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Research Article

Assessing the Efficacy of Nifedipine in the Management of Hypertensive Urgency among Blacks in Oyo Town

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Abstract

Background: Hypertensive crisis are burdensome in sub Saharan Africa than every otherpart of the world. Few studies have been done to assess the effectiveness of Nifedipine among blacks in sub-Saharan Africa , the region which ironicallyhas the highest burden of hypertensive urgency in the world hence the needfor this study

Results: Out of the 328 hypertensive patients that presented at the health center for the study, 40 were diagnosed with hypertensive urgency. The overall use of nifedipine was moderately efficacious, as nifedipine did not reduce the diastolic pressure by 10 percent or the mean arterial pressure by 25 percent in23 out of 40 participants(57.5%). However, it was effective by standardinaconsiderable 17 out of 40patients(42.5%). The oral route of administrationwas efficacious in only 2 out of 6(33.3%)participants, while the sublingual route was efficacious in 15 out of 34(44.1%). Nifedipine was efficacious in4out of 10(40%) of those who waited for 30 minutes before checking their post- administration blood pressure, 1 out of 2(50%) of those who waited for 45minutes, 10 out of 25(40%) of those who waited for 60 minutes, and 2 out of 3(66.6%) of those who waited for 120 minutes. Nifedipine was efficacious in17 out of 35(48.6%) of the participants administered 20 mg, while it was not efficacious in those administered 40 mg. However, the proportion of those administered 20 mg was overwhelmingly more than those administered 40mg.

Introduction

Background Information: Hypertension is arguably the most burdensome non-communicable diseaseinthe world, and almost half of the ailments that plague adulthood can be ascribed to hypertension [1]. The World Health Organization stated that anestimated 1.28 billion persons in the world are hypertensive, with forty-sixpercent of them not even knowing that they are hypertensive [1]. Unawareness, poor drug compliance, and low socioeconomic factors make it even more difficult to control. The World Health Organization emphatically statedthat hypertension is a major cause of premature deaths worldwide [1]. Contributing immensely to these premature deaths are two important effects of hypertension: hypertensive urgency and emergency [2]. Hypertensive urgency is defined as the elevation of diastolic pressure above 120mmHg without any acute target organ disease, while in hypertensive emergencies, both systolic and diastolic pressures are increased, usually with a systolic blood pressure of greater than or equal to 180mmHg and/or a diastolic pressure of greater than or equal to 120mmHg. There is acute target organdamage, which includes encephalopathy, acute left ventricular failure, aorticdissection, subarachnoid bleeding, and cerebrovascular accident [3].

Hypertensive crisis is particularly prevalent in sub-Saharan Africa, witha 5.1%prevalence in Uganda and a 2:1 ratio of hypertensive urgency over hypertensive emergency, mostly linked to poor drug compliance as the commonest risk factor in a study done in Uganda [4]. The prevalence is evenhigher in Cameroon, with a prevalence of 6.2%, a country closer to the location of the study. The prevalence in Mogadishu is lower, with a 2.1%prevalence and 45.3% being hypertensive urgency [5]. Hypertensive crises aremore burdensome in sub-Saharan Africa than in other parts of the world, withhypertensive crisis being less than 1 percent in advanced countries suchas theUnited States. This can also be due to the fact that hypertension is commoninsub-Saharan Africa. Hypertensive emergency is the more clinically fatal of thetwo and usually requires admission and parenteral treatment. Hypertensiveurgency is usually treated with the use of short-acting antihypertensives. The goal of therapy in the management of hypertensive crisis is to ensure aprompt but steady decrease in blood pressure levels [6]. A study fromthe NewEngland Journal of Medicine by David and Suzanne establishes that a reasonable goal in the management of hypertensive crisis is to reduce the

mean arterial pressure by 25 percent or reduce the diastolic pressure to 110mmHg or 100mmHg over a period of several minutes to hours [7]. Drasticreductions to normotensive or hypotensive levels should be discouraged, as they can lead to end-organ ischemia. Sodium nitroprusside is the drug of choice for hypertensive emergencies, while other short-acting antihypertensives like esmolol, labetalol, and nicardipine are also used sometimes [8]. However, sodiumnitroprusside should be used with caution due to its ability to cause a precipitous decreaseinblood pressure and its electrocardiographic side effects [9]. Sublingual nifedipine and clonidine are often used to treat hypertensive urgency [10]. However, they must be used at the right doses, usually 10mg and 20mg, respectively.

Justification for the study: Generally, there are few studies on hypertensive crises, possibly due to the fact that it is not much of a concern for the Western world. Few studies have beendone to assess the effectiveness of nifedipine among blacks in sub-SaharanAfrica, the region which ironically has the highest burden of hypertensive urgency in the world [11,12]. There are peculiarities in the pharmacokinetics of races all across the world, especially in drugs likely to undergo the hepatic first-pass effect [13]. Nifedipine particularly has been singled out to be influenced by racial differences in comparisons between Caucasians and the Chinese [14,15]. Nifedipine is a medication that undergoes a significant first-pass effect, especially in the small intestines. The currently specified dose of nifedipineforthe management of hypertensive urgency is based on the few existing studies, mostly done on Americans. The sublingual mode of administration is one of the popular routes to bypass the first-pass effect [16]. However, it is still necessary to administer a scientifically correct dose to black sub-Saharan Africans based on studies doneto assess the efficacy of these doses in them. Hence, the need for this study. Nifedipine is also known to induce renal dysfunction in patients, especiallythose with chronic renal insufficiency [17]. Chronic kidney disease is more common and more severe in sub-Saharan Africa than in any other part of theworld [18]. Hence, it is important to justify the rationale for its use in treatinghypertensive urgency in this region and to establish the correct dose. This study is hence overdue as it is needed to justify or not the need for sublingual nifedipine among blacks in sub-Saharan Africa by measuring its efficacy in this group. The need to also determine the right minimal effectivedose to avoid renal problems, to which blacks living in sub-Saharan Africaaremost predisposed, makes this study essential

Aim and objectives

Aim: To assess the efficacy of nifedipine in the management of hypertensive urgency among blacks in Oyo town.

Objectives: To assess the effect of the route of administration on the efficacy of nifedipinein the management of hypertensive urgency using the sublingual and oral routes of administration. To assess the effect of the dose of nifedipine given on the efficacy of nifedipinein the management of hypertensive urgency. To assess the effect of the waiting time post-administration of nifedipine onthe efficacy of nifedipine in the management of hypertensive urgency. To assess the side effects and their frequency associated with nifedipine inthemanagement of hypertensive urgency

Materials & Methods

Study location: The study was conducted in Oyo Town, a significant town in Nigeria due toitsancient heritage and cultural significance. Oyo Town is home to the capital of the defunct Oyo Empire, one of the most important regions that ever existedin Africa. Many black Americans can trace their ancestry to this region, as it was a major source of slaves traded in the Pan Atlantic slave trade. Oyo Town is located in Oyo State and comprises four local governments: Afijio, Atiba, Oyo East, and Oyo West. The study was carried out in the state hospital, Oyo, and private facilities dispersed in Atiba, Oyo West, and Oyo East local governments. These are the most populated health facilities in the townandrepresent the populace of patients that present to healthcare facilities inthetown. The healthcare facilities are low-resource settings where standard diagnostictools are rarely found.

Sample size determination: A purposive non-random sampling technique was used, as sample size determination was not applicable.

Study design: This study was a descriptive cross-sectional study conducted among knownhypertensive patients who had been diagnosed with hypertensive urgency byacertified physician in Oyo Town. The study utilized quantitative data collection methods.

Study population: Known hypertensive patients who had been diagnosed with hypertensive urgency (diastolic pressure of greater than or equal to 120mmHg without thepresence of an acute target organ disease) by a certified physician were included. The inclusion and exclusion criteria can be found in Table 1

Sampling technique: A purposive non-random sampling technique was used to select eligible respondents for this study. Stage One: The three health facilities with the largest volume of patients inOyo West Local Government and Oyo East Local Government were selectedfor the study. Physicians certified by the Medical and Dental Council of Nigeria were recruited to conduct the study and were taught the aimandmethodology of the study. Stage Two: Known hypertensive patients who came for clinic visits were selected, and their blood pressure was checked at every clinic visit. Stage Three: Known hypertensive patients with a diastolic pressure of greater than or equal to 120mmHg without any acute target organ disease were educated about the study, its aims, methods, and implications. Those whoconsented to participate were selected.

Data collection procedure: Data was recorded into Google Forms after the measurement of blood pressure before and after the administration of nifedipine.

Data analysis: Data was collated using Microsoft Excel and analyzed using R 4.4.0. Socio- demographic characteristics were summarized using frequency and proportions for categorical variables such as the age and sex of participants. This method was also used to summarize the mode of administration, doseof nifedipine administered, the time duration before post-administrationmeasurement of blood pressure, and the precipitant factor for the hypertensive urgency. Frequency and proportion were also used for variablessuch as systolic and diastolic blood pressure before and after the administration of nifedipine and the mean arterial pressure. Univariate analysis was done to determine the socio-demographics, systolic and diastolic blood pressure before and after the administration of nifedipine, mean arterial pressure, clinical effect post-administration, patient satisfaction, and side effects.

Bivariate analysis was done to determine the relationship between the doseof nifedipine, the mode of administration of nifedipine, the time durationbeforepost-administration measurement of nifedipine, and the resulting post- administration blood pressure and mean arterial pressure. A reductionof diastolic pressure by 10% or a drop in the mean arterial pressure by 25%inthe first hour is considered statistically efficacious [19].

Variables

Independent Variables

Dose of the drug: The dose of nifedipine administered was categorized intotwo: 20mg and 40mg. Time duration before post-administration blood pressure measurement: Thetime durations tested for post-administration effect were categorized into30minutes, 45 minutes, and 60 minutes. Route of administration: While the primary route of administration was thesublingual route, the study also determined the effect of the oral route of administration (by chewing) to compare it with the sublingual route. This wascategorized into two: sublingual and oral.

Dependent Variables

The dependent variable for the efficacy of nifedipine was determined by theblood pressure and mean arterial pressure measurement post-nifedipine administration. If the diastolic pressure reduces by 10% or the mean arterial pressure by 25% and the clinical effect is positive, then the nifedipine administered is said to be efficacious. If not, it is not efficacious.

Results

Tables 2, 3 show the socio-demographics of participants in this study, specifically the age group and sex of participants. Fourteen out of forty patients (35%) were in the 60-69 age group, which constituted the highest proportion of participants. The extremes of the age groups (20-29 and 70-79) were poorly represented, with only 2 out of 40 patients (5%) each. Twenty- eight out of the forty patients (70%) that participated in the study were female, while twelve out of forty patients (30%) were male.

Table 4 shows that most of the Nifedipine prescribed was given via the sublingual route of administration: 34 out of 40 patients (85%). Meanwhile, 6out of 40 patients (15%) were given Nifedipine via the oral route of administration

Table 1: *Inclusion and Exclusion Criteria*

Inclusion Criteria	Exclusion Criteria
Known Hypertensive patients who have been diagnosed of diagnosed of urgency by a certified physician and gave their consent to participate in the study	Patients who have been diagnosed of white-coat hypertension and masked hypertension
	Pregnant women
	Patients with evident or known renal disease
	Overweight/Obese patients with no access to an appropriate cuff size

Table 2: *Age group of participants*

Age Group	Frequency(n)	Percentage(%)
20-29	2	5.0
30-39	1	2.5
40-49	1o	25.0
50-59	11	27.5
60-69	14	35.0
70-79	2	5.0

Table 3: *Sex of participants*

Sex	Frequency(n)	Percentage(%)
F	28	70
M	12	30

Table 4: *Route of administration of nifedipine*

Route of Nifedipine Administration	Frequency(n)	Percentage
Oral	6	15
Sublingual	34	89

Table 5: *Waiting time before post administration blood pressure measurement data*

Waiting Time	Frequency(n)	Percentage(%)
120min	3	7.5
30min	10	25.0
45min	2	5,0
60min	25	62.5

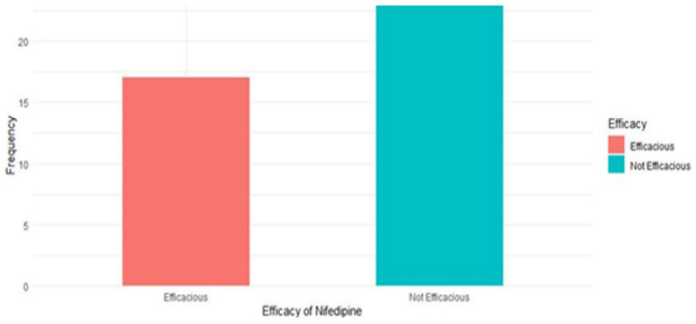

Figure 1: *Bar chart depictiong the efficancy of nifedipine amoung blacks in Oyo town*

(by chewing) for comparison between the two routes.

Table 5 shows that most participants, 25 out of 40 patients (62.5%), were asked to wait for 60 minutes before the final blood pressure was checkedpost- administration of Nifedipine. Ten out of 40 patients (25%) waited for 30minutes, 3 out of 40 patients (7.5%) waited for 120 minutes, and 2 out of 40patients (5%) waited for 45 minutes

Table 6 shows that while the precipitating factor responsible for hypertensiveurgency in most of the participants, 17 out of 40 patients (42.5%), was not known, poor drug compliance, indicated by the diagnosing physician, was identified as a common precipitating factor in 14 out of 40 patients (35%). Recent strenuous activity was identified as the precipitating factor in 9 out of 40 patients (22.5%).

Table 6: *Precipitating factors for hypertensive urgency data*

Precipitant Factor	Frequency(n)	Percentage(%)
Not Known	17	42.0
Poor Drug Compliance	14	35.0
Recent Stress	9	22.5

Table 7: *Data showing the comparison between the route of administration of nifedipine and its efficacy*

Route of Administration	Efficacy	Frequency(n)	Percentage(%)
Oral	Efficacious	2	5.0
Oral	Not Efficacious	4	10.0
Sublingual	Efficacious	15	37.5
Sublingual	Not Efficacious	19	47.5

Table 8: *Data showing the comparison between the waiting timepostadministration of nifedipine and its efficacy*

Waiting Time	Efficacy	Frequency(n)	Percentage(%)
30 min	Efficacious	4	10.0
30 min	Not Efficacious	6	15.0
45 min	Efficacious	1	2.5
45 min	Not Efficacious	1	2.5
60 min	Efficacious	10	25.0
60 min	Not Efficacious	15	37.0
120 min	Efficacious	2	5.0
120 min	Not Efficacious	1	2.5

Figure 1 shows that the overall use of Nifedipine, irrespective of the dose, mode of administration, and waiting time post-administration, is moderately efficacious. Nifedipine did not reduce the diastolic pressure by 10% or the mean arterial pressure by 25% in 23 out of 40 patients (57.5%). However, it was considered effective by standard in a significant 42.5%(17out of 40 patients).

Table 7 shows that the oral route of administration was efficacious in only 2out of 6 patients (33.3%) who used it, while the sublingual route was efficacious in 15 out of 34 patients (44.1%) who used it.

Table 8 shows that Nifedipine was efficacious in 4 out of 10 patients (40%) who waited for 30 minutes before checking their post-administration bloodpressure. Nifedipine was

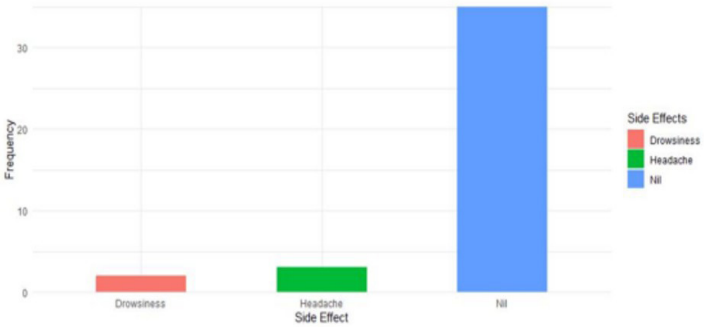

Figure 2: *Figure Showing the frequency of he side effects encountred post administration of nifrdine*

Table 9: *Data showing the comparison between the dose of nifedipine and its efficacy*

Dose of Nifedipine	Efficacy	Frequency(n)	Percentage(%)
20mg	Efficacious	17	42.5
20mg	Not Efficacious	18	45.0
40mg	Not Efficacious	5	12.5

Table 10: *Data showing the comparison between the precipitant factor for hypertensive urgency and the efficacy of sublingual nifedipine*

Precipitant Factor	Efficacy	Frequency (n)	Percentage (%)
Not Known	Efficacious	7	17.5
Not Known	Not Efficacious	10	25.0
Poor Drug Compliance	Efficacious	7	17.5
Poor Drug Compliance	Not Efficacious	7	17.5
Recent Stress	Efficacious	3	7.5
Recent Stress	Not Efficacious	6	15.0

Table 11: *Data showing the comparison between the route of Administration, waiting time, dose of nifedipine and efficacy*

Route of Administ Ration	Waiting Time	Dose	Efficacy	Frequency	Percentage(%)
Oral	60min	20mg	Efficacious	2	5.0
Oral	60min	20mg	Not Efficacious	1	2.5
Oral	60min	40mg	Not Efficacious	3	7.5
Sublingual	120min	20mg	Efficacious	2	5.0
Sublingual	120min	20mg	Not Efficacious	1	2.5
Sublingual	30min	20mg	Efficacious	4	10.0
Sublingual	30min	20mg	Not Efficacious	6	15.0
Sublingual	45min	20mg	Efficacious	1	2.5
Sublingual	45min	20mg	Not Efficacious	1	2.5
Sublingual	60min	20mg	Efficacious	8	20.0
Sublingual	60min	20mg	Not Efficacious	9	22.5
Sublingual	60min	40mg	Not Efficacious	2	5.0

efficacious in 1 out of 2 patients (50%) who waitedfor 45 minutes, 10 out of 25 patients (40%) who waited for 60 minutes, and2out of 3 patients (66.6%) who waited for 120 minutes.

Table 9 shows that Nifedipine was efficacious in 17 out of 35 patients (48.6%) who were administered 20 mg, while it was not efficacious in those administered 40 mg. However, the proportion of those administered 20mgisoverwhelmingly higher than those administered 40 mg.

Table 10 shows that only 7 out of 17 patients (41.2%) without a known precipitating factor found Nifedipine efficacious. Nifedipine was effective in7out of 14 patients (50%) with poor drug compliance. Only 3 out of 9 patients (33.3%) who had undergone recent stressful activity found Nifedipine efficacious.

Table 11 compares the route of administration, the waiting time post administration of nifedipine , the dose of nifedipine administered withthe efficacy of nifedipine.

Figure 2 shows the frequency of the side effects encountered post administration of nifedipine. 2 out of 40 patients (5%) complained of drowsiness after the administration of nifedipine, 3 out of 40 patients (7.5%) complained of headache while 35 patients had no side effects.

Discussion

This study assessed the efficacy of nifedipine in the management of hypertensive urgency among blacks in Oyo Town. The key variables studiedtodetermine their impact on the efficacy of nifedipine in managing hypertensiveurgency included the route of administration, the dose administered, andthewaiting time before blood pressure measurement post-administration. Theside effects associated with nifedipine management were also assessed, alongwith the frequency of each side effect.

The first objective was to assess the effect of the route of administrationontheefficacy of nifedipine in managing hypertensive urgency using the sublingual and oral routes. The efficacy of both routes of administration was belowaverage in managing hypertensive urgency among

However, the sublingual route was found to be more efficacious than the oral route. This is likely because the sublingual route bypasses the first-pass effect, as nifedipine is metabolized in the liver via the CYP3A4 pathway

This finding contrasts with a study done in Europe, which observed that oral nifedipine is more efficacious

than sublingual nifedipine [20]. However, this European study focused on untreated hypertensives rather than hypertensiveurgency. Another study by R.C. McAllister Jr. (M.D.) showed that the oral route is more effective than the sublingual route if the medication is bittenand swallowed, the same method used in this study. The study also questionedthe absorption of nifedipine via the buccal mucosa [21]. In obstetrics patients, sublingual nifedipine achieved faster tocolysis thanoral nifedipine in patients with premature labor [22]. Few recent studies have compared sublingual to oral nifedipine, but sublingual nifedipine has beenstudied more extensively and is the preferred route of administration for managing hypertensive urgency in most emergency rooms. Its use over oral nifedipine is supported by this study, although a limitation is that fewer participants were given the oral route due to its unpopularity among physicians.

The second objective was to assess the dose of nifedipine on its efficacy inmanaging hypertensive urgency in Oyo Town using 20mg and 40mg doses. Nifedipine was efficacious in almost half of those administered 20mg, whileit was not efficacious at all in those administered 40mg.

A similar study by Junichi Minami et al. showed that nifedipine CRadministered once daily was more effective than nifedipine retard administered at the same dose twice daily, supporting the findings of this study [23]. However, it should be noted that nifedipine CR and nifedipine retard are different formulations and might not be a perfect analogy.

The number of participants administered 20mg was overwhelmingly more than those administered 40mg due to precautions regarding potential side effects.

The third objective was to assess the effect of the waiting time before bloodpressure measurement post-administration of nifedipine on its efficacy amongblacks in Oyo Town. Nifedipine was found to be most efficacious in those whowaited for 120 minutes, while it was averagely efficacious at 30, 45, and60minutes.

Few studies have compared the waiting time before blood pressure measurement. However, most studies assessing nifedipine's effectiveness measured blood pressure 30 and 60 minutes post-administration [24, 25]. Olivari et al. found that nifedipine offers prompt control of diastolic pressureat 30 minutes and persistent control at 120 minutes [26]. Another study showed that nifedipine achieves peak levels after 15 to 90 minutes [22]

Most hypertensive patients studied had no side effects, and only one-tenthof the participants complained of a side effect post-administration. The only twoside effects observed were drowsiness and headache, which can be attributedto nifedipine's potent vasodilating effect. Both side effects had equal frequencyamong participants.

Overall, the efficacy of nifedipine in managing hypertensive urgency amongblacks in Oyo Town was average. While it reduced diastolic blood pressure byat least 10mmHg and achieved a diastolic blood pressure below 120mmHginmore than 90 percent of participants, it was only slightly below average inreducing diastolic blood pressure by 10% of the initial diastolic pressure or 25% of the mean arterial pressure, which were the criteria used to assess efficacy in this study.

Limitations: As with any purposive sampling technique, the representative nature of thesample could be debatable. The study was carried out in a few hospitals, sotheresults might not be generalizable to the entire population of Oyo Town. However, the study tried to overcome this by ensuring it was conductedinthehealth facilities with the highest turnover of patients in Oyo Town. The aimof the study is also not strictly dependent on representation fromall local governments in Oyo Town. To validate our findings, further studies canbe conducted in a community setting

Additionally, this study relied on blood pressure values recorded by physicianscertified by the Medical and Dental Council of Nigeria. This makes it susceptible to biases, such as parallax errors made by physicians while checking blood pressure. To reduce this bias, physicians were instructedtocheck blood pressure at least twice.

Recommendations: The efficacy of nifedipine in managing hypertensive urgency among blacks is at best average, so alternative anti-hypertensives should be considered if sublingual nifedipine fails 120 minutes after administration. Moreover, basedon the findings of this study, the recommended minimal effective dose of sublingual nifedipine is 20mg, as increasing the dose does not improve efficacy in managing hypertensive urgency

Conclusions

This study reveals that the efficacy of nifedipine in the management of hypertensive urgency among blacks in Oyo Town is at best average.

The sublingual route of administration is more effective than chewing the tablets (the oral route), and the dose of nifedipine administered does not affect its efficacy in steadily lowering blood pressure during hypertensive urgency.

The best time to check the blood pressure of patients after the administrationof nifedipine to manage hypertensive urgency is 120 minutes post- administration. The likely side effects encountered in blacks after the administration of nifedipine are headache and drowsiness, which are rare.

Declarations

Ethical Considerations: This study was approved by the Clinical Research Ethics Committee of the University of Ibadan/University College Hospital, Ibadan (Reference number: UI/EC/24/0032) as part of the Medical Internship Training Protocol (MINTING) in Nigeria. All methods were performed in accordance withtherelevant Helsinki Declaration guidelines.

Participants were informed about the purpose of the study, and writteninformed consent for participation was obtained from all participants

Credit authorship contribution statement: ISO conceived the study, requested for the data, wrote the first draft, andperformed the statistical analysis with support from SOA, AO, MAS, MOSandIA. MOS and SOA revised the first draft and made intellectual contributions. ISO also supervised others during the project.

Declaration of Competing Interest: We declared no competing interest

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