terms of foetal safety profiles. Further research should also explore strategies to minimize maternal side effects and optimize dosing intervals for faster blood pressure control.

Conflict of Interest

The authors declare no conflict of interest.

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