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Original Research Article

Prescribing patterns in systemic hypertension and pharmaco-economics (cost effectiveness and cost minimisation analyses) of the commonly prescribed antihypertensives in a district hospital in Enugu State, Southeast Nigeria

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ABSTRACT

Background: Prescribing patterns in systemic hypertension vary from place to place. Studies have shown that cost could be one of the factors responsible for non-adherence to treatment among hypertensive patients. Nigerian pharmacoeconomics studies have not provided a general guide on cost-effective prescribing for hypertensive patients in the country. The aim of the study was to examine the prescribing patterns, do cost effectiveness and cost minimisation analyses of the commonly prescribed antihypertensives, and determine if cost is a major reason many of the hypertensive patients of the District Hospital are usually lost to follow up.
Methods: 5267 adult (≥18 years) non-antenatal patients' cards of 2016 were reviewed for hypertension. Examination of the prescriptions, cost-effectiveness and cost-minimisation analyses of the commonly prescribed antihypertensives were done.
Results: 12.6% of the patients were hypertensive. 73% of these hypertensive patients were treated pharmacologically. 40.8% adhered to treatment. 73% of the adherent ones responded to treatment. Amlodipine was the most expensive prescribed antihypertensive (N22). Amiloride-hydrochlorothiazide with the largest cost effectiveness ratio (CER) (9) was the most cost effective of all the combinations. Lisinopril- hydrochlorothiazide (N17) was preferable to the triple combination of lisinopril-amlodipine-hydrochlorothiazide (N39), and amlodipine-hydrochlorothiazide (N32) in cost minimisation.
Conclusions: Cost of drugs probably had played a significant role in non-adherence to treatment among hypertensive patients in the District Hospital in 2016, since moduretic with the largest CER (9) and nifedipine with the greatest BP reduction when combined with hydrochlorothiazide (56/22 mm Hg) were rarely prescribed.

Keywords: Antihypertensives, Cost, Effectiveness, Hypertension, Minimisation, Pharmacoeconomics

INTRODUCTION

Hypertension is defined as any blood pressure (BP) ≥140/90 mm Hg. It has been projected that the global prevalence of hypertension would increase from 26.6% in 2000 to 29.2% in 2025, with Africa having the highest prevalence (46%) in the world.[1,2] Prescribing patterns in systemic hypertension vary from one part of Nigeria to another, and from one healthcare facility to another within the same state and zone. Factors responsible for this include availability or non-availability of drugs, affordability (cost) of the drugs, preference of the

healthcare facility and the doctors, and existing policy guiding the procurement of drugs in a particular state, among others. The choice of one drug over another, or combination of two or more drugs from different classes largely could be arbitrary, without regard for the cost. Often this choice depends on the preference of the doctor, his/her experience, level of the patient's BP on presentation, and patient's co-morbidity. More often than not, in many settings, consideration is usually not given to the costs of the prescribed drugs and the ability of the patient to pay for these drugs. Cost has been identified as one of the factors that could be responsible for patients' non-adherence to therapy.[3] Apparently, the high dropout rate from treatment among the hypertensive patients observed in many settings, including ours, is not unconnected with the high cost of drugs. Some past studies have reported adherence to antihypertensive treatment ranging from 36% to 49%.[4-6,2] Addressing the problem of adherence to therapy among hypertensive patients will require a multi-dimensional approach, one of which is analysis of the cost of the drugs. Economic analysis of the cost of treatment is the domain of pharmacoeconomics. Thus, pharmacoeonomics (PE), a term used for the first time by Ray Townsend during a presentation in a meeting of pharmacists in Toronto, Canada, provides us with the methodology to determine those treatment options, which will yield the maximum health gain per unit of currency spent.[7,8] In other words, PE assessment could be described as the practice of assessing both the benefits and costs of a pharmaceutical product, or therapeutic class of products, and comparing the two.[9] It is also defined as the description and analysis of the costs of drug therapy to healthcare systems and society.[10]

The cost of drug therapy relates not only to the price of the drug but also includes direct (e.g. staff and capital) and indirect (e.g. loss of earnings, loss of productivity and cost of travel to hospital) costs. The four evaluations most frequently used in PE include cost minimisation analysis (CMA) (used when treatments being evaluated have similar health outcomes), cost effectiveness analysis (CEA) (used when two or more drugs have the same treatment objective, but different degrees of efficacy), cost utility analysis (CUA) (applied when the effects of treatment on patient's quality of life and survival are considered together by converting both into a common unit of measure e.g. QALY- quality adjusted life year), and cost benefit analysis (CBA) (used when both the costs and benefits of the drug therapy are measured in monetary terms.

Some of the uses of PE include formulary decision-making (i.e., the decision to include or exclude a particular drug from the formulary), decision-making between drugs versus surgery and drugs versus ' watchful waiting' based on the effectiveness of the treatment and the cost, and creation of clinical guidelines for physicians that will assist them in prescribing the most efficient drug.[11] However, PE evaluation may be limited by the fact that the whole process may be open to bias in the choice of the comparator drug, the assumptions made, or the selective reporting of results because of conflict of interest (most PE evaluations are usually funded by pharmaceutical companies, or government).[12] For this reason, health economics is sometimes misused as a marketing ploy. Another limitation of PE evaluation is the difficulty in implementing the results of PE studies because of existing management structures, namely short-term spending versus long-term savings, isolated budget which is not flexible, non-affordability of a new intervention, no matter how cost-effective it might be.[13]

In Nigeria, adopting a general guide on cost-effective prescribing in the treatment of hypertension has not been possible, despite the efforts made by some researchers in the past.[14-19,3] This is partly due to the fact that prices of antihypertensive drugs are not uniform throughout the country, depending on the sources from which the drugs are procured, and partly because the perspectives of these pharmacoeconomics studies also differ from one another.

In District Hospital Awgu, the commonly prescribed antihypertensives in 2016 include lisinopril (ACE inhibitor) (41.4%), hydrochlorothiazide (thiazide diuretic) (30.6%), amlodipine (calcium channel blocker) (20.2%), moduretic (co-formulated hydrochlorothiazide and amiloride) (3.6%), losartan (ARB) (2.4%), and nifedipine (calcium channel blocker) (1.8%) as monotherapies, or in various combinations.

The prevalence of hypertension in the hospital in 2016 was 12.6% (663 out of 5267). 483 of 663 (73%) were commenced on antihypertensive treatments and 286 of 483 (59.2%) were lost to follow up, after commencing treatment. In our hospital setting, a case is defined as non-adherent, if the patient fails to come back for checkup within one month of the commencement of treatment. The high rate of dropout from treatment in this hospital has been a cause for concern among the doctors, hence the urgent need to examine the prescribing patterns and carry out some PE evaluations (cost-effectiveness and cost-minimization analyses) of the commonly prescribed antihypertensives to determine if cost could be one of the major reasons many of the hypertensive patients are usually lost to follow up.

METHODS

The study site, District Hospital Awgu, one of the seven District Hospitals in Enugu State, is situated in Awgu Local Government Area (Enugu West Senatorial District) of the State, located between latitudes 06 00' and 06 19' North of the Equator and longitudes 07 23' and 07 35' East of the Greenwich Meridian. The LGA is made up of 20 towns and has a population of 390 681.[20]

The study population was made up of 5267 adult (≥18 years) non-antenatal patients who presented to the hospital for medical care in 2016. 663 (12.6%) of these

adults who were found to be hypertensive constituted the sample size. This sample size was obtained by reviewing the cards of all the 5267 adults for hypertension. Inclusion criterion was any blood pressure ≥ 140/90 mm Hg (following JNC 7 classification). Criteria for treatment included BP ≥ 160/100 mm Hg; and any BP above 140/90 mm Hg with associated symptoms and signs of target organ damage. Using these criteria for treatment, 483 (73%) patients were commenced on antihypertensives. 286 (59.2%) patients on treatment were lost to follow up (they did not return for treatment review within one month after the initial visit). Out of the 197 that returned for continued care, 143 (73%) responded to treatment, while 54 (27%) did not. Response to treatment was defined as reduction of the systolic BP ≥20 mm Hg, or diastolic BP ≥10 mm Hg within 4 weeks of commencement of treatment.

The commonly prescribed antihypertensives in District Hospital Awgu in 2016 include amlodipine, amiloride-hydrochlorothiazide, lisionpril, and nifedipine, either as monotherpay, or in various combinations. These drugs were procured from the Central Medical Store (CMS) of the Enugu State Ministry of Health, Enugu. The dispensing prices of the drugs were as of December 2016.

The PE evaluations carried out in this study were cost minimisation and cost effectiveness analyses (CMA and CEA). Data were collected from September to October 2017. The data were analysed as descriptive statistics and analysis of variance (ANOVA) using MaxStat statistical software version 3.60. P-value of ≤0.05 was considered significant.

RESULTS

5267 cards of adult (≥ 18 years) non-antenatal patients who were seen at the hospital in 2016 were reviewed. Table 1 shows the prevalence of hypertension in District Hospital Awgu in 2016. According to the table, 663 (12.6%) of the 5267 adult patients were hypertensive, while 4604 (87.4%) had normal blood pressure.

Table 1: Prevalence of hypertension in D. H. Awgu (2016).

BP level	Number of patients
Hypertensive	663 (12.6%)
Normotensive	4604 (87.4%)
Total	5267

Table 2: Management of detected cases (N=663) of hypertension.

Category of patients	Number of patients
Treated	483 (73%)
Untreated	180 (27%)
With return visits	197 (40.8%)
Without return visits	286 (59.2%)

Table 2 shows the management of detected cases of hypertension in the District Hospital. As shown in the table, 483 (73%) of 663 patients received pharmacological treatment for hypertension, while 180 (27%) did not. The table also shows that 197 (40.8%) of 483 returned for checkup, while 286 (59.2%) did not.

Table 3 shows the treatment outcomes among hypertensive patients in the District Hospital. According to the table, 143 (73%) of 197 had positive outcomes (decrease in systolic or diastolic BP), while 54 (27%) did not.

Table 3: Treatment outcomes among hypertensive patients (N=197).

Response to treatment	Number of patients
With decrease in BP (systolic or diastolic)	143 (73%)
Without decrease in BP (systolic or diastolic)	54 (27%)

Table 4 shows mean BP reduction with two-drug monotherapy. As shown in the Table, lisinopril had greater BP (both systolic and diastolic) reduction ability (28.3 mm Hg /13.1 mm Hg) than amlodipine (26 mm Hg /8 mm Hg). Between the two drugs, there was no significant difference in both systolic (p=0.61) and diastolic (p=0.41) BP reduction.

Table 4: Mean BP reduction with monotherapy.

Mean BP reduction	Drugs			
	Lisinopril	**Amlodipine**	**t**	**p**
Systolic BP (in mm Hg)	28.3	26.0	0.51	0.61
Diastolic BP (in mm Hg)	13.1	8	0.84	0.41

Table 5 shows mean BP reduction with various combination therapies (hydrochlorothiazide with other drugs). From the table it is seen that nifedipine-hydrochlorothiazide combination had the greatest mean reduction in both systolic (56mmHg) and diastolic (22mmHg) BP, followed by amiloride-hydrochorothiazide combination (36.7/20mmHg). Lisionpril-hydrochlorothiazide, lisinopril-amlodipine-hydrochlorothiazide, and amlodipine-hydrochlorothiazide had almost the same degree of reduction (34.3, 34.3, 33.3mm Hg/16, 16, 16mm Hg respectively).

Amlodipine-lisionopril had the least reduction (31.7/13.3 mm Hg). Among the various drug combinations, there was a significant difference in the degree of systolic BP reduction (p=0.02). The difference among the various combinations in diastolic BP reduction was not significant (p=0.51).

Table 5: Mean BP reduction with combination therapy.

Drugs	Mean BP reduction	
	Systolic BP (in mm Hg)	Diastolic BP (in mm Hg)
Lisinopril+ Hydrochlorothiazide	34.3	16
Amlodipine+ Hydrochlorothiazide	33.3	16
Nifedipine+ Hydrochlorothiazide	56.0	22
Amlodipine + Lisinopril	31.7	13.3
Amiloride+ Hydrochlorothiazide	36.7	20
Lisinopril + Amlodipine + Hydrochlorothiazide	34.3	16
F	2.77	0.87
p	0.02	0.51

Table 6 shows the dispensing prices (per tablet) of the commonly prescribed antihypertensives in District Hospital Awgu as of December 2016. As shown in the table, the most expensive of all the drugs was amlodipine (N22), followed by hydochlorothiazide (N10), lisinopril (N7) and co-formulated hydochlorothiazide-amloride (moduretic) (N6). The cheapest was nifedipine (N4).

Table 6: Dispensing prices of commonly prescribed antihypertensives (2016).

Drug	Dispensing price (in Naira) per tablet
Amlodipine (10 mg)	N22
Hydrochorothiazide (25 mg)	N10
Lisinopril (10 mg)	N7
Nifedipine (20 mg)	N4
Moduretic (co-formulated Hydrochlorothiazide/Amiloride (50mg/5mg)	N6

Table 7 shows cost effectiveness analysis using the mean reductions of systolic and diastolic BP, cost of drugs, and cost effectiveness ratios (i.e., how much reduction in BP each one Naira spent on each drug caused). With respect to reduction in systolic/diastolic BP, nifedipine-hydrochlorothiazide caused the greatest reduction (56/22 mm Hg), followed by co-formulated hydrochlorothiazide-amiloride (36.7/20 mm Hg). Lisinopril-hydrochlorothiazide, lisinopril-amlodipine-hydrochlorothiazide, and amlodipine-hydrochlorothiazide combinations caused almost the degree of reduction of BP (34.3/16 mm Hg, 34.3/16 mm Hg, and 33.3/16 mm Hg respectively). Amlodipine-lisinopril caused the least reduction (31.7/13.3 mm Hg). The table further shows that co-formulated hydrochlorothiazide- amiloride (moduretic) with the biggest CER (9) was the most cost effective, followed by nifedipine-hydrochlorothiazide combination (4) and lisinopril-hydrochlorothiazide (2). Amlodipin-hydrochlorothiazide and amlodipine-lisinopril combinations had the same CER (1 each) and therefore the same cost effectiveness. Lisinopril-amlodipine-hydrochlorothiazide triple combination with the smallest CER (0.9) was the least cost-effective.

Table 7: Cost effectiveness analysis.

Drugs	Mean BP reduction SBP/DBP (in mm Hg)	Cost of drug (in Naira)	CER
Lisinopril+ Hydrochlorothiazide	34.3/16	17	2
Amlodipine+ Hydrochlorothiazide	33.3/16	32	1
Nifedipine+ Hydrochlorothiazide	56.0/22	14	4
Amlodipine + Lisinopril	31.7/13.3	29	1
Amiloride +Hydrochlorothiazide (co-formulated)	36.7/20	4	9
Lisinopril + Amlodipine + Hydrochlorothiazide	34.3/16	39	0.9

Key: CER= cost effectiveness ratio

Table 8: Cost minimisation analysis.

Drugs	Mean BP reduction SBP/DBP (in mm Hg)	Cost of drug (in Naira)
Lisinopril+ Hydrochlorothiazide	34.3/16	17
Amlodipine+ Hydrochlorothiazide	33.3/16	32
Nifedipine+ Hydrochlorothiazide	56.0/22	14
Amlodipine + Lisinopril	31.7/13.3	29
Amiloride +Hydrochlorothiazide (co-formulated)	36.7/20	4
Lisinopril + Amlodipine + Hydrochlorothiazide	34.3/16	39

Cost minimisation analysis using mean BP reduction and cost of drugs is as shown in Table 8. From the table, it is seen that lisinopril-amlodipine-hydrochlorothiazide combination was the most expensive (N39), followed by amlodipine-hydrochlorothiazide (N32), amlodipine-lisinopril (N29), lisinopril-hydrochlorothiazide (N17), and nifedipine-hydrochlorothiazide (N14). Co-formulated amiloride-hydrochlorothiazide (moduretic) was the cheapest (N4). The table also shows that lisinopril-hydrochlorothiazide and lisinopril-amlodipine-

hydrochlorothiazide combinations had the same outcome (reduction of systolic/diastolic BP by 34.6/16mm Hg), but lisinopril-hydrochlorothiazide combination was cheaper (N17) and preferable to the triple combination (N39). The table further shows that amlodipine-hydrochlorothiazide combination caused the same degree of reduction of diastolic BP (16 mm Hg) as lisinopril-hydrochlorothiazide, but slightly lower systolic reduction (33.3 mm Hg). Lisinopril-hydrochlorothiazide combination (N17) was also preferable to amlodipine-hydrochlorothiazide (N32).

DISCUSSION

With Africa, being projected to likely have the highest prevalence of hypertension (46%) in the whole world by 2025, systemic hypertension continues to remain a major problem of the Continent deserving urgent attention. Similarly, in Nigeria, it has been projected that the number of cases of hypertension might hit 39.1 million by 2030 going by the current trend.[21]

The present study found a prevalence of hypertension of 12.6% in District Hospital Awgu in 2016. This finding is comparable with what had been previously reported for Nigeria and Eastern Nigeria by some researchers.[2,22-24]

Not all detected cases of hypertension in the study area were treated pharmacologically. Following strict indications for treatment of hypertension, i.e. a systolic/diastolic BP of ≥160/100 mm Hg, 73% of the detected cases were eventually enrolled into treatment. Usually indications for pharmacological intervention in hypertension include diastolic BP ≥100 mm Hg or systolic BP ≥160 mm Hg, diastolic BP ≥90 or systolic BP ≥140 in the presence of target organ damage or other cardiovascular risk factors, and systolic BP ≥ 160 mm Hg in the elderly (aged ≥80 years).[25]

The study found that 59.2% of hypertensive patients commenced on treatment were later lost to follow up, making an already bad situation worse, as this will ultimately lead to an increase in the current prevalence of hypertension in Nigeria. Put differently, the study demonstrated an adherence rate of 40.8% among the hypertensive patients. This finding is in tandem with what had been reported in the past by other researchers.[4-6,2] Prominent among the factors that could affect adherence to therapy are cost of drugs, polypharmacies, dissatisfaction with healthcare providers and long waiting time.

Response to therapy can be influenced by several factors, chief among which is adherence. In this study, a response to therapy rate of 73% was established. Besides adherence to appropriate drug treatments, studies have shown that lifestyle modifications are also important to maintain BP at optimal levels.[26,27] Patient's co-morbid state is another factor that could affect response to therapy. However, the present study did not consider this factor.

In the treatment of hypertension, it is recommended to commence drug therapy with a single drug (monotherapy) using a thiazide or thiazide like diuretic, β-blocker (in patients < 60 years), long-acting calcium channel blocker (CCB), or angiotensin receptor blocker.[25] In the present study, lisinopril (ACE inhibitor) and amlodipine (CCB) were used as monotherapies. Although lisinopril monotherapy caused a greater reduction of both systolic and diastolic BP (28.3/13.1 mm Hg) than amlodipine (26/8 mmHg), there was no statistically significant difference between the two drugs in efficacy (p-values=0.41, 0.61).

For cases that did not respond adequately to monotherapy, combination therapy was used instead. Usually, if the BP is not controlled with the first-line drugs, thiazide can be combined with ACE inhibitor, ARB, β-blocker (in patients≥ 60 years) CCB, or α-blockers.[25]

In the present study, hydrochlorothiazide was combined with lisinopril (ACE inhibitor), amlodipine (CCB), nifedipine (CCB) and amiloride (potassium sparing diuretic). Nifedipine-hydrochlorothiazide combination achieved the greatest BP reduction (56/22 mm Hg), followed by amiloride-hydrochlorothiazide (co-formulated) (36.7/20 mm Hg). It is unknown why the same degree of BP reduction could not be achieved using amlodipine-hydrochlorothiazide combination, although nifedipine and amlodipine are both CCB. However, it could be speculated that other patient factors (e.g. idiosyncracies and co-morbidities, among others) not considered by the present study could contribute to this.

Over the past 20 years, PE has become more important due to an increased emphasis on efficient drug therapies for diseases, which increase health costs.[28] Escalating healthcare expenditures have led to the necessity to find the optimal therapy at the lowest price. PE strives to guide the utilisation of healthcare resources optimally.[29] Increasing cost of healthcare products and services has become a great concern for patients, healthcare professionals, insurers, politicians and the public.[30] This escalation in healthcare costs is due to increased life expectancy, increased technology, increased expectations, increased standard of living and an increased demand in healthcare quality and services.[31]

Cost of drugs has already been identified as one of the factors that could also affect patient's adherence to treatment in chronic non-communicable diseases such as hypertension. Expectedly, cost of treatment of hypertension will vary in accordance with the number of drugs in a particular treatment regimen. In general, the more complex the regimen is, the higher the cost of treatment.

The most expensive antihypertensive drug in our setting (as of December 2016) was amlodipine (N22 per 10 mg tablet). In cost effectiveness analysis (CEA) two or more drugs that have the same treatment objective, but different degrees of efficacy, are usually compared. In this study, findings have indicated that amiloride-hydrochlorothiazide with the biggest CER (9) was the most cost effective, followed by nifedipine-hydrochlorothiazide (CER of 4). Lisinopril-amlodipine-hydrochlorothiazide triple combination with the least CER (0.9) was the least cost-effective.

Cost minimisation analysis is used to compare treatments with the same health outcomes. In our setting, lisinopril-hydrochlorothiazide and lisinopril-amlodipine-hydrochlorothiazide combinations had the same health outcome-reduction of systolic/diastolic BP by 34.3/16 mm Hg. Whereas a combination of lisinopril and hydrochlorothiazide cost N17, addition of amlodipine to the combination, i.e. triple combination, increased the cost to N39. Since addition of amlodipine to the combination achieved no greater reduction of BP, rather it increased the cost, and probably side effects, lisinopril-hydrochlorothiazide combination was preferable to the triple combination. Although lisinopril-hydrochlorothiazide combination also had the same outcome (reduction of diastolic BP by 16 mm Hg) as amlodipine-hydrochlorothiazide, but slightly different systolic BP reduction (34.3 mm Hg versus 33.3 mm Hg), it is cheaper to use lisinopril-hydrochlorothiazide (N17) combination than amlodipine-hydrochlorothiazide (N32).

The results of this study suggest that cost of drugs (with all other factors held constant) probably had played a significant role in the observed high dropout rate from treatment among hypertensive patients in the District Hospital in 2016. Evidence in support of this includes that moduretic (co-formulated hydrochlorothiazide/amiloride) which had the largest CER (9) (prescribed in 3.6% of cases) and nifedipine which also caused the greatest BP reduction when combined with hydrochlorothiazide (56/22 mm Hg) (prescribed in 1.8% of cases) were rarely found in the hospital's prescriptions for hypertensive patients.

Some of the limitations to the study include that: Adherence to therapy (keeping to follow up) was defined as the ability of the hypertensive patient to return to the hospital for continued care, one month after the initial diagnosis of the case. Patients' co-morbidities (if any) which could affect response and adherence to treatment were not considered by the study.[32]

CONCLUSION

Prevalence of hypertension in Awgu District Hospital in 2016 was 12.6%. 73% of detected cases were treated pharmacologically. Adherence (the number that keeps to follow-up) of patients to treatment for hypertension was 40.8%. Response rate was 73%. Lisinopril was better than amlodipine as monotherapy (BP reduction of 28.3/13 mm Hg versus 26/8 mmHg). Amlodipine was the most expensive of all the prescribed antihypertensives (N22). In combination therapy, amiloride-hydrochlorothiazide with the largest CER (9) was the most cost-effective. Cost minimisation analysis found lisinopril-hydrochlorothiazide to be preferable to the triple combination of lisinopril-amlodipine-hydrochlorothiazide (the two caused the same reduction of BP by 34.3/16 mm Hg) and amlodipine-hydrochlorothiazide. Lisinopril-hydrochlorothiazide (N17) was cheaper than lisinopril-amlodipine-hydrochlorothiazide (N39) and amlodipine-hydrochlorothiazide (N32).

Since cost-effective prescribing and cost mimimisation may help to reduce the incidence of non-adherence to therapy among hypertensive patients, all healthcare facilities need to embark on periodic PE evaluations of their antihypertensives in order to achieve this. Furthermore, all patients with BP ≥140/90 mm Hg may be treated pharmacologically, for studies have shown that cardiovascular risk associated with chronic elevation of the BP begin to manifest above a critical BP level of 115/75 mm Hg.

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