



SOCIODEMOGRAPHIC AND CLINICAL DETERMINANTS OF ADHERENCE TO BLOOD PRESSURE MEDICATION IN HYPERTENSIVE SUBJECTS

<https://doi.org/10.60787/ajrmhs.v2i2.31>

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Abstract

Background. Blood pressure control in hypertension reduces cardiovascular disease morbidity and mortality. A significant factor that may contribute to blood pressure control is medication adherence. This study aimed to determine the sociodemographic and clinical factors that influence adherence to antihypertensive medication in hypertensive patients in Port Harcourt, Nigeria.

Methods. This descriptive cross-sectional study was conducted in the cardiology clinics of Rivers State University Teaching Hospital and the University of Port Harcourt Teaching Hospital. A total of 426 previously diagnosed hypertensive subjects on follow-up for at least 6 months were assessed. Medication adherence was assessed using Morisky's Medication Adherence Scale-8 with a score ≥ 3 indicative of nonadherence to medication. Data was analysed using statistical software package SPSS version 22. Bivariate logistic regression analysis was used to identify factors influencing adherence to anti-hypertensive medications.

Results. The mean age of the respondents was 57.9 ± 12.2 years and 237 (55.6%) were women. A total of 262 (61.5%) respondents were not adherent to their medication while 164 (38.5%) reported good medication adherence and the most frequent self-reported reason for poor adherence was "I only take them when I have symptoms I attribute to hypertension" in 148 (34.8%) persons. Significant predictors of medication nonadherence were older age group ($p < 0.001$), divorced marital status ($p < 0.001$), higher educational levels ($p < 0.001$), absence of comorbidities ($p < 0.001$) and absence of complications of hypertension ($p = 0.001$).

Conclusion. Adherence to antihypertensive medication in this study was poor, therefore, continuous adherence counselling should be encouraged in hypertensive patients with these identified factors to improve adherence, blood pressure control and ultimately, cardiovascular outcomes.

Cite as: *Oyan B, Aber S, Ajala AO, Okeke UF, Briggs FK, Chris-Biriowu H. Sociodemographic and Clinical Determinants of Adherence to Blood Pressure Medication in Hypertensive Subjects. AJRMHS. 2024;2(2):1-11*



INTRODUCTION

Hypertension is the foremost risk factor for cardiovascular disease, and its incidence is still rising worldwide [1] with the global burden projected to rise from 918 million adults in 2000 to 1.56 billion in 2025.[2] The prevalence of hypertension is higher in lower-and middle-income countries (LMIC), which translates to a much larger patient load considering the huge population in these regions, however, disease knowledge, treatment, and management remain suboptimal.[3] Rigorous blood pressure (BP) lowering offers significant health benefits that outweigh the risks of adverse events [4] as receiving antihypertensive therapy translates to a longer lifespan and higher adjusted quality of life.[5]

Various studies have detected that a significant number of hypertensive patients do not achieve the target levels for control of hypertension.[6,7] A population-based review on hypertension prevention, diagnosis, and therapy revealed a significant incidence of uncontrolled hypertension with control rates reported to be much lower in LMICs (26.6%) compared to high-income countries (51.1%) [6] and two major factors contribute to hypertension control in treated patients, namely, prescription of an adequate number and dose of BP medications and adherence with therapy defined as the extent in which the patient takes their medication as prescribed by their health care providers.[8,9]

Although Oung et al. [10] discovered that individuals with hypertension adhere better to treatment than patients with other chronic conditions, excellent compliance with antihypertensive medication is a complicated process. Several categories of factors including demographic, socioeconomic, concomitant medical-behavioural conditions, therapy-related, healthcare team and system-related factors, and patient factors all have an impact.[11,12,13] Understanding how these factors contribute to nonadherence is useful in managing nonadherence especially in patients at high risk for major adverse cardiovascular outcomes as, decreased adherence to antihypertensive medication itself has been associated with a higher risk for future CVD events and increased mortality.[14]

It is critical to improve hypertension treatment, control, and adherence by implementing measures that are achievable in ordinary healthcare settings. To increase therapeutic adherence, Parati et al. [13] supported home-based blood pressure telemonitoring while Frías et al. [15] employed non-invasive adherence evaluation technologies such as ingestible sensors in tablets, to provide real-time feedback on medication adherence. Realistically, these methods may not be feasible in LMICs,

however, high level of patient education can enhance adherence to antihypertensive medication by imparting greater awareness and comprehension of the condition and its implications.[16] Additionally, a dynamic physician-patient cooperation strategy along with greater chemist participation to support treatment objectives and inspire patients, can improve therapeutic adherence.[17]

The Morisky's Medication Adherence Scale 8 (MMAS-8) is an indirect method of assessing adherence to medication. It examines the psychometric properties and tests the concurrent and predictive validity of a structured, self-reported medication adherence measure in patients with hypertension. [18]

The purpose of this study was to define the degree of adherence to antihypertensive therapy as well as determine the sociodemographic and clinical factors that influence this adherence in hypertensive patients in Port Harcourt, Nigeria.

METHODOLOGY

Study design

Rivers State is one of the thirty-six states in Nigeria, located in the southernmost part of the country and there are 5 tertiary hospitals within the state. The study design was a descriptive cross-sectional study conducted in the Rivers State University Teaching Hospital which is the tertiary hospital owned and funded by the state government and the University of Port Harcourt Teaching Hospital, owned and funded by the federal government. The study site was the Cardiology clinics in both hospitals.

Study population

The study population consisted of 426 previously diagnosed hypertensive subjects, historically defined as mentioned in the patient's clinical records and verified as systolic BP greater than or equal to 140mmHg and/or diastolic greater than or equal to 90mmHg or currently on anti-hypertensive medication; receiving treatment for hypertension for at least 6 months while attending the Cardiology clinic. Patients were recruited via convenience sampling between September 2022 and January 2023. Patients older than 18 years of age who gave informed consent were recruited consecutively as subjects. Patients who did not give consent, acutely ill patients and pregnant women were excluded from the study.

Ethical approval was obtained from the Rivers State University Teaching Hospital Health Research Ethics Committee and



individual written informed consent was obtained from all participants before recruitment.

Study procedure

Data was collected through patients' interview and review of patients' medical charts. A self-administered structured profoma was used to obtain sociodemographic information as well as to evaluate knowledge and practice of lifestyle interventions for the management of hypertension. The presence of comorbidities (obesity, diabetes mellitus and dyslipidaemia) and complications of hypertension (stroke, heart disease, kidney disease and hypertensive retinopathy) was obtained from the patient's medical chart. Adherence to medication was assessed using the Morisky's Medication Adherence Scale 8 (MMAS-8) and a score of less than 3 was used to establish adherence while a score ≥ 3 indicated nonadherence to medication.[18]

Data analysis

Data was entered and analysed using into Statistical Package for Social Sciences (SPSS) version 22. Categorical variables were reported as frequencies and percentages and compared with the Chi square test. Continuous variables were reported as means \pm SD and bivariate logistic regression analysis was applied to identify independent sociodemographic and clinical predictors of adherence to antihypertensive medications. A p value of <0.05 was considered to be statistically significant.

RESULTS

A total of four hundred and twenty-six (426) hypertensive subjects were recruited into this study. The mean age of the respondents was 57.9 ± 12.2 years (range of 20-86 years) with 46(10.8) persons classified as young while 253(59.4%) and 127(29.8) persons were grouped as middle-aged and elderly respectively. There were more women than men as 237(55.6%) were women and 189(44.4%) were men, giving a female-to-male ratio of 1.25:1.

The majority of the respondents were married 270 (63.4%) and living with their nuclear family 262 (85.0%). Tertiary level of education was attained by 168 (39.4%) of the patients while 138 (32.4%) had completed secondary education and 6(1.4%) had no formal education. The average household monthly income was less than N100,000 in 300 (70.4%) respondents while only 55(12.9%) persons reported their monthly income to be greater than N200,000. (Table 1)

The duration of hypertension was greater than 5years in 172 (40.4%) persons, 1-4years in 157(36.9%) and less than one year in 97(22.8%) persons while 199(46.7%) had concomitant comorbidities which included obesity in 123(28.7%) persons, diabetes mellitus in 83(19.5%) and dyslipidaemia in 40(9.4%) persons. Complications of hypertension were reported in 100 (23.5%) persons and the complications consisted of prior stroke in 30 (7.0%) patients, coronary artery disease in 29 (6.8%), heart failure in 23 (5.4%), kidney disease in 14 (3.3%) and retinopathy in 48 (11.3%) patients.

Table 1. Sociodemographic characteristics of the study population

Variable	Frequency (%)
Marital status	
Single	29(6.8)
Married	270(63.4)
Widow/widower	58(13.6)
Separated	10(2.3)
Divorced	59(13.8)
Living status	
Living alone	26(6.1)
Living with nuclear family	362(85.0)
Living with extended family	38(8.9)
Educational level	
No formal education	6(1.4)
Primary education	80(18.8)
Secondary education	138(32.4)
Tertiary education	168(39.4)
Postgraduate education	34(8.0)
Average household monthly income (Naira)	
<20,000	76(17.8)
20,000-49,000	109(25.6)
50,000-99,000	115(27.0)
100,000-199,000	71(16.7)
>200,000	55(12.9)

Although the majority of the respondents were aware of the various lifestyle interventions in the management of hypertension such as reduced salt intake, moderate alcohol consumption, abstinence from smoking, regular physical exercise and eating a well-balanced diet, the practice of these interventions ranged from 33.1% reporting undertaking regular physical exercise to 96.5% abstaining from tobacco use in any form as illustrated in table 2.

Table 2. Knowledge and practice of lifestyle interventions in the management of hypertension

Lifestyle intervention	Knowledge frequency (%)	Practice frequency (%)
Reduced salt intake	420(98.6)	237(55.6)
Alcohol moderation	417(97.9)	340(79.8)
Abstinence from smoking/tobacco use	420(98.6)	411(96.5)
Regular exercise (30 minutes, 5 times weekly)	414(97.2)	141(33.1)
Diet rich in fruits, vegetable, low in fats	421(98.8)	284(66.7)

Using the Morisky’s Medication Adherence Scale 8 (MMAS-8), 262(61.5%) respondents were not adherent to their medication while 164 (38.5%) reported medication adherence.

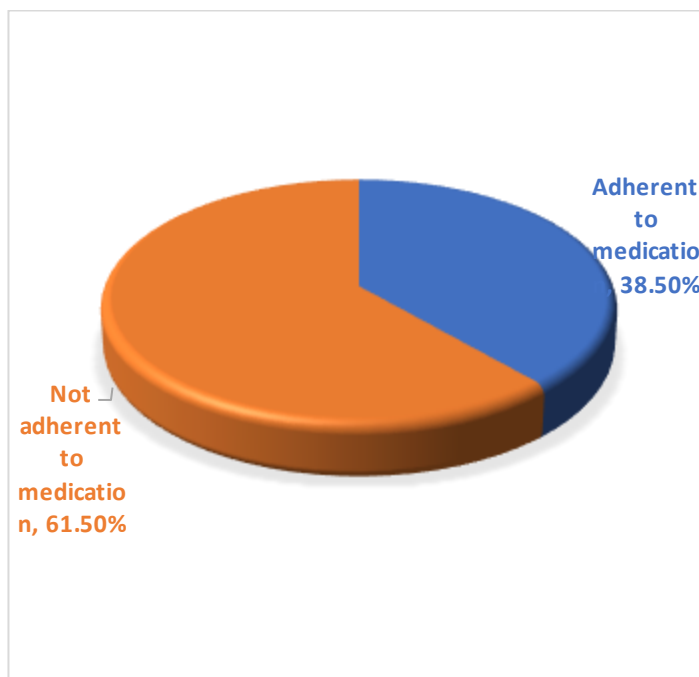


Figure 1. Adherence to blood pressure medication in the study population

Self-reported reasons given for nonadherence in this cohort of patients ranged from medication not being easily accessible or being too expensive, to a preference for complimentary/alternative medicine as reported in table 3.

Table 3. Self-reported reasons for nonadherence to anti-hypertensive medication

Reasons given for nonadherence to medication	Frequency (%) N=262
The drugs are too expensive	26(9.9)
The drugs are not easily available/accessible	32(12.2)
Side effects of the drugs	52(19.8)
I only take them when I have symptoms I attribute to hypertension	148(56.5)
I prefer alternative/complimentary medicines	34(13.0)
I forget to take my medication	60(22.9)

Poor adherence to medication was significantly higher in the middle-aged group (58.8%), respondents who were married (66.4%) and those with secondary level of education (38.2%). A longer duration of hypertension (≥ 5 years) was also significantly associated with medication nonadherence as well as the absence of both comorbidities and complications of hypertension as illustrated in table 4.

Binary logistic regression was carried out to assess the effect of sociodemographic and clinical characteristics on adherence to blood pressure medication. Older age group ($p < 0.001$) divorced marital status ($p < 0.001$), higher educational levels ($p < 0.001$), absence of comorbidities ($p < 0.0001$) and absence of complications of hypertension ($p = 0.001$) emerged as significant predictors of poor medication adherence whereas duration of hypertension ($p = 0.281$) did not. (Table 5)



Table 4. Relationship between respondents' sociodemographic and clinical characteristics and adherence to antihypertensive medication

Variable	Adherent to medication frequency (%) N=164	Not adherent to medication frequency (%) N=262	χ^2	p value
Sex				
Male	71(43.3)	118(45.0)	1.250	0.401
Female	93(56.7)	144(55.0)		
Age group				
Young	27(16.5)	19(7.3)	11.914	0.003
Middle-aged	99(60.4)	154(58.8)		
Elderly	38(23.2)	89(34.0)		
Marital status				
Single	9(5.5)	20(7.6)	29.180	<0.001
Married	96(58.5)	174(66.4)		
Widow/widower	38(23.2)	20(7.6)		
Separated	7(4.3)	3(1.1)		
Divorced	14(8.5)	45(17.2)		
Living status				
Living alone	9(5.5)	17(6.5)	2.421	0.298
Living with a nuclear family	136(82.9)	226(86.3)		
Living with extended family	19(11.6)	19(7.3)		
Educational level				
No formal education	2(1.2)	4(1.5)	21.515	<0.001
Primary education	47(28.7)	33(12.6)		
Secondary education	38(23.2)	100(38.2)		
Tertiary education	66(40.2)	102(38.9)		
Postgraduate education	11(6.7)	23(8.8)		
Average household monthly income (Naira)				
<20,000	29(17.7)	47(17.9)	3.647	0.456
20,000-49,000	41(25.0)	68(26.0)		
50,000-99,000	42(25.6)	73(27.9)		
100,000-199,000	34(20.7)	37(14.1)		
>200,000	18(11.0)	37(14.1)		
Duration of hypertension				
<1year	47(28.7)	50(19.1)	6.632	0.036
1-4years	61(37.2)	96(36.6)		
≥5years	56(34.1)	116(44.3)		
Comorbidities				
Present	100(61.0)	99(37.8)	21.790	<0.0001
Absent	64(39.0)	163(62.2)		
Complication of hypertension				
Present	55(33.5)	45(17.2)	15.030	<0.0001
Absent	109(66.5)	217(82.8)		



Table 5. Bivariate logistic regression analysis to identify factors associated with medication nonadherence in the study population

Variable	Adjusted Odds ratio (95% CI)	p value
Age group		
Young	Reference	
Middle-aged	2.590(1.260-5.325)	0.010
Elderly	5.973(2.510-14.211)	<0.001
Marital status		
Single	Reference	
Married	0.192(0.068-0.543)	0.002
Widow/widower	0.143(0.026-0.799)	0.027
Separated	0.693(0.284-1.695)	0.456
Divorced	1.538(0.499-4.740)	0.456
Educational level		
No formal education	Reference	
Primary education	0.184(0.024-1.399)	0.102
Secondary education	1.282(0.165-9.944)	0.812
Tertiary education	0.835(0.110-6.353)	0.862
Post graduate education	1.341(0.158-11.363)	0.788
Duration of hypertension		
<1year	Reference	
1-4years	1.507(0.831-2.735)	0.177
≥5years	1.049(0.574-1.916)	0.877
Comorbidities		
Present	Reference	
Absent	2.417(1.609-3.632)	<0.0001
Complications of hypertension		
Present	Reference	
Absent	2.219(1.390-3.542)	0.001

adherence. Various studies from different parts of the globe have reported marked disparities in adherence to antihypertensive medication with very high adherence rates of 83% to 92% in high income countries [20,21] while adherence rates in LMICs are much lower at 36% to 67%. [12,22-24] A meta-analysis of non-adherence to antihypertensive therapy showed major regional differences with a higher percentage of poor adherence levels among African patients (62.4%) compared to Asians (43.5%), Europeans (36.6%), and Americans (36.6%).[25]

Prior studies carried out in Nigeria by Adisa et al [26] and Adeoye et al [27] have described very low rates of adherence to antihypertensive medication at 8.9% and 4.1% respectively and both studies utilized the MMAS-8 to assess adherence, while in neighboring Ghana, a similar low adherence rate of 6.7% was reported.[28] Poor adherence of this magnitude substantially contributes to the inadequate blood-pressure control that prevails in more than two-thirds of the hypertensive population, and to the fact that in spite of antihypertensive treatment, cardiovascular morbidity is higher among hypertensives than normotensives. [29] Differences in levels of adherence in different studies may be due to the method by which adherence was assessed [8] as adherence may be assessed by patient questionnaire and self-reporting, [26,27] pill count, pharmacy refill data as well as direct methods such as biochemical monitoring of drug levels in serum or urine samples.[20,21] The medical interview is the most readily available method of detecting non-adherence in clinical practice and is more widely used [30] while the direct methods, although more accurate, tend to be costly, labour-intensive, difficult to conduct in real clinical practice and are time consuming. [6]

The most common self-reported reason for non-adherence was “I only take them when I have symptoms I attribute to hypertension.” Given the largely asymptomatic nature of hypertension, treatment often has to be justified to patients through abstract health advantages, such as long-term benefits and decreased risk for future disease. [30] Education about the clinically silent nature of hypertension needs to be repeatedly emphasized. “I forget to take my medication” was another reason reported by this cohort of patients and this finding was mirrored in another study where forgetfulness was the most common cause of low adherence and the authors recommended interventions to avoid forgetfulness as a way to improve adherence. [31] However, to be effective such interventions must be tailored to the particular economical, geographical, sociological and educational context of the patients. Other self-identified barriers to antihypertensive medication adherence and treatment discontinuation by patients in other studies include high cost of medications, side effects of

DISCUSSION

This study provides important insight into the socio-demographic and clinical characteristics which determine adherence to antihypertensive medication as antihypertensive medications are an important aspect in the management of hypertension and blood pressure control. [19]

Using the Morisky’s Medication Adherence Scale 8 (MMAS-8), almost two thirds (61.5%) of the respondents were not adherent to their medication while just over a third reported good medication



medication, preference of traditional medicine, lack of support from family and community, afraid of becoming dependent on antihypertensive medication and discontinuation of medication when blood pressure is within normal values.[31,32,33] Maintaining good adherence to antihypertensive medications in developing countries remains a challenge and there is a serious need to accurately assess the barriers and behaviours that influence adherence to medication.

Medication nonadherence is multifactorial, [8] and understanding the predictors of good drug adherence in hypertension is important in improving blood pressure control. This study noted a significant relationship between increasing age and poor medication adherence. The exact association between age and medication adherence is still being debated as several studies have reported poor adherence in the younger age group, [20,34] however, Hussein et al [24] noted poor medication adherence in the older age group while Kretchy et al [28] reported that the odds of a patient adhering to medication decreased by 3% with every year advancement in age. Cognitive decline associated with aging as well as multimorbidity with a high pill burden may contribute to poor adherence in elderly persons. Older persons may have multiple morbidities with a higher pill burden which may lead to non-adherence. Also, the presence of age-related decline in cognitive function can also contribute to forgetfulness to take prescribed medication. Whereas this study did not reveal any significant relationship between gender and adherence to medication as was also reported by Ola Undrum Bergland et al, [20] some studies have found female gender to be associated with nonadherence [13,35] but Abegaz et al [25] had an opposing view where the authors found the risk of nonadherence to antihypertensive medication to be 1.3 times higher in males than females. Further research will be needed to better understand the underlying risk factors associated with nonadherence in different age groups and between the sexes

Financial inequalities represent a barrier to treatment and adherence and the situation is potentially even more noticeable in sub-Saharan Africa although this study did not reveal a relationship between total household monthly income and adherence to antihypertensive therapy, however, various studies have described that low adherence and the economic level of the patients are related.[12,23,24,31] In a cross-sectional survey across 12 African countries, more than one-quarter of patients admitted having stopped their treatment due to financial reasons and this proportion was 4-fold higher in the lowest compared to the highest wealth group, [31] whilst various authors reported that the odds of adherence to antihypertensive medications was much higher in respondents who had got the medication/s free of charge

or with low cost as compared to those who had got the medication/s with high cost. [12,23] In addition to the financial implication of the price of medication, another study reported that participants were more probably to be nonadherent if they had missed appointments due to lack of transport/money for transportation to the health care facility.[28]

A longer duration of hypertension in this study was significantly related to medication nonadherence and this finding has been mirrored in several studies [28,36,37] as patients who had a diagnosis of hypertension of 5 years and above were less likely to adhere to treatment than those who had been diagnosed for less than five years. This may be due to the rising cumulative cost of an asymptomatic disease as well as fatigue to ingestion of long-term drugs. The absence of complications of hypertension significantly contributed to poor adherence to hypertensive therapy in this study as well as a similar Nigerian study [26] as due to the asymptomatic nature of the disease, the patient may not be motivated to take daily medication, however, patients will be more likely to take medication when they experience symptoms of any of the cardiovascular complications of hypertension. Hashmi et al [38] found that cases suffering from hypertension-related complications were more likely to be adherent to medications. Nevertheless, a cross-sectional survey of 12 African countries did not demonstrate any significant association between low medication adherence and the presence of cardiovascular complications or comorbidities.[31]

BP lowering in hypertensive patients with comorbidities is important to reduce vascular risk and patients with comorbidities on treatment may have more complications as well as be on multiple medications for the treatment of the various conditions. [6] In this study, poor drug adherence was significantly associated with the absence of comorbidities and subjects with multiple comorbidities were more likely to be adherent to antihypertensive medication. Comorbidities such as diabetes and obesity may be symptomatic and thus encourage better drug adherence as various global studies [39,40,41] also noted a significant association between the presence of comorbid conditions in hypertensive patients and good adherence to antihypertensive medications. A Nigerian study specifically noted that hypertensive persons with associated obesity had higher adherence to medication compared to those who had a normal body weight. [27] Conversely, an African study did not reveal any significant association between the presence of comorbidities and adherence to antihypertensive medication, [31] but hypertensive patients without other comorbidities have a simple treatment regimen that theoretically, should make adherence easier, and multiple studies have demonstrated this relationship. [6,12,23,24,25] Mekonnen et al



reported that study participants who had no co-morbidity were four times more likely to adhere to antihypertensive medications than their counterparts, [12] while a meta-analysis by Asgedom et al concluded that nonadherence to antihypertensive medications was significant in hypertensive patients with comorbidities.[23]

The knowledge of moderate to high intensity exercise for management of hypertension among the study participants was good but only a third of the recruited patients regularly exercised and various factors may contribute to this deficiency of structured exercise which include lack of formalized physical activity guidelines, limited exercise facilities, neighbourhood safety and lack of community support.

Optimal management and control of hypertension, in addition to antihypertensive medication includes lifestyle interventions [42] and adopting a healthy lifestyle can also serve as a primary preventive measure against hypertension, consequently lowering the risk of CVD. [19,43] High blood pressure is known to be influenced by physical inactivity, diets low in fruits and vegetables, high sodium intake and being overweight or obese, especially high levels of visceral adipose tissue as demonstrated in a randomized controlled trial study where the authors concluded that multimodality lifestyle modification improved BP control.[44] In addition to these direct benefits, lifestyle modifications can also amplify the effect of the pharmacological treatment of hypertension.[19]

To overcome such barriers, individuals should be stimulated to use any means possible to be physically active, encouraging activities that are enjoyable to increase adherence and sustain it long term, while governments and town developers should plan environments conducive and safer to walk, cycle and exercise. [19]

Diet plays an important role in the healthy functioning of the body and many different dietary patterns are hailed as useful for improving BP control with recommendations of low saturated fat intake, reduced salt, high fibre (from wholegrains, fruits and vegetables) and adequate lean protein. [45,46,47] Actual implementation of these dietary recommendations regarding reduced salt was 55.6% in recruited patients while consuming a diet rich in fruits, vegetable and low in fats was 66.7% and this low consumption of healthy foods may be due to rising food costs because of the worsening global economy, seasonal availability of healthy food options or difficulty or unwillingness to adhere because of cultural heritage or beliefs. This low practice of healthy food ingestion has also been reported in high income countries where only 12% of Europeans and 5% of the Australian

population achieve the recommended five servings of fruit and vegetables per day.[48] Dietary sources of sodium in Nigeria include salt, seasoning cubes and processed foods [49] which means the estimated daily salt intake in Nigeria of 5.8g/day [50] is much higher than the WHO daily recommendation level.[51] Limiting the amount of salt in processed foods, as well as restricting how companies can advertise their food can help to reduce salt intake.[52]

Although lifestyle changes are effective, they remain difficult to implement and maintain long-term because many people live in environments that are not conducive to achieving and sustaining a healthy lifestyle [43] as was demonstrated in this cohort of patients where practice of most of these lifestyle interventions was poor. Healthcare providers and clinicians should receive adequate training in working with patients to adopt lifestyle changes and take an active role in the implementation. Lifestyle intervention requires a multidisciplinary approach as patients should receive counselling from family physicians, nurses, kinesiologists, and registered dietitians which must be tailored to different ethnic and cultural backgrounds, health literacy and food availability.[19]

CONCLUSION

Non-adherence to antihypertensive medication poses a great challenge to the management of hypertension in Nigeria and this study revealed the high level of poor adherence to antihypertensive medication in patients with hypertension and identified the associated factors specific to the regional context. Early identification of patients' barriers as well as continuous adherence counselling and targeted interventions that incorporate lifestyle modifications in addition to pharmacological treatment are essential to improve adherence, blood pressure control and ultimately improve cardiovascular morbidity and mortality.

Limitations of this study

This study assessed adherence with patient interview, which is an indirect method and can both overreport or underreport adherence levels when compared to the more accurate direct measurements of drug concentration or its metabolite in body fluids.

Disclosure of conflict of interest

The authors declare no conflict of interest

Statement of Ethical approval

Ethical approval was given by the Rivers State University Teaching Hospital Health Research and Ethics Committee (RSUTH/REC/2022226).



Statement of Informed consent

Informed documented consent was obtained from all individual participants included in the study

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