Cost-Effectiveness of Drug Therapies in Management of Hypertension in a Nigerian Teaching Hospital: a Utility-Based Analysis

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ABSTRACT: Efficient resource allocation is vital for managing hypertension in Nigeria due to the high disease burden and limited healthcare resources. This study aims to assess the cost effectiveness of hypertension therapies at the University of Ilorin Teaching Hospital over one year by reviewing drug use, analyzing costs effectiveness of treatment options and examining their impact on healthcare policy and resource allocation. A sample size of 356 case notes was derived from 40,009 ambulatory hypertensive patients. The drug utilization study involved a one-year retrospective review of the 356 case notes, conducted from January to December 2023. The EuroQol 5-Dimensions 5-Level questionnaire (EQ-5D-5L) was used to determine the effectiveness of treatment options based on quality-adjusted life years (QALYs). Of the 693 prescriptions identified, 94 (13.56%) contained monotherapy, 328(47.3%) two-drug combination and 271(39.11%) three-drug combination. Amlodipine + lisinopril appeared to be more cost-effective than amlodipine + telmisartan, which in turn was more cost-effective than both amlodipine + indapamide and amlodipine + ramipril, leaving amlodipine+ lisinopril as the most cost effective out of analysed options for the Nigeria healthcare system. ICERs obtained were robust to parameter variation on probabilistic sensitivity analysis. Inclusion of amlodipine + lisinopril in the WHO essential medicine list, hospital formularies, and standard treatment guidelines as components of drug policy is justified and would promote rational drug use, improve treatment outcomes and optimize resource utilization in the management of hypertension in Nigeria.

Key words: Hypertension, antihypertensives, cost -minimization analysis, Nigerian teaching hospital.

INTRODUCTION

Hypertension is a leading cause of premature death, claiming nearly 10 million lives annually worldwide.[1] It is a major preventable risk factor for cardiovascular disease.[2] Although majority of patients with hypertension remain asymptomatic, some people with HTN report headaches, light-headedness, vertigo, altered vision or fainting episode.[3]

The prevalence of hypertension is rising globally owing to ageing of the population and increases in exposure to lifestyle risk factors including unhealthy diets (i.e. high sodium and low potassium intake) and

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lack of physical activity.[1] However, changes in hypertension prevalence are not uniform. The prevalence of hypertension among adults was higher in low- and middle-income countries (31.5%, 1.04 billion people) than in high-income countries (28.5%, 349million people).[6] Despite the increasing prevalence, the proportions of hypertension awareness, treatment and blood pressure control are low, particularly in low- and medium-income countries (LMICs).[1] The prevalence of hypertension in Nigeria is reported to be approximately 30% (men 29.5%, women 31.1%).[4] This is believed to be due to an increasing older population, rapid urbanization and uptake of western lifestyles, including high consumption of processed foods (with high salt and fats), tobacco and alcohol products.[5] Nigeria currently has a population of over 200 million, and is the most populous African country and the prevalence of hypertension in the country hugely contributes to the overall burden in Africa.[5]

Antihypertensive pharmacotherapy in addition to lifestyle modifications are effective in reducing the morbidity and mortality associated with hypertension (risk of stroke, coronary events, heart failure and progression of renal disease).[7-9] however the rate of successful blood pressure control remains low among treated patients[10] over the past decade, several clinical guidelines on antihypertensive treatment have been published, contributing to a better understanding of hypertension management. Diuretics were considered as first-line treatment for hypertension many years ago. Recently, the Joint National Committee (JNC8 guidelines) recommends both calcium channel blockers as well as angiotensin converting enzyme inhibitors as first-line drugs, in addition to diuretics. Antihypertensive drug combinations are generally used for effective long-term treatment of hypertension and comorbid conditions[7].

The economic burden of hypertension is on the rise with the costs of its treatment consuming a substantial portion of healthcare resources in many countries.[8,9]

The choice of medication for treatment of hypertension has a large impact on both patient outcomes and healthcare costs.[11] The rising expense of treatment influence patient adherence and prescribing patterns of physicians.[9]

In the management of chronic diseases like hypertension, cost is a major consideration. In Nigeria a large number of the population are low-income earners who access healthcare from public hospitals, pay out of pocket, and have to treat hypertension lifelong. Pharmacoeconomic evaluation plays a major role in the effective and efficient management of medication cost and treatment outcomes. It is a tool that should be utilized routinely by healthcare professionals to maximize treatment outcomes.[12]

In resource-limited settings like many tertiary health facilities in Nigeria, the economic burden of hypertension management is a significant concern. The cost of medications, coupled with the need for long-term treatment, poses a challenge for both patients and healthcare systems.[11] Therefore, it is imperative to evaluate the pharmacoeconomic impact of antihypertensive therapies to ensure that the most cost-effective and clinically effective treatments are utilized.

This study aims to conduct a cost-effectiveness analysis of therapies used in the management of hypertension among patients at the University of Ilorin Teaching Hospital over a one-year period. By identifying treatment options through drug utilization review, assessing treatment costs using mean cost calculations, and evaluating outcomes with the EQ-5D-5L instrument, the study seeks to generate evidence-based recommendations to optimize hypertension management, enhance patient care and improve resource allocation.

MATERIALS AND METHODS

Study area. The study was conducted at University of Ilorin Teaching Hospital (UITH) located in Ilorin the capital city of Kwara State, Nigeria. It is a second-generation Teaching Hospital in Nigeria alongside Jos, Sokoto, Calabar, Port-

harcourt and maiduguri. the hospital has three comprehensive health centres located in esie (kwara state), Ihima (Kogi state) and kishi (Oyo state).

University of Ilorin Teaching Hospital, a hospital with a vision to become the hub of quality and standard healthcare service delivery in Africa (uithilorin.org.ng), has many notable breakthroughs including the successful performance of open-heart surgery. It is a 650 bedded hospital with 21 clinical service department, including the General Out-Patient department (GOPD) also called Family Medicine Department.

The GOPD runs daily clinic attending to over 200 patients both adult and paediatric patients, with various disease conditions including hypertension.

Ethical approval. Ethical approval was sought and obtained from the University of Ilorin teaching hospital-Health Research and Ethics committee (HREC) Approval Number: ERC/PAN/2024/04/0481.

Study population and sample size. The study population comprised of a total of (forty-two thousand and nine) 42,009 patients with hypertension who registered at the general out-patient clinic of University of Ilorin Teaching Hospital in the last ten (10) years, from January 2013 to December 2022. Fischer's formula[13] was applied to determine the sample size from this estimate. The required sample size was 356.

All cases of hypertension who presented for treatment in UITH from ages 18 and above were included in the study while in-patients, patients with co-morbidities and pregnant hypertensive patients were excluded.

Study design for drug utilization review. A drug utilization study was conducted through a one year retrospective review (January 2023 to December 2023) of the 356 case notes. Treatment options/drug utilization pattern of thevarious treatment options available were identified from case-notes of the subjects.

Study design for cost-effectiveness analysis. A prospective study was conducted among patients with hypertension at the general out-patient clinic of University of Ilorin Teaching Hospital, llorin, Kwara state. This was done to determine effectiveness of their therapy. Data relevant to the study were collected using a European Quality of life five-dimensional five-level (EQ5D5L) standardized questionnaire. This is a renowned generic instrument measuring quality of life indifferent diseases; it includes 5 dimensions (mobility, self-care, daily activities, pain-discomfort, anxiety and depression) and a Visual Analogue Scale (VAS) that evaluates patients' perceive dutility status.[22]

After all available treatment options were identified, a utility value was determined for patients on the selected regimens the overall utility value for all patients on all regimens and overall EQVAS score/Visual analog scale (VAS) were also determined. The QALY is obtained by multiplying the duration of time spent in a health state by the HRQoL weight (i.e. utility score) associated with that health state. This was done by multiplying the overall utility and the duration of therapy for the administration of the drugs used in the management of hypertension.

Data collection procedure. The selected patients from there prospective review–were coded with the assigned hospital numbers on each of the selected 356 case notes, and the appointment days of each patient noted. Our team were present on all appointment days, identified the patients with case note numbers/code and administered the questionnaires at the point of exit of each patient from the consultation rooms. The signature of each researcher was appended to the case notes to prevent multiple administrations of the questionnaire to the patients.

Cost measures. For cost of medications, costs were obtained from the Pharmacy Department and the cost per defined daily dosage (DDD) for each identified treatment option was calculated. DDD units are recommended standard by WHO for drug use analysis. One DDD usually represents the daily dosage of treatment options per day.[23] The duration of therapy that is most frequently prescribed was multiplied by the cost per DDD to obtain the cost

component used in the "Cost effectiveness analysis". This was done for each treatment option.[24]

Cost effectiveness analysis (CEA). Cost effectiveness analysis enables a decision-maker to make an informed decision about apreferred choice among possible alternatives. It indicates the intervention that provides highest value for money. It involves calculating and comparing the cost (resources needed for intervention implementation) and the effectiveness (outcome). The incremental cost-effectiveness ratio (ICER) was computed using the formula given below[25].

$$\frac{\text{change in cost}}{\text{change in effectivenes}} = \frac{\text{cost of option A} - \text{cost of option B}}{\text{effectiveness of A} - \text{effectiveness of option B}}$$

Monte carlo simulations. Monte Carlo simulations were conducted using 1000 iterations of the base case incremental cost and QALYs. The probabilities of the ICERs being dominant and being cost-effective were found.

Data analysis. The data obtained were analyzed using descriptive and inferential statistics. The data collected were entered into and analyzed using Statistical Package for Social Sciences (SPSS) version 25, computer software packages. In carrying out the different analyses, 95 % CI and p-value of 0.05 were used for deciding statistical significance of differences observed.

Exchange rate. During the period of this study, $1US dollar equaled 1,605.44 NGN

RESULT AND DISCUSSION

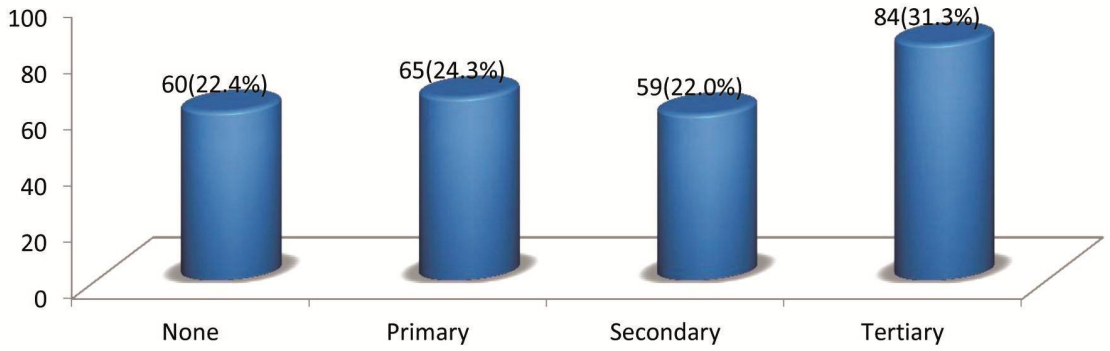
Socio-demographic characteristics. The respondents, consist of 73 (27.2%) males and 195 (72.8%) females. Their age ranged from 26 to 80 years, with a mean age of 57 years. The smallest number of respondents was observed in the age group of below 40 years (6.7%) while age group 60-69 years had the largest frequency (32.5%). 22.0% of the respondents were unemployed, 57.0% were self-employed, 13.4% are employed by the government, and 7.5% are employed in the private sector, as shown on table 1.

Among the respondents, 31.3% had tertiary level of education, those respondents with primary level of education accounted for 24.3% (65), while respondents were not schooled accounted for 22.4%, as shown in figure 1.

Table 1. Socio-demographic characteristics of respondents.

Variables	Frequency	Percentage	Mean ± SD	t-test/F-test	p-value
Gender				2.231	0.025
Male	73	27.2	6.47 ± 5.96		
Female	195	72.8	5.41 ± 5.33		
Age groups				60.433	0.001
< 40	18	6.7	1.54 ± 0.86		
40 – 49	40	14.9	1.92 ± 1.26		
50 – 59	80	29.9	3.51 ± 2.45		
60 – 69	87	32.5	6.25 ± 4.33		
≥ 70	43	16.0	13.61 ± 7.17		
Occupation					
Unemployed	59	22.0	8.95 ± 6.85		0.001
Self employed	152	57.0	5.30 ± 5.2		
Government employed	36	13.4	3.31 ± 2.64		
Private employed	20	7.5	3.20 ± 2.80		
Level of education				6.084	0.001
None	60	22.4	8.37 ± 6.45		
Primary	62	23.1	5.94 ± 5.52		
Secondary	59	22.0	3.90 ± 3.80		
Tertiary	84	31.3	5.40 ± 4.72		
Cleric	3	1.1	6.00 ± 3.60		

Sample no (n):356



Sample no (n): 356

Figure 1. Level of education of respondents.

EQ -VAS and health index of respondents. The EQ-VAS mean score was 69.12 ±12.31, ranging from 30 to 100. This scale measures the respondents' self-rated health on a scale from 0 to 100, where higher scores indicate better perceived health (Table 2).

Table 2. EQ-VAS and health index of respondents.

Variables	Mean ± standard deviation	Range
EQ -VAS	69.12 ± 12.31	30 - 100
Health state index	0.86 ± 0.55	0.202 - 9.00

Sample no (n): 356

Distribution of antihypertensive drugs. Twenty-six antihypertensive medications were prescribed 693 times, either as monotherapy or polytherapy with some being fix-dose combinations therapies.

The most prescribed antihypertensive drugs were amlodipine (29.1%), amiloride + hydrochlorothiazide (12.84%), lisinopril (12.6%) and telmisartan (7.36%), either as monotherapy or in polytherapy regimen.

Less commonly prescribed drugs include nifedipine (1.73%), losartan (1.01%) and zofenopril (1.15%). Drugs like nebivolol, valsartan, enalapril, and ramipril are prescribed even less frequently, each constituting less than 1% of the total prescriptions.

Combination therapies such as ramipril + amlodipine (2.87%) and indapamide + amlodipine (3.61%) are also part of the treatment regimen. Thiazide and thiazide-like diuretic containing medications together account for 24.54% of the prescribed medications (Table 3).

Table 3. Distribution of antihypertensive drugs.

Sl. No.	Drugs	Number (n)	Percentage (%)
1.	Amlodipine	202	29.1
2.	Lisinopril	87	12.6
3.	Hydrochlorothiazide	23	3.32
4.	Telmisartan	51	7.36
5.	Atenolol	10	1.44
6.	Indapamide	27	3.90
7.	Bisoprolol	50	7.22
8.	Nifedipine	12	1.73
9.	Nebivolol	6	0.87
10.	Valsartan	3	0.43
11.	Enalapril	1	0.14
12.	Losartan	7	1.01
13.	S-amlodipine	10	1.44
14.	Methyldopa	21	3.03
15.	Telmisartan + amlodipine	23	3.32
16.	Ramipril + amlodipine	20	2.87
17.	Ramipril	1	0.14
18.	Valsartan + amlodipine	3	0.43
19.	Amiloride/hyrochlorothiazide	89	12.84
20.	Indapamide + amlodipine	25	3.61
21.	Enalapril + hydrochlorothiazide	4	0.58
22.	Atenolol + chlorothiazide	2	0.29
23.	Propranolol	3	0.43
24.	Zofenopril	8	1.15
25.	Labetalol	2	0.29
26.	Carvedilol	3	0.43
Total Number of antihypertensive		693	99.97%

Sample no (n): 356

Average number of drugs per prescription. Average number of drugs per prescription was 1.95 which is approximately (Table 4).

Table 4. Average number of drugs per prescription.

Total drugs prescribed	Number of prescriptions	Average
693	356	2

Sample no (n): 356

Classes of antihypertensive drugs prescribed. Antihypertensive medications were mostly prescribed from the classes calcium channel blockers (32.3%), diuretics (20%), ACEI (14%), ARB (8.8%) and beta blockers (10%) (Table 5).

Table 5. Distribution according to class of antihypertensive drugs.

Sl. No.	Class of drug	Frequency (N)	Percentage (%)
1.	Diuretics	50	7.2
2.	Calcium channel blockers	224	32.3
3.	Angiotensin-converting enzyme inhibitors	97	14.0
4.	Angiotensin II receptor blockers	61	8.8
5.	Alpha- and beta-adrenergic blockers	5	0.7
6.	Beta adrenergic blockers	69	10.0
7.	Centrally acting alpha-2 agonist	21	3.0
8.	Combined diuretics	89	12.8
9.	Fixed-dose combined antihypertensive therapy	77	11.1
TOTAL		693	99.9%

Sample no (n): 356

Distribution of antihypertensive drugs: monotherapy or combination therapy. 14.0% of the patients received monotherapy, 47.0% of received dual therapy (2 drugs), 39.1% received polytherapy (3 or more drugs). Various combinations in fixed doses were among the medications prescribed for hypertensive patients for the management of the condition (Table 6).

Table 6. Distribution of antihypertensive drugs: monotherapy or combination therapy.

Regimen	Frequency	Percentage %
Monotherapy	94	13.56
Two-drug therapy	328	47.33
Three or more (Polytherapy)	271	39.11
Total	693	100

Sample no (n): 356

Cost effectiveness analysis of main regimens for hypertension treatment.

Cost effectiveness analysis of amlodipine/ telmisartan compared with amlodipine/ indapamide. The total costs of regimens A (amlodipine/ telmisartan) and regimen B (amlodipine/ indapamide) were $15.61 and $30.4 respectively, while their effectiveness was 0.2248 and 0.2101QALYs respectively (Table 7).

Table 7. Cost effectiveness analysis of amlodipine/ telmisartan compared with amlodipine/ indapamide.

Treatment option	Total cost in USD	Effectiveness QALYs	Average cost effectiveness ratio ($/QALYs)	Remarks
Regimen A				
Amlodipine /telmisartan 80/10mg once daily	15.61	0.2248	69.43	DOMINANT
Regimen B				
Amlodipine /indapamide 10/1.5mg	30.4	0.2101	144.69	

p-value = 0.847, sample number n=356, during the period of this study ,$1US dollar equaled 1,605.44 NGN

Cost effectiveness analysis of amlodipine/ telmisartan compared with amlodipine/lisinopril. Total cost of regimen C (amlodipine/lisinopril) was $8.12 as against $15.61 of regimen A (amlodipine/telmisartan). In terms of effectiveness, regimen C recorded 0.2914 QALYs while regimen A was 0.2248 QALYs (Table 8).

The study revealed a significant gender disparity in clinic attendance, with females displaying a higher positive health seeking behaviours than men. This finding highlights an important trend, differences in health seeking behaviours between genders which may be due to factors such as awareness, access to healthcare and societal norms.[14]

Cost effectiveness analysis of amlodipine/ temisartan compared with amlodipine/ ramipril*:* Regimen D cost $90.44 while regimen A cost $15.61 and effectiveness of A and D were 0.2266 QALYs and 0.2266 QALYs respectively (Table 9).

Table 8. Cost effectiveness analysis of amlodipine/telmisartan compared with amlodipine/lisinopril.

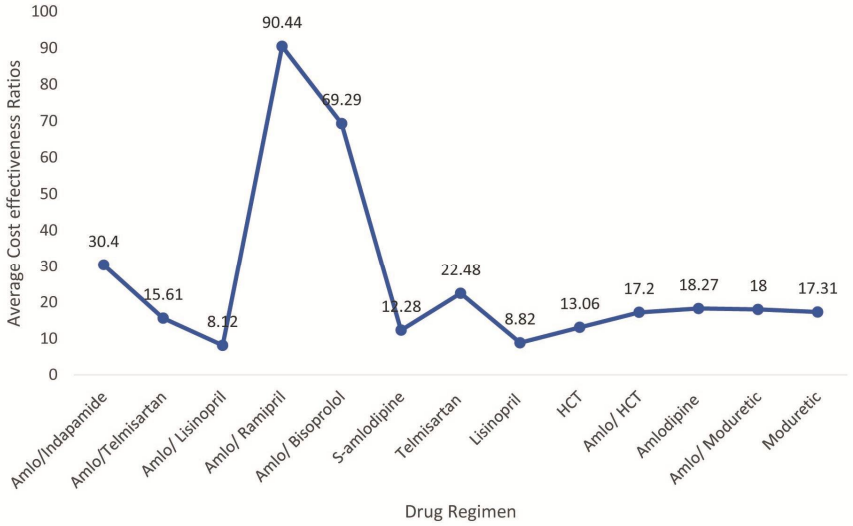
Treatment option	Total cost in USD	Effectiveness QALYs	Average cost effectiveness ($/QALYs)	Remarks
Regimen A Amlodipine /telmisartan 80/10 mg once daily	15.61	0.2248	69.43	
Regimen C Amlodipine 10mg once daily & lisinopril 10 mg once daily	8.12	0.2914	27.87	DOMINANT

p-value = 0.707, sample number n = 356, during the period of this study , $1US dollar equaled 1,605.44 NGN

Table 9. Cost effectiveness analysis of amlodipine/temisartan compared with amlodipine/ramipril.

Treatment option	Total cost in USD	Effectiveness QALYs	Average cost effectiveness QALYs	ICER ($/QALYs)
Regimen A Amlodipine /telmisartan 80/10 mg once daily	15.61	0.2248	69.43	$41,572 per extra unit of effectiveness of regimen D
Regimen D Amlodipine/ramipril 10/5 mg once daily	90.44	0.2266	399	

*The 1000 iterations in ICER had the probability of the ICER (dominant< GDP/capita of Nigeria $1,637.47[24]) as 0.02%
p-value = 0.001, sample number n = 356, during the period of this study, $ 1US dollar equaled 1,605.44 NGN.



Sample number n=356

Figure 2. Average cost effectiveness ratios of some identified treatment options for management of hypertension.

This result is similar to that obtained from a study assessing treatment seeking behaviours among adults with hypertension, where more females attend clinics than males due to factors such as the female gender, availability of medicines and medical personnels, and perceived good quality of care.[15]

The majority of respondents fall within the age groups of 50-59 and 60-69 years, suggesting that the study population is predominantly middle-aged to elderly. This finding is in tandem with studies which indicate that by this age group, more than half of the population is affected by hypertension.[15]

About 2/3 of the respondents were employed, out of which more than half were self-employed and this provides insight into the economic activities and employment status of the study population.[16] Majority of the hypertensive patients were either traders or business men/women.

An average health state index of 0.86 implies a population experiencing some degree of health limitation but is still relatively healthy compared to a score closer to (zero) 0 which would indicate severe health impairment.

The most frequently prescribed antihypertensive drugs were amlodipine, amiloride/hyrochlorothiazide, lisinopril, telmisartan as monotherapyor in combination with other drug class. This finding deviates from the results of a study conducted in Ethiopia which reported only diuretics and ACE inhibitors as the most frequently prescribed antihypertensives.[17]

Amlodipine is a calcium channel blocker (CCB) which is a commonly recommended class of antihypertensive drugs. According to various guidelines CCBs are often recommended as first-line or second-line therapy for hypertension due to efficacy and safety profile. Diuretics (thiazide/ thiazide-like) are first-line treatment option for hypertension treatment, particularly for patients with certain co-morbidities and those patients resistant to other classes of antihypertensive.[18] Angiotensin-converting enzyme inhibitors (ACEIs), such as lisinopril, are commonly recommended as first-line therapy due to their proven effectiveness in reducing cardiovascular events and mortality.[18]

Amlodipine/ telmisartan, amlodipine/ ramipril, and amlodipine/ indapamide were among the notable fix-dose combination therapy prescribed, while amlodipine /lisinopril was also frequently prescribed regimen but not as a fix-dose combination.

This pattern reflects adherence to guidelines that recommend a combination of medications tailored to individual patient needs and comorbidities.[19]

The average number of drugs per prescription was two this is similar to a previous report.[20] This implies that prescribers adhere to treatment guidelines which recommend combination therapy for better BP control.[20] using 2 or more classes of antihypertensive medications can improve blood pressure control rates, reducing the risk of cardiovascular complications.[21] However, the use of multiple antihypertensive drugs per prescription suggests that hypertension management often require multifaceted approach, and this can lead to increased monitoring potential drug interactions, and higher costs for patients.[17.20]

While combination therapy can be more effective, it may also complicate medication regimens, potentially affecting patient adherence. Fixed-dose combination pills (combining two drugs in one pill) can help improve adherence by simplifying the regimen.[17]

Results of cost effectiveness analysis taking into account the GDP per capita for Nigeria[24] and WHO Choice guidelines.[25] Revealed that amlodipine + lisinopril appeared to be more cost-effective than amlodipine + telmisartan, which in turn was more cost-effective than both amlodipine + indapamide and amlodipine + ramipril, leaving amlodipine + lisinopril as the most cost effective out of the compared treatment options. This can be further explained to mean that, using a standard pharmacoeconomic approach—which involves calculating the incremental cost-effectiveness ratio (ICER) and comparing it with Nigeria's GDP per capita—amlodipine + lisinopril was found to be the most cost-effective among the four treatment options compared. This result was robust to parameter variations on probabilistic sensitivity analysis (Monte Carlo simulations).

The average cost-effectiveness ratio reflects the cost per unit of effectiveness in the absence of a comparator; however, it does not necessarily indicate true cost-effectiveness. Among the treatment options assessed, the combination of telmisartan and lisinopril exhibited the lowest average cost-effectiveness ratio.

Limitations to study. The one-year study period may not fully capture long-term treatment outcomes or cost variations over time.The retrospective nature of data collection poses potential challenges with data completeness and accuracy. Despite these limitations, the study provides valuable insights into the cost-effectiveness of antihypertensive therapies within the study setting.

CONCLUSION

Amlodipine (CCB), lisinopril (ACEI), telmisartan (ARB) and amiloride/ hydrochlorothiazide (thiazide diuretic) are the most frequently prescribed antihypertensive medications for this current study. The average number of drugs per prescription is two. Out of analyzed treatment options, amlodipine + lisinopril appeared to be more cost-effective than amlodipine + telmisartan, which in turn was more cost-effective than both amlodipine + indapamide and amlodipine + ramipril.

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