UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

A STUDY TO INVESTIGATE FACTORS ASSOCIATED WITH POOR ADHERENCE TO ANTIHYPERTENSIVE TREATMENT IN THE HYPERTENSIVE POPULATION, AT THE UNIVERSITY TEACHING HOSPITAL LUSAKA, ZAMBIA.

THESIS FOR MASTER OF MEDICINE IN INTERNAL MEDICINE

Author: Morgan Dimakweenda Mweene

BSc. H.B. MBCHB

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SUPERVISOR: DR SHABIR LAKHI,

                       HEAD OF DEPARTMENT OF MEDICINE

                       UNIVERSITY TEACHING HOSPITAL

                       LUSAKA, ZAMBIA

CO-SUPERVISER: DR BENJAMIN ANDREWS

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A dissertation submitted in partial fulfillment of the requirement for the award of the degree of Masters of Medicine in Internal Medicine.

DECLARATION

I hereby declare that this dissertation represents my own work and has not been presented either wholly or in part for a degree at the University of Zambia or at any other University.

Signed…………………………………………………………….

Student: **Dr Morgan Dimakweenda Mweene** (BScHb, MBcHB).

Signed…………………………………………………………..

Supervisor: **Dr Shabir Lakhi (BScHb, MBcHB, MMED Internal Medicine, MPH)**

Head of Department of medicine

University Teaching Hospital.

Lusaka, Zambia.

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APPROVAL

This dissertation of Dr. Morgan Dimakweenda Mweene is approved as fulfilling the requirement for the award of the degree of Masters of Medicine in internal Medicine by the University of Zambia.

Head of Department:

Name   :--

Signed   :--

Date   :--

DEDICATION

This work is dedicated to my three boys, Simon, Chitebula and Morgan (Jr) and my ever supportive wife Mwate Mwambazi-Mweene. I would also like to dedicate this work to my late father Bruno Nelson Mweene who taught me how to live life and my late mother Elizabeth Moya Mweene.

ACKNOWLEDGEMENTS

LIST OF ACRONYMS

AHT   Anti hypertensive treatment

BP   Blood Pressure

DBP   Diastolic blood pressure

Hg   Mercury

JNC   Joint National Committees

MM   Millimeter

RCT   Randomized Controlled trials

SBP   Systolic Blood pressure

UTH   University Teaching Hospital

WHO   World Health Organization

TABLE OF CONTENTS   PAGE

List of Tables

Abstract

Objectives
To determine the prevalence of drug adherence and factors associated with poor adherence to antihypertensive treatment among adults seen in the department of medicine at UTH. To investigate patient related and health care system related factors associated with poor adherence to antihypertensive Drugs

Methods
Adult patients aged 18 and above with previous diagnosis of essential hypertension receiving outpatient care in the UTH medical clinics were recruited from the first week of November to the second week of December 2010. Data was collected from patients regarding patients' social demographic factors, level of education, income per month and family history of hypertension. Information was also collected regarding health care system related factors and care giver related factors to patient non adherence using self report and modified hill bone compliance scale.

Results
Data was collected from 234 participants. The mean age was 57.8 ± 12.0 SD. 51 patients (22%) had diabetes mellitus and 44 patients (19%) had the diagnosis of heart failure. The commonest side effects of drugs reported in the study were dizziness and excessive urination, affecting 35% and 31% of patients, respectively. Patients on three antihypertensive drugs were less likely to be non-adherent (odds ratio 0.21, 95% CI 0.06-0.79) than patients taking only one drug.

Majority (60%) of the patients were reviewed at least twice in the last 6 months at the time of the interview. 195 (83%) patients reported that drugs prescribed were not available at the hospital pharmacy, but 186 (79%) of these were able to purchase the drugs elsewhere.

221 patients (94%) were counseled by the doctor on how to take medicines. Patients counseled by the nurse were more likely to be adherent than those not counseled by the nurse, OR 2.7 (1.0-7.3). Those who were counseled for more than 5 minutes had significantly less non-adherence as reported by both self report and modified Hill Bone with OR of 0.3(95% CI 0.2-0.8) and 0.3(95% CI0.1-0.5), respectively.

In multivariable analysis, participants were more likely to be non-adherent by self-report if they had attained a primary level of education, had missed appointments due to lack of transport, or had experienced the side effect of dizziness. Patients with heart failure were more likely to be non-adherent based on the modified Hill-Bone scale, whereas those taking 3 antihypertensive drugs and those who were counseled for more than 5 minutes on drugs were significantly less likely to be non-adherent.

Conclusion
The prevalence of adherence among hypertensive patients was found to be higher than anticipated. The factors associated with non-adherence included side effect of dizziness, missed appointment due to lack of transport, and living at a distance of more than 10 km from the hospital. Taking 3 BP drugs and receiving more than 5 minutes of counseling about how to take medications were both associated with decreased likelihood of non-adherence. This information provides baseline data to help improve and address the issues of adherence in hypertensive patients seen in our health institutions.

CHAPTER 1

1.0 INTRODUCTION

High blood pressure (BP) is a major cause of death and disability worldwide causing an estimated 7.1 million deaths. Available data shows that age-adjusted mortality, case-fatality and prevalence of disabling complications in Africa are similar to or higher than those measured in most high-income regions [1]. Comprehensive surveillance data in Africa are lacking. However, awareness of hypertension and its prevention, treatment and control remain very low in Africa even though recent surveys show an increasing prevalence of the disease [1].

The use of antihypertensive drug therapy has been shown to reduce the risk of stroke and coronary heart disease by an estimated 34% and 21%, respectively, in long-term randomized controlled trials (RCTs) [2]. Adherence is defined by WHO as ''the extent to which a person's behavior–taking medication, following a diet, and/or executing lifestyle changes-corresponds with agreed recommendations from a health care provider". Generally, antihypertensive therapy should be maintained indefinitely.[3] However, findings in clinical practice have raised concerns about the high extent of under treatment and nonadherence to AHT, which hampers the effectiveness of these medications.[4] In RCTs, antihypertensive drug discontinuation rates range from 5% to 10% per year, and rates up to 50% to 60% after 6 months have been reported in actual practice.[3,4] Adherence to AHT has been associated with improved BP, decreased hospitalizations rates, and lower medical care costs[5,6].

Adherence is dependent on numerous factors and has been shown to vary from 0 to 100% in different populations studied.[5] These factors can be divided into patient related factors, system related factors and physician related factors. Patient related factors include: age, gender, low socio-economic status and severity of disease, patient's inadequate understanding of the disease and importance of the treatment, forgetfulness, and presence of psychological problems, especially depression and co-morbid medical conditions. System related factors include lack of social support, side effects of medication and cost. Physician related factors such as class of drug prescribed, number of pills per day, poor patient-provider relationship, have all been shown to affect adherence in various populations [7].

Safe and effective strategies for the prevention and control of high BP have been widely available in many countries for more than 50 years. However, overall BP control rates remain poor in most countries [5] mainly because of poor adherence to medication and difficulties in accessing drugs, thus many patients coming in with complications of essential hypertension.

In Africa, access to safe and effective BP control medication is limited; BP control rates remain low; and stroke mortality, case fatality, and morbidity remain high [8].

The World Health Organization (WHO) defines essential hypertension in adults using a systolic BP threshold of 140 mm Hg and the ascertainment of overall cardiovascular risk to establish thresholds for initiation and goals of treatment in adults.[1] These definitions are important in appropriately interpreting the epidemiological data and their implications for addressing the burden of high BP in sub-Saharan Africa.[1]

The University Teaching Hospital (UTH) is a public secondary and tertiary hospital that services patients in Lusaka and patients from all the 72 districts of Zambia. Lusaka has a catchment population of 2 million. Many hypertensive patients who come to UTH are seen in the medical emergency ward and in the out patient clinic (Clinic 5). Adherence to antihypertensive therapy as well as rate of blood pressure control is not well known. Hypertension ranks as the 9th leading cause of admission and mortality among adult patients seen in the medical department [9].Like most hospitals in Africa, the university teaching hospital has a huge patient burden. Patients with different ailments have to compete for the limited resources available. There is only one cardiovascular unit that also takes care of other medical cases and hence there is no specialist ward or clinic to offer special care. Apart from the limited number of heath workers, the supply of antihypertensive drugs to the hospital is limited and patients are issued drugs from the pharmacy according to availability and patients are forced to buy the short falls and this further affects adherence in most patients.

This study therefore was conducted in order to shed more light on factors that lead to poor adherence to antihypertensive treatment in patients seen in the department of medicine at UTH.

CHAPTER 2

2.0. LITERATURE REVIEW

Hypertension affects approximately 20% of the disease population in most western countries, and is a major risk factor for cardiovascular morbidity and mortality. It accounts for around 20% of mortality world wide and some 50% of deaths in developed countries.[1] Studies world wide indicate that despite the availability of medical therapy, over half of all the hypertensive patients do not take any medicines and more than half of those on treatment have blood pressure over 140/90 mm. [10]. The world health organization (WHO) describes poor adherence as the most important cause of uncontrolled blood pressure and estimates that 50-70% of people do not take their antihypertensives as prescribed.[10] Since hypertension is a chronic condition with mild and unspecific symptoms, treatment has to be justified to patients through abstract health advantages such as long term benefits and decreased risk for future disease.[11] Despite the proven efficacy of antihypertensive drugs patient adherence (i.e. the degree to which the patient's behavior coincides with medical recommendations) with antihypertensives in clinical practice is commonly as low as 20-50%.[,11,12,14,] Poor adherence of this magnitude substantially contributes to inadequate blood pressure control that prevails in more than two thirds of the hypertensive population, and to that fact, in spite of antihypertensive treatment.[15]

Epidemiological surveys have revealed that BP control is adequate in only a small percentage of hypertensive populations.[,16,17,18] In some selected populations facing higher risk, especially for those with diabetes or renal disease, the sixth joint national committee on the prevention, detection, evaluation and treatment of high BP (JNC-VI) and the WHO-international society of hypertension guidelines established or suggested the adequacy of a goal BP <130/85 mm Hg [19]. It was also suggested that treating a lower target BP (<130 SBP and <85 DBP) than that for most hypertensive patients maybe useful in preventing strokes and heart failure progression. [19]

Various means of measuring adherence to antihypertensive medications are currently available for use in clinical practice.[4] The choice of the specific measure used in clinical practice depends on the intended use of the information, the resources available to the provider, as well as patient acceptance and convenience of the method.[4] Indirect methods used to measure adherence in the

outpatient setting include self report, electronic adherence monitoring (e.g. medication event monitoring system), pharmacy refill rates, and pill counts.[20] Direct methods include the use of bioassays or biomarkers, which involve laboratory detection of the drug or a metabolic product of the drug in a biologic fluid, or laboratory detection of a biologic marker. [4] Direct observation of the patient taking the medication is also another direct method; however, it is impractical in the outpatient setting, especially for long-term treatment.[4] Methods used for self reporting are varied and can include patient kept diaries of medication taking, interviews conducted during office visits, and responses to adherence specific questionnaires have been developed and tested in outpatient settings with explicit aim of ascertaining valid and reliable estimates of adherence to antihypertensive medication [10]. In an effort to facilitate the identification of barriers to adequate adherence, Morisky *et al*. developed the medication adherence survey, a multi item scale designed to assess patient adherence to blood pressure medication regimes in outpatient setting.[21] Another multi item scale, the Hill Bone compliance scale to high blood pressure therapy scale comprises 14 items, eight of which are directed at assessing medication taking behavior in hypertensive patients [22]. In a study done in South Africa a modified Hill Bone scale was validated among cross cultural group in Cape town by Lambert et al and it demonstrated reasonable internal consistency with an average interim correlation of 0.26.[23]

Social and economic factors often combine to yield poor adherence outcomes. Among an indigent sample in South Africa, Simoni et al found low levels of adherence to the correct number of pills, dosing schedules and special instructions.[24] Poverty in itself is likely to affect adherence, as financial resources may need to be directed elsewhere, funds for travel to the doctor's office may not be available.[25] The competing demands of several responsibilities such as work and family life, along with the stresses associated with poverty and difficult life circumstances, obviate an acknowledgement of the importance of complying with treatment regimens [25]. These competing demands may be especially important threats to adherence among the rural poor. [24]

In addition to the psychosocial factors, considerable evidence suggests that mental status, specifically depressive illness, plays a role in treatment adherence [24,25]. Among general medical patients, DiMatteo et al, found that depressed patients were three times less likely than non-depressed patients to adhere to medical treatment. [26]

Suboptimal practice patterns by doctors, leading to inadequate adherence to antihypertensive drugs by patients have been implicated as contributors to poor blood pressure control as well [27].

CHAPTER 3

3. 1 STUDY JUSTIFICATION

Medication adherence is critical to achieve the beneficial effect of well controlled blood pressure in clinical practice. Lack of adherence to prescribed antihypertensive medication is a major potential barrier to adequate blood pressure control and prevention of cardiovascular out comes [26]. Improving medication adherence hence reduces the incidence of stroke and hypertensive heart disease. Understanding the factors associated with non-adherence could help improve patient care by finding an effective way of addressing these barriers and hence reduce the burden on the health institution individual and family.

3.2 RESEARCH QUESTIONS

1. What is the level of drug adherence among the hypertensive population in the department of medicine at the UTH?
2. What are the factors associated with non-adherence among the hypertensive population in the department of medicine at the UTH?

3.3 HYPOTHESIS

More counseling on the importance and effects of antihypertensive drugs are associated with improved drug adherence among hypertensive patients at UTH

3.4 GENERAL OBJECTIVE

To determine the prevalence of drug adherence and factors associated with poor adherence to antihypertensive treatment among adults seen in the department of medicine at UTH.

3.5 SPECIFIC OBJECTIVES

1. To determine the prevalence of drug adherence in patients on antihypertensive drugs.

2. To investigate patient related factors associated with poor adherence in the studied population

3. To determine health system related factors associated with poor adherence to antihypertensive drugs

CHAPTER 4

4.1 STUDY DESIGN AND METHODOLOGY

This descriptive study was a questionnaire-based cross-sectional analysis. The study was conducted at the university teaching hospital in the department of medicine. Patients were recruited from the adult filter clinic and adult medical clinic.

The study population were adult patients aged 18 and above with previous diagnosis of essential hypertension, seeking outpatient care in the UTH medical clinics. Patients were recruited during working days, except holidays and weekends, from the first week of November to the second week of December 2010. Consecutive patients were enrolled from adult filter clinic and adult medical clinic in the first week; subsequently, consecutive patients were enrolled only from adult medical clinic.

The inclusion criteria were 1) Adults equal or more than18 years, 2) Diagnosed with systemic hypertension prescribed antihypertensive drugs for 3 months or more prior to enrolment. Patients with coexisting medical conditions were also included.
The exclusion criteria was lack of consent and patients who were unable to answer for themselves like the deaf and dumb or with any medical condition that handicapped them from volunteering information.

4.2 ETHICAL CONSIDERATIONS

This study was approved by university of Zambia (UNZA) research ethics committee (REC). Patients who agreed to participate were explained the nature and objectives of the study, and informed consent was formally obtained. All patients' records were kept confidential and none of the patients' information was used except for research purposes and only the principal investigator had access to this information. No reference to the patient identity was made at any stage during analysis of the data or in this paper.

4.3 DATA COLLECTION

The data collection tool was a questionnaire and the modified Hill Bone adherence scale that was administered by trained interviewers. The questionnaire extracted information regarding patients' social demographic factors, level of education, income per month and family history of hypertension. Patients were also asked about details on their prescribed medication regimen. The information obtained was tabulated. Antihypertensive drugs were categorized by specific drugs, classes of drugs, number of drugs prescribed, number of times taken per day(once daily, twice per day or three times per day) and total pill burden, trade names of all prescribed drugs along with the drug class frequency per day, and any side effects associated with the drug.

Prescriptions and information from the medical record was used to get reliable data, particularly from illiterate patients. The other information extracted was system related factors such as duration taken to secure an appointment for reviews, spacing of reviews, number of appointments missed in last six months, reasons for missing appointment, number of prescribed drugs, number of drugs issued and how often patient bought drugs. The physician related factors included, explanation of types of drugs, emphasis made on adherence and duration spent on explaining medicines being taken by the patient.

Hypertensive patients were defined as those with raised BP of more than or equal to 140/90 mmHg on three clinical visits.

4.4 MEASUREMENT OF ADHERENCE

Adherence was defined as 'the extent to which patients followed their medication schedules as prescribed by their health care providers. To measure adherence, patients' self-reports were used. Patients were asked the total number of tablets prescribed per day and how many pills taken and missed in the last 7 days. Adherence rates were calculated as pills taken over a specific period of time, divided by pills prescribed for that specific period of time [3]. Adherence for self report was defined as more than or equal to 80 percent.

To further increase the strength and consistency of the results, the modified Hill Bone blood pressure compliance scale [23], a 10-item questionnaire with a high reliability and validity, which has been particularly useful in chronic conditions such as hypertension, was used. It is used both to diagnose and monitor compliance behaviors. In contrast to the previous two instruments the Hill Bone compliance scale measures patient behaviors for three domains of high blood pressure management, i.e.: 1)reduced sodium intake; 2) appointment keeping; and 3) medication taking.   Adherence was defined on the modified Hill Bone scale as a score of less than 16, while non adherence was scored as greater than or equal to 16.This was correlated with patients self report of pill taken over the prescribed period and expressed as percentages.

4.5 VARIABLES

4.5.1 Dependent variable:
Adherence was measured using self report and defined as an individual who takes more than 80% of the prescribed drugs. Secondary definition of adherence was a modified Hill Bone compliance score of less than 16.

4.5.2 Independent variables:

Independent variables were subdivided into patient related.

4.5.2.1 Patient related factors

Age, Gender, level of education, Income per month, Class of drug prescribed, Number of pills per day, Side effects of drugs,   forgetfulness and Family history of hypertension. Categorical variables included: Sex (Female/Male), Family history of hypertension (yes/no). Income per month was measured as proportions and categorized as low income (< K1, 335, 000), medium income (K1, 335, 000-K4, 100, 000) and high income (>K4, 100,000) [28].

4.5.2.2 *System related factors*

This included: number of reviews in last 6months, spacing of reviews, number of missed appointments in last six months, duration for each review, supply of drugs, reasons for not getting prescribed drugs, How often patient buys drugs and distance from house to the hospital.

4.5.2.3 *Care giver related factors*

This included: explaining how to take BP drugs prescribed and explaining importance of adherence, duration taken to explain how to take drugs and number of doctors seen in last four visits.

4.6 STATISTICAL ANALYSES

All statistical analyses was performed using Epi info, v3.5.1.The questionnaire was pre-coded and all data entered and counter checked. This study intended to detect a 15% absolute increase in adherence among patients receiving 5 minutes or more of counseling. It was estimated that 60% of patients received less than 5 minutes of counseling regarding their medication usage and that adherence among patients receiving less than 5 minutes counseling was 20%. Using 95% confidence intervals at 80% power, the calculated sample size was 236 patients.

For continuous variables means and percentages were used to describe participants in the study. For categorical variables proportions, frequencies and percentages were used.

4.4.1 Analytical

As described previously, for analysis of adherence by self-report, a cut-off value of 80% was used for categorizing patients as adherent or non-adherent.[3] T-test chi-square and ANOVA were used to measure association of non-adherence and the factors that lead to patients' non adherence. Logistic regression analysis was used to measure the association of non-adherence and associated factors. Adherence was analyzed as a discrete numerical variable using patient self report and the modified

Hill Bone compliance scale. Independent variables were checked for confounding and interactions. Odds ratios (with 95% confidence intervals, CI) were calculated from the tables. A p-value of less than 0.05 was considered to be statistically significant for all analyses. Separate multivariable logistic regression models utilized patient self non adherent and modified Hill Bone non-adherent as the outcome variables. Various study variables were used as independent variables. We performed multivariable stepwise logistic regression modeling, to identify factors independently associated with medication non-adherence. We began with the following variables: age, level of education, I

income, co-morbidities of diabetes mellitus and heart failure, number of BP drugs patient takes, total number of pills per day, side effect of dizziness, number of reviews, lack of transport, drugs not available, distance from home to hospital and total time spent to counsel patients on how to take drugs. Categorical variables with 3 or more categories were analyzed as dummy variables. In a stepwise fashion we eliminated the variable with the highest p value, if p > 0.5. Dummy variables were eliminated only if p > 0.5 for all categories.

CHAPTER 5

RESULT

After pilot testing and refining the questionnaire with 50 individuals, we interviewed 237 patients in medical clinic 5 and adult filter clinics. After excluding patients in which adherence could not be calculated, 234 cases were included in the analysis.

Patient demographic and clinical characteristics

The mean age of all the patients was 57.8 years ± 12.0 (SD). There were a total of 157 women in the study, making up 67% of the study participants. Majority of the participants (71%) were low income earners. 159 participants (68%) had a positive family history of hypertension. The commonest co-morbid conditions included diabetes mellitus and heart failure making up 22% and 19%, respectively. 127 patients (55%) were taking two BP drugs. It was encouraging to note that about 186 of the participants (68%) reported that they were able to buy drugs that were not supplied by the pharmacy. The commonest side effects of drugs reported in the study were dizziness and excessive urination, affecting 35% and 31% of patients, respectively. Patient demographic details are shown in table 1.

Patient related factors to non adherence

Table 1 and table 2 show the patient related factors to non-adherence as measured by self report and modified Hill Bone compliance scale, respectively. Odds for non-adherence were reported.
By self report, patients on three antihypertensive drugs were less likely to be non adherent (odds ratio 0.21, 95% CI 0.06-0.79) than patients taking only one drug. Patients experiencing side effect of dizziness were more likely to be non adherent (odds ratio 3.17, 95% CI 1.6-6.4). Those who missed their clinic appointments due to lack of transport were more likely to be non-adherent than those who kept their appointments (odds ratio 2.9, 95% CI 1.9-5.9).

Modified Hill Bone scale showed that those who were able to name drugs were less likely to be non-adherent to their treatment than those who couldn't (odds ratio 0.3, 95 CI 0.14-0.5). Similarly as

reported in self report those who experienced side effects of dizziness were more likely to be non-adherent to treatment.

TABLE 1

PATIENT FACTORS ASSOCIATED WITH MEDICATION NON-ADHERENCE AS MEASURED BY PATIENT SELF-REPORT†

		N	Adherent	Non-adherent	OR (95% CI)*
Total		234	194 (83)	40 (17)	--
Age, mean (SD)		--	58.1 (12.2)	56.3 (11.4)	∞
Sex	Male	77	65 (84)	12(26)	1
	Female	157	129(82)	28(28)	1.2 (0.6-2.5)
Income	Low	166	140(84)	26(16)	1
	Middle	59	47(80)	12(20)	1.4(0.7-2.9)
	High	9	7(78)	2(22)	1.6(0.3-7.7)
Family history of hypertension	Yes	159	133(84)	26(16)	0.9(0.4-1.7)
	No	75	61(81)	14(19)	
Co-morbidities:					
DM	Yes	51	42(83)	9(17)	1.1(0.5-2.4)
	No	183	151(83)	32(17)	
Heart Failure	Yes	44	34(77)	10(23)	1.6(0.7-3.6)
	No	190	160(84)	30(16)	
Number of BP drugs	1	52	39(75)	13(25)	1
	2	127	103(81)	24(19)	0.7(0.3-1.5)
	3	46	43(94)	3(6)	0.2(0.1-0.8)**
	>4	9	9(100)	0	--
Able to name drugs	Yes	159	133(84)	26(16)	0.9 (0.4-1.7)
	No	75	61(81)	14(19)	
Side effects:					
Cough	Yes	19	17(90)	2(10)	0.6(0.1-2.5)
	No	215	177(82)	38(18)	
Dizziness	Yes	81	58(72)	23(28)	3.2(1.6-6.4)**
	No	153	136(89)	17(11)	
Diarrhea	yes	6	6 (81)	0 (0)	--
	No	228	188(83)	40(17)	
Excessive Urination	Yes	73	60(82)	33(18)	1.1(0.5-2.2)
	No	161	134(83)	27(18)	
Missed Appointments Ω	Yes	75	46(71)	19(29)	2.9(1.4-5.9)**
	No	169	48(88)	21(18)	

¥ Odds ratio for non-adherence
 **Statistically significant variables with OR 95% CI
†Adherence defined as self-report of >80% of prescribed pills taken in the past 7 days
Ω Patients who missed their clinic appointment due to lack of transport

∞ p=0.375

TABLE 2

PATIENT FACTORS ASSOCIATED WITH MEDICATION NON-ADHERENCE AS MEASURED BY MODIFIED HILL-BONE SCALE Ĭ

		N	Adherent	Non-Adherent	OR(95%CI)
Total		234	163 (70)	71 (30)	
Age mean SD		---	57.7 (12.4)	58.3 (11.3)	Ω
Sex	Male	77	53(69)	24 (31)	1.1(0.6-2.1)
	Female	157	110(70)	47(30)	
Income	Low				
	Middle	166	117(71)	49(29)	1
	High	59	40(68)	19(32)	1.2(0.3-5)
		9	6(67)	3(33)	1.1(0.6-2.1)
Family history of hypertension	Yes	159	107(67)	52(33)	1.4(0.8-2.7)
	No	75	56 (75)	19(25)	
Co-morbidities Diabetes mellitus	Yes	51	31(61)	20(39)	1.7(0.8-3.2)
	No	183	132(72)	51(28)	
Heart Failure	Yes	44	27(61)	17(39)	1.7(0.8-3.1)
		190	136(72)	54(28)	
Number of BP drugs					
	1	52	33(64)	19(36)	1
	2	127	87(69)	40(31)	0.8(0.4-1.6)
	3	46	36(78)	10(22)	0.5(0.2-1.3)
	>4	9	7(78)	2(22)	0.5(0.1-2.6)
Able to name drugs					
	Yes	186	141(76)	45(24)	0.3(0.1-0.5)**
	No	48	22(46)	25(54)	
Side effects Cough	Yes	19	15(79)	4(21)	0.6(0.2-1.9)
	No	215	148(69)	67(31)	
Dizziness	Yes	81	38(47)	43(53)	5.1(2.8-9.7)**
	No	153	125(82)	28(18)	
Diarrhea	Yes	6	6(100)	0	--
	No	228	157(69)	71(31)	
Excessive urination	Yes	73	49(67)	24(33)	1.2(0.7-2.2)
	No	161	114(71)	47(29)	
Missed appointments	Yes	65	46(71)	19(29)	7.7(0.7-14.2)
	No	169	148(88)	21(12)	
Missed appt due to lack of transport	Yes	169	139(82)	30(18)	3.2(1.1-9.5)**
	No	65	24(37)	41(63)	
Unable to be seen due to late for appt ɛ́	Yes	22	6(27)	16(73)	7.6(2.9-20.4)**
	No	212	157(74)	55(26)	

¥ Odds ratio for non-adherence

†Adherence defined as modified Hill-Bone score < 16

Ω p=0.707

** Statistically significant results as measured by OR at 95% CI

ɛ́ Patients who missed their clinical appointment due to coming late

Health care system related factors to non adherence

Majority of the patients were reviewed at least twice in the last 6 months at the time of the interview making up 60 % of the patients (n-144). These reviews were mostly over a period of every three months in about 54% of the participants. Most patients about 72%   missed their clinic appointment due to lack of transport as shown in table 3 and 4.About 83% of the patients reported that the drugs prescribed were not available.

Patients self reports showed that patients who missed appointments due to lack of transport were more likely to be non-adherent to their antihypertensive treatment (odds ratio 3.2 at 95% CI 1.1-9.5). Living 10 km from the hospital was associated with missing appointments(p=0.02) but was not associated with being late for appointment(p=0.29).There was statistical significance of increased non-adherence in people who lived more than 10 kilometers or more as reported by the modified Hill Bone scale as shown in table 4. Patients who missed their clinical appointments due to coming late were more likely to be non-adherent than those than who kept their appointment (Odds ratio 7.6 at 95% CI 2.9-20.4).

TABLE 3

HEALTHCARE SYSTEM RELATED FACTORS ASSOCIATED WITH MEDICATION NON-ADHERENCE AS MEASURED BY SELF-REPORT

		N 234	Adherence	Non adherence	OR (95% CI)
Number of reviews	0 or 1	36	29(81)	7(19)	1
	2	141	119(84)	22(16)	0.8(0.0-2.1)
	3	31	22(71)	9(29)	1.3(0.5-3.5)
	4	18	17(94)	1(6)	0.3(0.1-1.8)
	5 or more	8	7(88)	1(12)	0.6(0.3-6.7)
Spacing of Reviews (months)	1	22	14(84)	8(16)	1
	2	41	31(76)	10(24)	1.7(0.6-4.7)
	3	137	109(86)	18(14)	0.9(0.4-2.1)
	4 or more	17	13(72)	4(28)	1.3(0.3-5.6)
Unable to be seen due to late for appt	Yes	22	18(82)	4(18)	1.1(0.4-3.4)
	No	212	176(83)	36(17)	
Reported drugs not available in pharm.	Yes	195	163(84)	32(16)	0.8(0.3-1.7)
	No	39	31(80)	8(20)	
Distance from home to hospital					
	< 5 km	35	29(83)	6(17)	1
	5km-10km	140	121(86)	19(14)	0.8(0.3-2.1)
	> 10 km	74	59(80)	15(20)	1.6(0.6-4.8)

** Statistically significant results as measured by OR at 95% CI

TABLE 4

HEALTHCARE SYSTEM RELATED FACTORS ASSOCIATED WITH MEDICATION NON-ADHERENCE AS MEASURED BY MODIFIED HILL BONE SCALE

		N 234	Adherence	Non adherence	OR (95% CI)
Number of reviews	0 or 1	36	25(69)	11(31)	1
	2	141	99(70)	42(30)	1.0 (0.4-2.7)
	3	31	20(64)	11(36)	1.3 (0.5-2.5)
	4	18	14(78)	4(22)	0.7 (0.2-2.4)
	5 or more	8	5(63)	3(37)	1.4(0.3-6.7)
Spacing of Reviews (months)	1	49	37(76)	12(25)	1
	2	41	23(56)	18(44)	1.7(0.6-4.7)
	3	127	93(73)	34(27)	0.9(0.3-2.1)
	4 or more	17	10(57)	7(44)	1.3(0.3-5.6)
Reported drugs not available in pharm.	Yes	195	134(69)	61(31)	1.3(0.6-2.9)
	No	39	29(74)	10(26)	
Distance from home to hospital					
	< 5 km	35	28(80)	7(20)	1
	5-10km	140	103(74)	37(26)	1.4(0.6-3.6)
	> 10 km	59	32(54)	27(46)	3.3(1.3-9.1)**

** Statistically significant results as measured by OR at 95% CI

Care Giver related factors to non adherence

Table 5 and 6 shows the care-giver factors associated with non-adherence. About 221 patients (94%) were counseled by the doctor on how to take medicines. Patients counseled by the nurse as reported by self reports were more likely to be non-adherent with odds ratio 2.7(1.0-7.3) .However, those who were counseled for more than 5 minute had a statistically significant increase in adherence as reported by Self report (odds ratio 0.3 95% CI 0.2-0.8).

 Modified Hill Bone scale on the other hand unlike self report showed that those who were counseled by the nurse were more adherent(odds ratio 0.4 95% CI 0.2-0.7) including those counseled for more than five minutes on how to take their medicines (odds ratio 0.3 95% CI 0.1-0.5).

TABLE 5

CAREGIVER FACTORS ASSOCIATED WITH MEDICATION NON-ADHERENCE AS MEASURED BY SELF-REPORT

		N	Adherence	Non adherence	OR (CI 95%)
Counseled by:∞					
Doctor	Yes	221	181(82)	40(18)	--
	No	13	13(100)	0	
Nurse	Yes	175	140(80)	35(20)	2.7(1.0-7.3)
	No	59	54(92)	5(8)	
Other/Family	Yes	20	18(90)	2(10)	1.9(0.4-8.7)
	No	214	176(82)	38(18)	
Total time spent ¥					
	<5 min α	144	112(78)	32(22)	1
	5min or more	90	2(91)	8(9)	0.3(0.2-0.8)**

∞ Patients were asked "Have any of the following people ever explained to you how to take your medicines?"

** Statistically significant results as measured by OR at 95% CI

¥Time spent to counsel patients on how to take antihypertensive drugs in minutes

TABLE 6

CAREGIVER FACTORS ASSOCIATED WITH MEDICATION NON-ADHERENCE AS MEASURED BY MODIFIED HILL-BONE SCALE

		N 234	Adherence	Non adherence	OR (CI 95%)
Counseled by: ∞					
Doctor	Yes	221	155(70)	66(30)	0.7(0.2-2.2)
	No	13	8(62)	5(38)	
Nurse	Yes	175	131(75)	44(25)	0.4(0.2-0.7)
	No	59	32(54)	27(46)	
Other/Family	Yes	214	152(71)	62(29)	0.5(0.2-1.3)
	No	20	11(55)	9(45)	
Total time spent Explaining how to take drugs ¥					
	<5 minutes	144	86(60)	58(40)	1
	5 minutes or more	90	77(86)	13(14)	0.3(0.1-0.5)

∞ Patients were asked "Have any of the following people ever explained to you how to take your medicines?"

¥ Patients were asked on total time spent on explaining how to take medication

** Statistically significant results as measured by OR at 95% CI

Multivariable logistic regression modeling was used to assess variables associated with non-adherence. Table 7 shows the results of logistic regression modeling for non-adherence based on self report and modified Hill Bone scale.

TABLE 7

LOGISTIC REGRESSION FOR NON ADHERENCE: SELF REPORT AND MODIFIED HILL BONE SCALE

		Non adherence by Self Report	Non adherence by modified Hill Bone
		Odds Ratio (95% CI)	Odds Ratio (95% CI)
Age		1.05	--
Distance			
	<5 km	1	1
	5-10 km	1.9(0.5-7.0)	1.8(0.6-5.3)
	>10 km	3.9(1.0-16.2)**	3.1(0.9-9.9)
Co-morbidities:	Heart failure	1.9(0.6-16.2)	1.5(0.7-3.5)
Number of BP drugs	1	1	1
	2	0.8(0.3-2.3)	0.6(0.2-1.5)
	3	0.2(0.1-1.6)	0.2(0.1-0.9)**
	4 or more	--	0.3(0.1-2.7)
Level of Education	Non	1	1
	Primary	4.7(1.1-21.4)**	1.3(0.5-3.8)
	Secondary	1.7(0.4-7.5)	0.5(0.2-1.5)
	Tertiary	1.6(0.3-8.7)	0.8(0.2-2.7)
Total number of pills per day	1	1	1
	2	2.4(0.5-11.3)	2.0(0.5-8.2)
	3	0.4(0.1-2.3)	0.8(0.2-3.6)
	4	0.3(0.1-2.3)	2.5(0.5-11.7)
	5 or more	0.3(0.1-1.9)	1.9(0.4-9.4)
Total time spent∞	<5min	1	1
	>5min	0.5(0.2-1.3)	0.4(0.2-0.9)**
Reasons for missing appointment	Lack of transport	6.8(1.5-30.8)**	3.8(1.9-7.6)**
Side effects	Dizziness	3.1(1.3-7.6)**	3.8(1.9-7.6)**
Number of Reviews in last 6 months	0 or 1	1	1
	2	0.5(0.1-9.6)	0.7(0.3-1.8)
	3	3.0(0.7-12.7)	1.2(0.4-3.9)
	4	0.3(0.1-2.8)	0.6(0.1-2.9)
	5 or more	0.8(0.1-9.4)	1.1(0.2-6.7)

∞Patients were asked on the total time spent to explain how to take drugs

** Statistically significant results using OR at 95% CI

Factors independently associated with non adherence by self report

Patients who missed their clinical appointments due to lack of transport were more likely be non adherent than those who kept their appointments (odds ratio 6.8 95% CI 1.5-30.8). Patients who had attained primary level education were more non-adherent as reported by self report (odds ratio 4.7 95% CI 1.1-21.4).Those who lived more than 10 km from the hospital were more non-adherent to treatment (odds ratio 3.9 95% CI 1.0-10.2).

Factors independently associated with non adherence by modified Hill Bone

Similar to the self report the modified Hill Bone scale reported that those who missed their clinical visit due to lack of transport were more likely to be non adherent (odds ratio 3.3 95% CI.1.0-11.3). and those who were experiencing side effects of dizziness as in the self report were also more likely to be non adherent to their antihypertensive treatment (odds ratio 3.8 95% CI 1.9-7.6). On the other hand those taking 3 types of BP medicines and those counseled for more that 5 minutes were found to be more adherent to their BP medication as shown in table 7.

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CHAPTER 6

DISCUSSION

We conducted a study to determine the levels of adherence and factors associated with non-adherence to antihypertensive treatment. Our results showed that 83% of the patients were adherent to their prescribed medications by self report. Modified Hill Bone scale reported 70% adherence. Adherence was more comparable to other studies done in Africa such as the study done in Nigeria by Nnodimele *et al* in which adherence levels were found to be 69.3% and adherence of 74.1% reported in an Egyptian study.[30,31]. In both studies self reports were used to determine adherence. Age and sex of the patient had no bearing on adherence to treatment. The mean age was relatively comparable to studies done in Nigeria in which mean age was 62.2±12.19 and in Pakistani study that showed a mean age of52±12.[30,31] In our study, age had no bearing on adherence, even though other studies have shown increasing adherence with age.[12,31,33]

Being a third world country most patients had only attained primary level education and majority were low income earners. Comparing with other factors we found that those who had attained primary education were more likely to be non adherent as reported with self report compared to those who had no education. This finding was not significant using modified hill bone .This may be due to the fact that less educated people may more likely overestimate their adherence. This can also be explained by lack of time given to educate patients in a manner that will enable them understand the importance of adherence.

 A family history of hypertension did not have a bearing on adherence. Patients with co-morbid medical conditions did not show any statistical bearing on adherence similar to other studies. [30,34]

Our study also showed that participants taking 3 types of hypertensive treatment were more adherent to their medications than those taking more than 3 drugs or less. These findings could be due to the perception of those taking more drugs of having severe disease and hence become significantly more cautious with their treatment even though those taking 4 types of antihypertensive medicines were non adherent to treatment. Increased pill burden could have contributed to these findings.

Patients experiencing side effects of dizziness also showed high levels of non-adherence with statistical significance. Side effects commonly hinder adherence since a perception of dizziness is more unpleasant than the subtle symptoms of hypertension.

Patients who come late for clinic visits i.e. after patients' vitals signs have been taken and assigning of patients to a particular doctor has been done, are not seen that day and are given an appointment for a later day. Those who missed their clinical appointment due to lack of transport and coming late were found to be non-adherent. Patients who missed appointments had no medicines to take at home.

The health care system factors that significantly affected adherence were living at a distance of more than 10 km from the health institution. These could have been the same patients that were unable to come for reviews due to lack of transport. The number of clinical reviews and spacing of reviews did not affect adherence to medication.

Duration taken to counsel patients on adherence also showed an increase in adherence with statistical significance (0.3(0.1-0.8) 95% CI) in those who had five minutes or more. This highlights the importance of patient education to address adherence. Studies done in developed countries however, did not show any statistical significance in terms of knowledge and adherence to drugs [31]. This affirmed the hypothesis made in this study. This also highlight the need for comprehensive individualized patient education on disease management, including providing detailed explanation regarding side effects of prescribed medication and patients future options. [35]

The level of adherence in our study was comparable to studies in the region. This information was validated by the use of modified Hill Bone that strengthens the findings in our study. The other important finding was the increase in adherence levels in patients that were counseled by nurses and those who received 5 minutes or more of counseling on how to take drugs. This could be important information that can be used to improve adherence by using specialized trained nurses to educate patients on knowledge of hypertension and the importance of adherence. Care givers should also address the side effect of dizziness when prescribing a type of drug by avoiding such a drug. Those

who live more than 10 kilometers or more can be encouraged to go to their nearest clinic after stabilizing their BP to avoid missing of appointments.

STUDY LIMITATIONS

The primary measure of adherence to medication was self reporting and hence may not provide a true picture of actual adherence. Recall bias could have under estimated or over estimated the level of adherence reported in the study. Patients generally give overly optimistic reports about adherence so as not to disappoint their doctors or the researchers. This was supported by the discrepancy between self report and modified Hill Bone score showing lower prevalence of adherence probably close to reality. However, patient self report is a simple and inexpensive way of assessing adherence. The use of validated tools, however, helped to strengthen our findings. The cutoffs used for defining non-adherence both with self-report and modified Hill Bone score were pre-determined, but there is no standard cutoff for these measures.

This was a hospital based study and hence the results may not be generalized to the entire population. Patients who could not volunteer information on their own were also excluded and this further restricts the generalization of these findings.

CONCLUSION

The prevalence of adherence among hypertensive patients was found to be higher than anticipated. The factors associated to poor adherence included: taking 3 BP drugs, side effect of dizziness, missed appointment due to lack of transport, living at a distance of more than 10 km from the hospital, duration of counseling and being counseled by a nurse on how to take medications. This information provides baseline data to help improve and address the issues of adherence in hypertensive patients seen in our health institutions.

Based on an association between increased counseling received and adherence we recommend that specialist nurses be used in adherence counseling as is done for patients on anti-retroviral therapy. These can also be used to educate patients on the natural history and complications of hypertension. Physicians or care givers should pay special attention to patient education and counseling when reviewing these patients. This can also be complimented with print and audiovisual material to help patients have more information on the conditions and importance of adherence. Patient support groups can also be used to help those who are non adherent. The government should ensure adequate supply of antihypertensive drugs even if this study showed that most patients were able buy medicines that were not issued.

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APPENDIX

ANNEX I

QUESTIONNAIRE

Study No

Location of interview

□ 1 - Medical Clinic (Clinic 5)   □ 2 - Adult Filter Clinic

Patient related factors

1. Socio-demographic factors

   Age: _____ (years) (Nearest birthday)

   Sex: □ M   □ **F**

2. Level of education

□None   □Primary   □Secondary   □Tertiary

3 Residential address _____

4. Income   □   (< K1, 335, 000)

                   □   (K1, 335, 000-K4, 100, 000)

                   □   (>K4, 100,000)

Family History

5. Hypertension in first degree relative   □ Yes   □ No

Medical History

6. Do you have high blood pressure?   □ Yes   □ No

7. Do you have any of the following medical problems?

□ Kidney disease   □ HIV   □ Diabetes

□ Tuberculosis   □ Heart failure   □ Other _____

8. How many medicines do you take for non-BP-related illnesses? _____

Drug history

9. How many BP drugs do you take? _____

10. Can you name the drugs that you are taking? □ Y □ N

11. Names of drugs

□ Enalapril □ Lasix/furosemide □ Hydrochlorothiazide/Moduretic

□ Amlodipine □ Atenolol □ Nifedipine

□ Hydralazine □ Losartan □ Carvidelol

□ Others _____

□ Patient cannot name and no record available

12. Total number of pills per day _____

13. How many drugs missed in last 3 DAYS _____

5 DAYS _____

7 DAYS _____

14**. Side effects**

□ Dizziness □ Excess urination □ Diarrhea □Cough

Other_____

15**. Reasons for not taking antihypertensive**

□ Cannot afford to buy drugs

□ felt better

□ Side effects

□ Do not like the drugs

□ Forgetfulness

□ Cured

Others_____

System related factors

1. Number of reviews in last 6 months _____

2. Spacing of reviews

□One month   □Two months   □Three Months

□Four months   □Five months   □> Six months

3. Number of appointments missed in last 6 months _____

4. Reasons for missing appointment

a. □ Lack if transport

 b.□ Late for appointment C.□ Commitments

d. OTHERS _____

5. Duration taken to secure appointment

□> 15 minutes   □15-30 minutes   □30-60 minutes   □ >60 minutes

6. Number of prescribed drugs   _____

7. Number of drugs issued by pharmacy   _____

8. Reasons for not getting prescribed drugs

       a, □Long queue

       b. □Drugs not available

       c. □Pharmacy closed

       d. □Could not locate Pharmacy

       e. other _____

 9. Able to buy drugs not supplied   □ Yes   □No

10. Distance from Home to the Hospital

□1—5km   □6----10km   □11----15km   □16-----20km   □>20km

Physician related factors

1. Have any of the following people ever explained to you how to take your medicines?

□ Doctor   □ Nurse   □ Family member   □ Other

2. Have any of the following people ever explained the importance of taking your medicines?

□ Doctor   □ Nurse   □ Family member   □ Other

3. How much total time do you think has been spent in explaining your medicines to you?

□ < 5   minutes   □ 5 minutes or more

4. When you were told how to take your medicines, how long did they tell you that you would need BP medications?

□ 1 month or less   □ >1 month but < 1 year   □ > 1 year but not forever

□ For the rest of your life

5. Do you see the same doctor every time you come to clinic?

□ Yes   □No

6. If no, how many doctors have you seen in clinic your last four visits?

□ 1   □ 2   □ 3   □ 4   □ >5

Modified 10–Item HB Blood Pressure Compliance Scale

HILL-BONE HIGH BLOOD PRESSURE COMPLIANCE SCALE

NA-Not applicable DN-Don't know	None of the time	Some of the time	Most of the time	All the time	NA	DK
	1	2	3	4	8	9
1. How often do you forget to take your HBP medicine?						
2. How often do you decide not to take your HBP medicine?						
3. How often do you eat salty food?						
4. How often do you miss scheduled appointments?						
5. How often do you run out of HBP pills?						
6. How often do you skip your HBP medicine 1–3 days before you go to the clinic?						
7. How often do you miss taking your HBP pills when you feel better?						
8. How often do you miss taking your HBP pills when you feel sick?						
9. How often do you take someone else's HBP pills?						
10. How often do you miss taking your HBP pills when you care less?						

ANNEX II

CONSENT FORM

Invitation

You are invited to participate in this study that is looking at factors associated with poor adherence to antihypertensive drugs in hypertensive patients seen at University Teaching Hospital. This study is been conducted to identify factors associated with poor adherence to antihypertensive treatment in hypertensive patients to help improve treatment of the disease

Nature and purpose of the study

The study is being conducted to know factors associated with poor adherence in antihypertensive patients to help improve treatment of hypertension.

Procedures of the study

If you agree to participate in the study, we will obtain information from you regarding age and social data, information regarding your hospital visits, taking of drugs and supply. Your blood pressure will also be measured.

Possible risks and discomforts

You will not be exposed to any risks by enrolling into the study. However, you may be inconvenienced during the interview.

Possible benefits

The information obtained in his study will help in the management of other hypertensive patients

Confidentiality

All the information collected in this study is strictly confidential. Data that will be collected and reported will not include your name and therefore cannot be traced to you.

Consent

Your participation in this study is strictly voluntary. You will not suffer any consequences if you decide not to participate in this study. You may also withdraw from the study at any time for any reason without consequences to you.

Thank you for considering participation into the study. If you have any questions, concerns and clarifications, please contact Dr Morgan D Mweene of Dept of Medicine or in ward EO2 or Phone number +260 977 374 504.or The University of Zambia Research Ethics committee on the following addresses;

The University of Zambia
Biomedical research ethics committee
Ridgeway Campus
P.O Box 50110
Lusaka-ZAMBIA.
Telephone; 256067
Telegrams; UNZA LUSAKA
Telex; UNZALU ZA 44370
Fax;+260-1-250753
E-mail; unzarec@zamtel.zm,Dimakweenda@yahoo.com.

Consent Form

I, -------------------------------------- hereby confirm that I have been sufficiently explained to about the nature, conduct benefits and risks of this clinical study. I have also received, and/or read and understood the above written information about the study. I am aware that my personal details and will be anonymously processed into the research report. I have understood that I may voluntarily, at any point, withdraw my participation without suffering any consequences. I have been given sufficient time to ask questions and seek clarifications, and of my own free will declare my participation into the research study.

I have received a signed a copy of this agreement

Participant's signature or thumb print   Date_____

Person obtaining informed consent   Date_____