ADEQUACY OF BLOOD PRESSURE CONTROL,

LEVEL OF ADHERENCE

AND

REASONS FOR NON ADHERENCE TO

ANTIHYPERTENSIVE THERAPY

AT KENYATTA NATIONAL HOSPITAL.

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DECLARATION

I certify that this is my own original work and has not been presented for a degree at any other university.

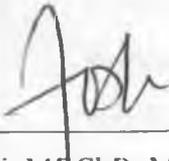Dr Loice Achieng, MB, ChB (University of Nairobi)

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ABBREVIATIONS

ALLHAT	The antihypertensive and lipid-lowering treatment to prevent heart attack trial
BMI	Body mass index
BP	Blood pressure
CAD	Coronary artery disease
CONVINCE	Controlled Onset Verapamil Investigation of Cardiovascular Endpoints
CVD	Cardiovascular disease
DASH	Dietary approaches to stop hypertension
DBP	Diastolic blood pressure
HB	Hill Bone compliance with high blood therapy score
HOT	Hypertension Optimal Treatment
JNC 7	Seventh report of the joint national committee on prevention, detection, evaluation and treatment of high blood pressure
KNH	Kenyatta National Hospital
LDL	Low density lipoprotein
MEMS	Medication event monitoring system
PAMELA	Pressioni Arteriose Monitorate E Loro Association study
SBP	Systolic blood pressure
TOD	Target organ damage
WHO-ISH	World health organization – International society of hypertension
WHR	Waist hip ratio

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ABSTRACT

Background

Hypertension is a common cardiovascular risk factor in Sub Saharan Africa and is associated with high morbidity and mortality. However, it is often insufficiently controlled in clinical practice, a prominent reason for this being poor patient adherence to prescribed therapy.

Little is known about control, adherence, and the underlying reasons for poor adherence in our set up.

The study was designed to investigate the adequacy of blood pressure control, level of adherence to prescribed therapy and the patient perceived reasons for non adherence.

Methods

This was a cross-sectional descriptive study, it was carried out in two parts; quantitative methods were used to analyse adequacy of BP control and level of adherence to antihypertensive therapy, and qualitative methods were used to analyse the patient reasons for non adherence.

BP control was assessed using clinic BP measurement; adherence was assessed using the HB questionnaire and a qualitative analysis of in-depth interviews with non adherent patients was carried out.

Results

Two hundred and sixty four patients participated in the quantitative arm of the study, sixty eight (26%) were found to have adequate BP control. Of those who had poor blood

pressure control, defined as BP ≥140/90 mmHg, one hundred and fourteen (58.5%) had BP of ≥ 160/100mmHg.

Poor BP control was significantly associated with non adherence (p=0.006, r^2=0.54 for systolic BP, 0.63 for diastolic BP), obesity (p=0.03), and increasing number of medication (p=0.012 for diastolic BP and 0.038 for systolic BP). Other causes of poor BP control included suboptimal therapy and lack of lifestyle modification.

Eighty four (31.8%) of the patients were fully adherent to antihypertensive therapy. Non adherence was not significantly associated with any socio-demographic factors. 37.3% of patients who were adherent had good BP control compared to 20.8% of those who were non adherent (p=0.005). Of the patients who were fully adherent to therapy yet had poor BP control, 86.3% were on suboptimal therapy.

12 patients were recruited into the qualitative arm of the study. The patient perceived reasons for non adherence were: high cost of drugs, unavailability of drugs, competing alternative therapies including herbal therapy and prayer, convenience, side effects of the medication, relief of symptoms, fear of low blood pressure, conflicting information from heath care providers, and due to poor understanding of hypertension and its management modalities.

Conclusion

There was poor BP control in our population, largely due to non adherence. The in-depth interview identified patients' reasons for non adherence and solutions to these problems should be adopted in programmes to improve adherence with antihypertensive medication and blood pressure control.

1. LITERATURE REVIEW

1.1. INTRODUCTION

Enormous challenges still persist in the control of infectious diseases in Sub-Saharan Africa. However, non-communicable diseases are also rapidly increasing and pose important threats to the health of adult Africans (1).

Hypertension in Sub-Saharan Africa is a wide spread problem of immense economic importance because of its increasing prevalence, especially, in urban areas, its frequent under diagnosis and the severity of its complications (2). It is also a major modifiable risk factor for cardiovascular and renal disease and its effective treatment reduces the mortality and morbidity related to end-organ damage.

Despite availability of effective medical therapy for hypertension, only about 31% of persons with hypertension are adequately controlled. A significant factor contributing to poor blood pressure control is patient non-adherence to prescribed therapy (3).

1.2. EPIDEMIOLOGY

Global estimates of hypertension indicate that 26.4% of the world's adult population in 2000 had hypertension, 29.2% (>1.5 billion) are projected to have hypertension in 2025. Men and women have similar overall prevalence of hypertension (4).

Hypertension is a greater population burden in developing rather than developed countries. Although hypertension is more common in developed countries (37.3%) than in developing ones (22.9%), the much larger population in developing countries results in a considerably larger absolute number of individuals affected (4).

In 1929, Donnison wrote that in over two years at a native hospital in the south of Kavirondo in Kenya, during which period approximately 1800 patient were admitted, no case of raised BP was encountered (5). This has changed over the years and studies done in Africa attest to this. In Ghana, the prevalence of hypertension in urban areas rose from 8% in 1990 to 28.3% in 2004 (6); in South Africa, the 1998 demographic and health survey indicated that 21% of the overall population was hypertensive with rates as high as 50-60% in those over the age of 65 years (7). In Tanzania, cross-sectional population surveys carried out in 1996 and 1997 found a prevalence of above 37% in an urban area and more than 26% in a rural population (8).

There are few population studies in Kenya, most of which were carried out more than 15 years ago and used a BP cut off of 160/90mmHg which may explain the low prevalence. Cross-sectional community based surveys done in 1985 and 1991 showed a prevalence of 4.1% in rural Meru (9), 5.4% in rural and urban Nakuru (10) and 6.4% in Rural and urban Kitui (11). There have been no recent studies on prevalence but as has been shown in several studies in Africa, hypertension is becoming more common as urbanization increases (1).

1.3. ASSOCIATED MORBIDITY AND MORTALITY

Hypertension has been arbitrarily defined as BP levels of ≥140/90mmHg. However, there is a continuous relationship between the level of blood pressure and the risk of cardiovascular events starting at BP levels of 115/75mmHg (12,13). Blood pressure levels, both systolic and diastolic, have been shown to be positively and continuously related to the risk of cardiovascular disease i.e. for every 20mmHg systolic or 10mmHg diastolic rise in BP, there is a doubling of mortality from both coronary artery disease and stroke.

Hypertension contributes to about 30% of world mortality (4). Death and disability from CAD and CVD are increasing rapidly in developing countries and will rank number one and four respectively as causes of global burden of disease by the year 2020 (14).

Not only does hypertension affect more people in economically developing countries, but the onset of cardiovascular disease is also at an earlier age in these countries (15). In 1990, the proportion of deaths from cardiovascular disease before the age of 70 years was 46.7% in economically developing countries compared with 26.5% in developed countries (17).

Hypertension accounts for 18% of the population attributable risk of a first myocardial infarct and is associated with a relative risk of 2-5 for a stroke. The risks of heart failure and renal disease have been observed to be related to blood pressure levels (18). About 10% of the deaths caused by hypertension are due to renal failure (19). A six-year study in South Africa reported hypertension as the cause of end stage renal disease to be 20.9% in blacks (20). A local study showed nephropathy to be present in 21.5% of the hypertensive patients studied (21). In 1999 Oyoo et al in a hospital based descriptive study reported among the causes of congestive heart failure in patients admitted in KNH, 17.6% was associated with hypertensive heart disease (22). In 2003, Mohammed et al found clinical cardiac disease in 32.3% of the hypertensive patients studied (21).

1.4. MANAGEMENT OF HYPERTENSION

Antihypertensive treatment translates into significant reductions of cardiovascular morbidity and mortality (12). The absolute benefits of blood pressure lowering therapy are higher in groups which are at high risks of cardiovascular events that are BP related. Such populations include many of those in the Eastern Asian region and sub-Saharan Africa as well as African American populations in the USA. (17).

Guidelines have been established for physicians to use in blood pressure control: these include the World Health Organization – International society of Hypertension (18), the United States joint national committee on prevention, detection, evaluation and treatment of high blood pressure (23), the European society of hypertension, European society of cardiology hypertension management guidelines (12), and the British society of hypertension guidelines (13). The guidelines advocate for both non-pharmacologic and pharmacologic management.

1.4.1. Non-Pharmacologic (lifestyle measures):

Lifestyle measures are used to lower BP in the individual patient, to reduce the need for and maximize the efficacy of antihypertensive drugs, to address other CVD risk factors present, and for primary prevention of hypertension and associated cardiovascular disorders in populations (18). The measures include weight reduction, dietary changes, physical activity and moderation of alcohol intake.

Weight reduction of as little as 5kg reduces BP in large proportion of hypertensive individuals who are more than 10% overweight. Maintaining a normal body mass index leads to approximately 5-20 mmHg drop in SBP. (24)

Dietary measures such as dietary sodium restriction not only lower BP but also lead to a significant reduction in the need for antihypertensive therapy. Reducing sodium intake to <100mmol/day reduces SBP by 2-8mmHg (18, 25). Adopting DASH eating plan

(dietary approaches to stop hypertension) contributes to 8-14mmHg decline in SBP (18). The DASH eating plan includes a diet rich in fruits, vegetables, low fat dairy products and reduced content of saturated and total fats, it is also rich in potassium and calcium.

Increasing physical activity (regular aerobic physical activity such as brisk walking at least 30min/day, most days of the week) reduces SBP by 4-8mmHg. (23, 26)

Reduction of alcohol consumption to no more than two drinks per day in men and no more than one drink per day in women and lighter weight persons leads to a reduction of SBP by 2-4mmHg. (18, 23)

1.4.2. Pharmacologic therapy:

The six main drug classes used, worldwide, for BP lowering treatment are diuretics, β-blockers, calcium antagonists, angiotensin converting enzyme inhibitors, and angiotensin II antagonists.

Thiazide diuretics are the best evaluated agents, show morbidity and mortality benefit and are recommended as first line agents by the WHO-ISH and JNC guidelines. They are cheap, effective even in blacks and are well tolerated in low doses. Their side effects include hypokalaemia, impaired glucose tolerance, small increments of LDL cholesterol, triglycerides and urate.

B-blockers are cheap, though thought to be less effective in blacks. Their side effects include lethargy, erectile dysfunction, impairment of blood glucose control and worsening of dyslipidaemia. Calcium channel blockers are effective especially in blacks and are well tolerated. Side effects include tachycardia, flushing and ankle oedema. ACEIs and ARBs are effective in reducing morbidity and mortality in heart failure and in retarding the progression of renal disease in diabetes mellitus. There's poor response in black patients when used as monotherapy. Their side effects include angioedema and dry cough which is less with ARBs

The choice among the different antihypertensive drugs has not generally been made on the basis of efficacy, since each of these agents is roughly equally effective, producing a good antihypertensive response in 30-50% of cases (26). Trials have not shown superiority of newer agents over conventional cheaper drugs such as diuretics and beta blockers (27, 28& 29).

There have been no truly large scale, randomized, outcome studies in black Africans with regard to first line antihypertensive agent. However, studies done in South African blacks suggest that calcium channel blockers may be superior to diuretics and angiotensin receptor blockers (30).

Lower doses of combination antihypertensive drugs are recommended as this reduces side effects of the component agents. A meta-analysis of several antihypertensive drug trials indicated that efficacy of drugs in combination was additive, but adverse effects were less than additive. Combinations of two or three drugs at low dose are therefore preferable to one drug at standard dose. Within each drug category, no one drug was better than another hence choice of drug should be based on low cost, availability and ease of administration (32).

The use of long acting drugs, providing 24-hour efficacy on a once a day basis is advantageous as such drugs improve adherence to therapy and minimize BP variability, as a consequence of smoother more consistent BP control. This may provide greater protection against the risk of major cardiovascular events and development of target organ damage (33).

Drug combinations are often necessary to achieve adequate blood pressure control. In the ALLHAT study (27), BP control was achieved in 60% of those on two or more agents and in only 30% of those on one agent.

1.5. MANAGEMENT GOALS

The primary goal in management of patients with high blood pressure is to achieve the maximum reduction in the total cardiovascular risk. As the relationship between cardiovascular risk and BP is continuous, without a lower threshold, the goal of antihypertensive therapy should be to levels defined as normal or optimal (18).

The target blood pressure goal for most patients with uncomplicated hypertension is <140/90mmHg. However, the more stringent goal of <130/80mmHg is indicated for patients with other CVD risk factors such as diabetes mellitus or renal disease (23).

1.6. ADEQUACY OF BLOOD PRESSURE CONTROL

Community control of hypertension can be assessed against the 'Rule of Halves', whereby half of those affected are detected, half of those detected are treated and half of those treated are adequately controlled.

Even in developed countries, there has been little progress in the quality of control of hypertension. In mainly population-based surveys carried out between the years 1986-1998, the control of hypertension in adults aged 35-64 years was 28% in North America and about 10% in Europe (29). There was an increase in controlled patients in the US to 49% in 1999 (23). In Australia, a retrospective study showed level of control to be 33% of treated patients (29).

In Egypt (1993) in subjects >25 years of age and in China (1991) in subjects aged >15 years of age, only 8% and 5% respectively of the hypertensive population were treated and controlled (34).

A study in Ashanti, West Africa found that only 2.8% of 291 patients studied had their BP adequately controlled whereas in Accra, the level was 6.2%. (4) In Tanzania, a study of the urban population of Dar es Salaam found good BP control in 7-13% (35).

In a 2003 study of CVD risk factors and TOD among hypertensive patients at a national tertiary referral hospital (KNH), Mohammed et al found adequate BP control in 21.5% of the study population (21), a figure that is considerably higher than in most population based African studies, this may be explained by the fact that his study was carried out in a tertiary hospital.

Studies assessing adequacy of BP control and attributable risk of CVD have shown that between 23% and 47% of strokes occur because of inadequate control on treatment (36). Treated but poorly controlled hypertension and untreated hypertension remain important predictors of the risk of stroke. This was shown in a Swedish study of stroke patients in whom the population attributable risk of poorly treated hypertension was 46% (37).

Poor BP control should now be regarded as a waste of resources. Even though medical attention has been achieved, either the patient or medical team appear to accept that the main effort is to start treatment, rather than the now established imperative of BP control (35). It is important that treatment be adequate: it is not enough to treat; the responsibility is to reach treatment goals (37).

1.7. CAUSES OF POOR BLOOD PRESSURE CONTROL

High clinic BP readings have been thought to be contributed to by a white coat effect. However, an Italian study (PAMELA) found that in the hypertensive population, the number of patients with inadequate BP control is high not only when assessed in the clinic but also when assessed by ambulatory blood pressure monitoring or at home. The high BP value commonly found in treated hypertensive individuals cannot be accounted for by a white coat effect but by a true lack of daily-life BP control (38).

Various explanations have been proffered to explain why such a large percentage of patients have uncontrolled hypertension including secondary hypertension and endogenous resistance to treatment. However, the main reason for inadequate control of BP is poor adherence to the treatment regimen, both pharmacologic and non-

pharmacologic (39). Poor adherence to antihypertensive treatment is estimated to contribute to the lack of adequate blood pressure control in more than two thirds of patients.

When therapeutic response to a drug is not the one expected, it is a major challenge for many physicians to decide whether the patient is a non-responder or a non-complier. Poor adherence is therefore often incorrectly interpreted as a lack of response to treatment. Not detecting non-adherence can lead to the wrong measures being taken. A reliable assessment of adherence would have a great impact on medical costs by preventing unnecessary investigations or dose adaptations (40).

Understanding the reasons for patient non-adherence with antihypertensive medication is essential if hypertension is to be more effectively managed (39). Some of the factors that may affect adherence include complexity of medication regimen, side effects of drugs, patient knowledge, awareness, beliefs and attitudes, and health care system issues.

Complex medication regimen/ multiple dosing frequencies reduce level of adherence and it has been shown that a reduction in frequency of dosing from three times a day to once a day increases patient compliance by as much as 25% (41).

Hypertension is often asymptomatic but treatment may result in side effects such as dry cough, dizziness, nausea, headache, sexual dysfunction, depending on the drug administered and this may reduce level of adherence (42). Patients who understand the nature of their illness and believe in the necessity of medication are more likely to be adherent (43).

Factors related to patient perception of the health care system such as lack of a primary health care provider, lack of support form the health care system, lack of follow-up by the clinic, or lack of information about hypertension, negatively affect medication adherence (39, 44). The nature of the physician-patient interaction is an important determinant of the quality of care patient satisfaction and adherence to treatment, and a less authoritarian

and more co-operative relationship i.e. partnership in care, fosters the satisfaction and adherence. Knowledge of patients' common reasons for not adhering to treatment would facilitate development of a partnership in care.

Studies to assess reasons for non-adherence have often used semi structured interviews or detailed interviews. No studies on non-adherence to antihypertensive treatment have been undertaken in Kenya but cost and availability of drugs is expected to be a major factor.

1.8. ADHERENCE

Compliance has been defined as the extent to which a person's behaviour coincides with medical care or advice (45). Adherence more accurately recognizes the greater degree of patients' responsibility and involvement in their medical care and is a more politically correct term than compliance. (3) The terms 'compliance' and 'adherence' have been used interchangeably in literature.

To be adherent, one has to take at least 80% of all prescribed antihypertensive medication. It is estimated that 25-30% of all patients adhere to their prescribed medications; while 30-50% are completely non-adherent and the rest are partially adherent (42, 44). Some studies have reported compliance rates as high as 90% in the setting of clinical trials. (45)

Correctly estimating adherence is challenging. Several studies have demonstrated that clinicians' estimate of non-adherence is very poor. Gilbert et al showed that the sensitivity and specificity of the clinical judgement was 10% and 86% respectively, other studies found sensitivity and specificity of 38 and 92% respectively (40). This indicates that physicians are good at detecting good adherence but are poor at detecting non-adherence, i.e. those patients that need to be identified.

The various instruments available for estimating adherence include electronic monitoring, pharmacy refill rates, pill counts, drug assays and self-report (46, 3).

Electronic devices to monitor medication adherence (e.g. Medication Event Monitoring System, MEMS) are reported to be highly reliable and are considered the gold standard. MEMS is a pill box that electronically records the date and time of each opening of the box, data can be transferred to a computer, processed and presented graphically. It provides information of daily intake and dosing, and may be used in analysis of long-term patterns and potentially captures white-coat compliance. Its disadvantages include the fact that medication consumption is assumed but not confirmed, it is expensive and can be intrusive since the patient must carry it; the device can fail and may be inaccurate if subject to interference by the patient.

Pharmacy refill rates are considered objective, they capture the amount and frequency of medications obtained by the patient, reflect patient's decision to remain on the drug and provide information on average adherence over time. However, medication consumption is assumed but not confirmed, data may be incomplete if the patient uses several pharmacies or receives free samples and there is a lag time for data availability.

Pill counts are objective though are reliant on patient to bring in pills, assume that drugs were consumed, may overestimate adherence (e.g. pill dumping or sharing). It is considered invasive since the patient has to carry the pills.

Drug assays either in blood or urine is considered invasive, is influenced by patient drug metabolism and white coat compliance. It is also subject to errors due to sample collection method (e.g. 24 hour urine collection).

Self-report is simple, economical and provides information on social, situational and behavioural factors that affect adherence. It may however overestimate adherence, be subject to recall bias and elicit socially acceptable responses. A study comparing the

different methods of measuring adherence, found that self-report correlated well to the gold standard, MEMS (46).

Self-report has been widely used to assess adherence (40, 46, 47), and several instruments have been developed to assess self-reported adherence. These include the Hill-Bone compliance to high BP therapy scale, the Morisky instrument, The COMpliance Praxis Survey (COMPASS) (44), the Medical Outcomes Study (MOS) General Adherence Scale, SHEA and Haynes (46)

The Hill-Bone compliance to high BP therapy scale assesses patient behaviour for 3 important behavioural domains of high BP treatment: Reduced salt intake, appointment keeping and medication taking (51)

The Morisky instrument has been shown to provide good specificity for drug adherence (50). This consists of four questions about medication taking, which cover forgetfulness, carelessness and stopping medication due to improvement or deterioration in symptoms. Patients are then divided into high, medium and low compliance categories on the basis of the number of positive answers.

1.9. HILL-BONE COMPLIANCE TO HIGH BLOOD PRESSURE THERAPY SCALE

This was designed as a simple tool for clinicians to evaluate patient's self-reported adherence levels. It assesses three behavioural domains of high blood pressure treatment: medication taking, appointment keeping and reduced sodium intake. It was designed for self-administration or interviewer-assisted administration and takes about five minutes to complete.

The scale consists of 14 items: a sodium subscale containing 3 items which assess dietary intake of salty foods, an appointment keeping subscale with 3 items that assess appointments for doctor visits and prescription refills and a medication taking subscale with 8 items that assess medication taking behaviour.

Each item has a four-point Likert response format. For example, for the question "How often do you forget to take your high blood pressure medication?" the responses are as follows: none of the time=1, some of the time=2, most of the time=3, and all of the time=4. The items are additive and the total scale score ranges from 14 (minimum) to 56 (maximum), with a higher score reflecting poorer adherence to antihypertensive therapy.

It has been validated in different communities with a cronbach alpha of 0.74 to 0.84 (51, 53). Its use was validated in a black South Africans in a primary health care setting (52). The scale has been shown to have significant predictive validity in that non-adherence predicted higher diastolic and systolic blood pressure. In a South African study, the appointment making and dietary salt-intake subscales were not found to be internally consistent. However, the 8-item medication taking behaviour subscale showed good consistency and predictive validity and may be used on its own (51, 52 & 53).

2 JUSTIFICATION OF THE STUDY

Hypertension is common and the most frequent cardiovascular risk factor in Kenya. The prevalence of hypertension is rising, as is the morbidity and mortality associated with it

Inadequate blood pressure control is frequent and is directly, positively and continuously, related to risk of cardiovascular morbidity and mortality. Knowledge of the adequacy of BP control and understanding of the reasons for patient non-adherence to antihypertensive medication is essential if hypertension is to be more effectively managed.

There is no Kenyan data on adequacy of BP control, reasons for lack of control, level of adherence or reasons for poor adherence to antihypertensive therapy. Such data would be useful in improving patient management and reducing the high costs associated with inadequate BP control.

3. OBJECTIVES

3.1 Broad objective

To determine the adequacy of BP control, level of adherence to pharmacologic therapy, the relationship between non adherence and BP control, and the reasons for non adherence in hypertensive patients seen in the medical outpatient clinics at KNH.

3.2 Specific objectives

1. To determine the proportion of hypertensive patients with adequate blood pressure control.
2. To determine the proportion of patients adherent to pharmacologic therapy as defined by the Hill-Bone questionnaire.
3. To describe the socio-demographic characteristics of non-adherent patients.
4. To determine the correlation between BP and level of non-adherence.
5. To determine the patient perceived reasons for non-adherence.

4. STUDY METHODOLOGY

4.1. Study design:

A cross-sectional descriptive study.

4.2. Study area:

The general medical outpatient clinics at a tertiary referral and teaching hospital, the Kenyatta National Hospital.

4.3. Study population:

All patients with hypertension followed up in the general medical outpatient clinics.

4.4. Case definition:

Hypertensive – any patient with a diagnosis of hypertension, as documented in the hospital file, who was on pharmacologic therapy for the same.

4.5. Screening and recruitment:

The Kenyatta National Hospital runs 7 medical outpatient clinics in a week, 5 of which run in the morning and 2 in the afternoon on different days of the week. For the purposes of this study, 3 clinics were randomly chosen to be representative of all the clinics; these included 2 morning and 1 afternoon clinic. This process was repeated at the beginning of every week.

Files of all hypertensive patients attending a particular clinic were obtained from the records office before start of the clinic. These were perused and all those that met the case definition were assigned a number. From these files, eight were randomly chosen.

The patients chosen were then approached and an informed consent obtained after the consent explanation. All patients were seen after the primary doctor review.

4.6. Sample size:

The sample size for the study was estimated using the following sample size formula for a one-sample situation:

$$n = \frac{\left(Z_{\alpha/2}\right)^2 \, p(1-p)}{d^2} = 264$$

Where:

n = sample size

Z = 1.96 at 95% confidence interval

P = estimated prevalence of adequate BP control of 21.5%

d = margin of precision of error of 0.05

4.7. Patient selection:

4.7.1. Inclusion criteria:

1. Patients who met the case definition
2. Patients who had a prescription of recognized antihypertensive drugs from the clinic. These drugs included diuretics, β-blockers, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, calcium channel blockers, drug combinations of any of the above drugs, central α agonists, α blockers.
3. Patients who had at least one renewal of prescription indicating that the prescribed medication had been taken at least once.
4. Patients who had at least two clinic visits prior to the recruiting visits. This was done to allow for adequate time to achieve blood pressure control.
5. A duly signed written informed consent from the patient.

4.7.2. Exclusion criteria:

1. Known or suspected cause of secondary hypertension.

4 8. Clinical methods:

History was obtained as per the proforma (appendix I). A full physical examination inclusive of anthropometric measurements was carried out.

Blood pressure was measured as per the World Health Organization recommendation (18), with the patient in sitting position using a standard cuff with a bladder that was 13cm by 35cm and a mercury sphygmomanometer, after an initial rest of 15 minutes or more. We ensured that the patient had not smoked or taken coffee in the last 30 minutes.

The systolic blood pressure was determined by the perception of phase 1 Korotkoff sound and diastolic pressure by the phase 5 korotkoff sound. Two measurements were taken at five-minute intervals and the average of the two readings taken as the patient's blood pressure. Patients were then classified as adequately or poorly controlled.

Height was measured to the nearest half centimetre. Subjects were barefoot, standing straight with their arms hanging by their sides and the back of the head, back, buttocks, calves and heels touching the upright. The head was positioned so that the top of the external auditory meatus was level with the inferior margin of the orbit.

Weight was measured to the nearest 100g with the subjects barefoot and lightly dressed. Waist and hip measurements were made to the nearest centimetre. Subjects stood with their feet 12-15cm apart, with their weight equally distributed on each leg. Waist circumference was measured with the waist uncovered at the mid point between the iliac crests and the lower margin of the ribs with the subject in gentle expiration. Hip girth was measured over the subjects underwear as the circumference around the greater trochanters with the tape measure in the horizontal plane.

Details of the patient's treatment were obtained from the file: this included the all drugs the patient was taking, their doses and frequency.

Level of adherence was assessed using the Hill-Bone compliance with high blood pressure therapy medication taking sub scale (appendix II). The administration of this was interviewer-assisted with standardized translations. Patients were then classified as adherent or non-adherent depending on the total score.

Qualitative methods were used to assess reasons for non-adherence. 12 patients who were found to be non-adherent from the Hill Bone questionnaire were randomly selected for the qualitative method. An in-depth interview technique was used. Consenting patients were interviewed by the principal investigator; interviews and recordings were carried out in the presence of the patient and the interviewer only. Interviews were semi-structured and all questions were asked in an open ended manner in order to allow patients to freely express their opinions

Questions aimed at elucidating patients' understanding of hypertension and medication taking, for example, "how does high blood pressure affect you, how long do you have to take the drugs?" Probes on reasons for non adherence were used and the answers were further clarified by more specific follow-up questions, and were analysed together with any relevant information that surfaced in response to other questions.

Interview conversations were tape recorded in their entirety and later transcribed verbatim. Each interview took an average of 30 minutes.

4.9. Definition of outcome variables:

Adequate BP control was defined as a blood pressure of less than 140/90mmHg. Both the SBP and DBP had to be below these thresholds for BP to be considered controlled (18, 54). For patients with diabetes, adequate control was defined as a blood pressure of less than 130/80mmHg.

The poorly controlled patients were further classified according to grade of hypertension (WHO/ISH and ESH/ESCclassification)

Grade of hypertension	SBP(mmHg)	DBP(mmHg)
I	140-159	90-99
II	160-179	100-109
III	>180	>110

Adherence was be defined as per the Hill-Bone compliance with high blood pressure therapy scale. A patient was defined as fully adherent if they had a minimum score of 8. A score ≥ 9 was considered representative of non-adherence. Non-adherence was graded from 9-32, with higher scores reflecting poorer levels of adherence.

BMI was classified as normal ($18-24.9kg/m^2$), overweight ($25-29.9 kg/m^2$), and obese ($\geq 30 kg/m^2$).

Visceral obesity was defined as per the NCEP-ATPIII definition: waist circumference >102cm in males and >88cm in females.

5. DATA MANAGEMENT AND STATISTICAL ANALYSIS

All data from the study was verified, cleaned and entered into data entry sheets. Statistical analysis was performed using statistical package for social sciences, version 15.0 software for windows.

Analysis involved descriptive statistics such as means for continuous variables and frequency distributions for categorical variables. Comparisons for continuous data were made using the t-test and for categorical data using the chi-square test.

Proportions were obtained for categorical data:-
- Proportion of study population with adequate BP control
- Proportion of study population adherent to therapy
- Proportion with adequate BP control among those who were adherent to therapy and among those who were non adherent to therapy

Adherence score was analysed as a continuous variable, and correlated to the level of blood pressure using Pearson correlation. The strength of association between adherence score and level of blood pressure obtained using linear regression. The adherence score was also analysed as a categorical variable using a one way analysis of variance and spearman rank correlation, and the results were similar to those obtained with analysis of adherence score as a continuous variable.

The level for statistical significance was $P \leq 0.05$.

6. ETHICAL CONSIDERATIONS

The study was conducted after approval by the department of clinical medicine and Therapeutics, University of Nairobi, and the Kenyatta National Hospital Ethical and Review Committee.

A detailed written and verbal consent explanation was given to the study participants (Appendix IV). All participants signed an informed consent form (Appendix V).

All patients were educated on hypertension and counselled on adherence with prescribed therapy. All issues that arose regarding adherence were communicated to the primary physician

RESULTS

The study was conducted between June and November, 2007. 783 files were screened, out of which, 575 met the inclusion criteria. Out of these, 268 were randomly selected, four were excluded for various reasons and 264 patients were recruited into the study (figure 1). All 264 patients were assessed both for adequacy of blood pressure control, and level of adherence with antihypertensive medication.

There were more females representing 67.6 % of the study population. The mean age was 57.26 years; the mean duration of hypertension was 6.75 years with a range of 6 months-31 years. The demographic characteristics of the patient population are shown in table 1.

Figure 1: FLOW CHART ON PATIENT SCREENING AND RECRUITMENT
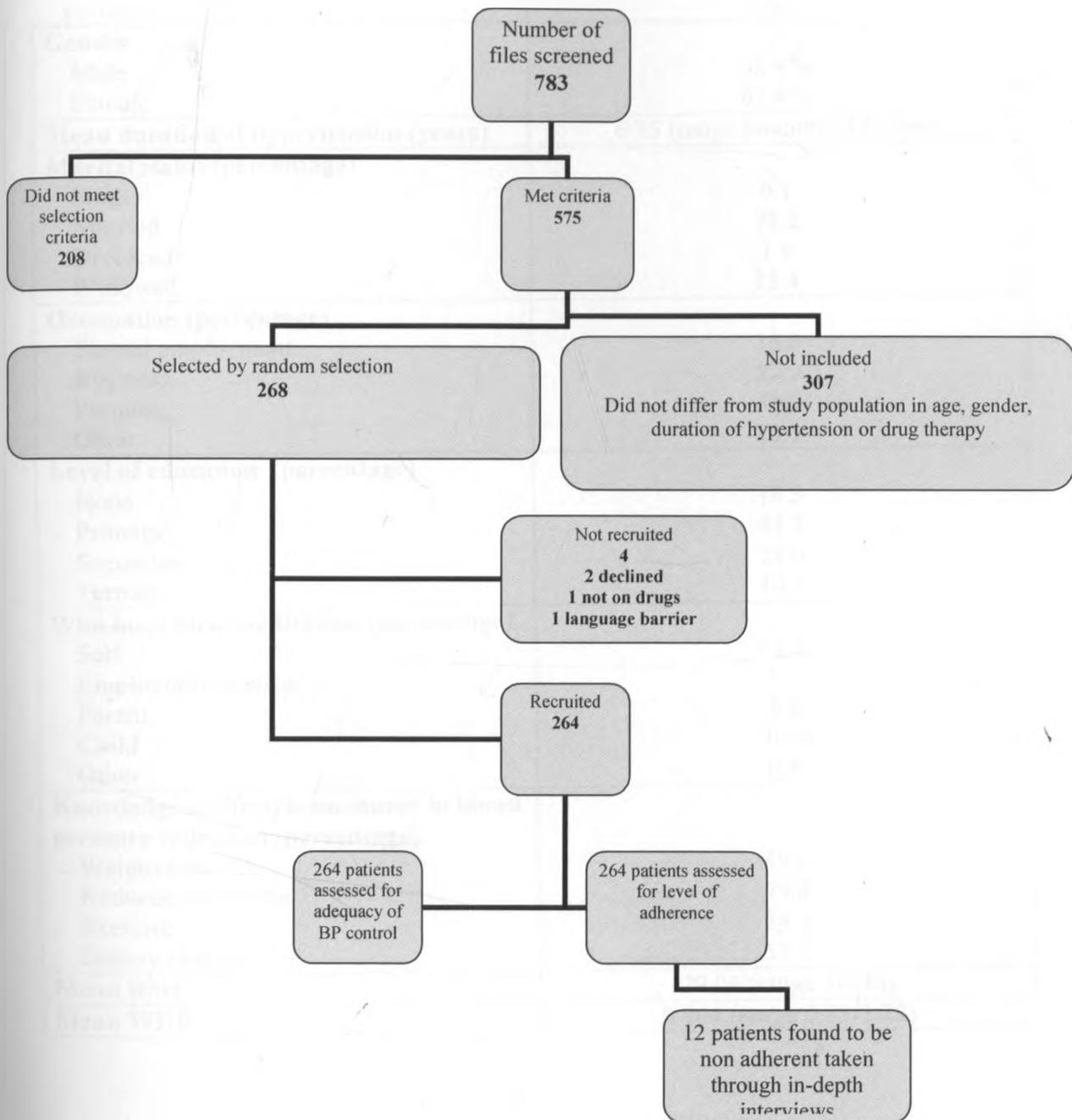
Table 1: DEMOGRAPHIC CHARACTRERISTICS OF STUDY POPULATION

Mean Age (years)	57.26 (range 28-93years)
Male	59.55
Female	56.23
Gender	
Male	32.4%
Female	67.6%
Mean duration of hypertension (years)	6.75 (range 6months-35years)
Marital status (percentage)	
Single	6.1
Married	78.2
Divorced	1.9
Widowed	13.4
Occupation (percentage)	
Formal employment	16.8
Business	27.9
Farming	30.9
Other	23.3
Level of education (percentage)	
None	18.3
Primary	41.2
Secondary	29.0
Tertiary	10.3
Who buys their medication (percentage)	
Self	62.2
Employer/insurance	3.1
Parent	0.4
Child	30.9
Other	0.8
Knowledge of lifestyle measures in blood pressure reduction (percentage)	
Weight loss	49.6
Reduced salt intake	79.8
Exercise	54.2
Dietary changes	53.1
Mean BMI	29.04 (range 16-46)
Mean WHR	0.704 (range 0.52-1.28)

Table 2: OTHER CARDIOVASCULAR RISK FACTORS*

Smoking %	11.1
Diabetes % **	3.4
BMI (mean)	29.2
Normal(%)	21.6
Overweight (%)	38.2
Obese (%)	40.2
Waist circumference (mean)	98.13
Normal (%)	37.4
Visceral obesity (%)	62.6

* Cholesterol level not included
** Could be under represented as most diabetic patients attend the diabetic clinic

Table 3: CARDIOVASCULAR DRUGS USED BY THE PATIENTS

Number on:	
Thiazide diuretics (%)	64.1
B-blockers (%)	55.7
Calcium channel blockers (%)	55.3
ACE inhibitors (%)	50.4
Angiotensin receptor blockers (%)	19.1
Methyl dopa (%)	3.4
Fixed dose combination (%)	3.8
Statins (%)	19.5
Aspirin (%)	10.7

Figure 2: NUMBER OF ANTIHYPERTENSIVE DRUGS PER PATIENT

Figure:
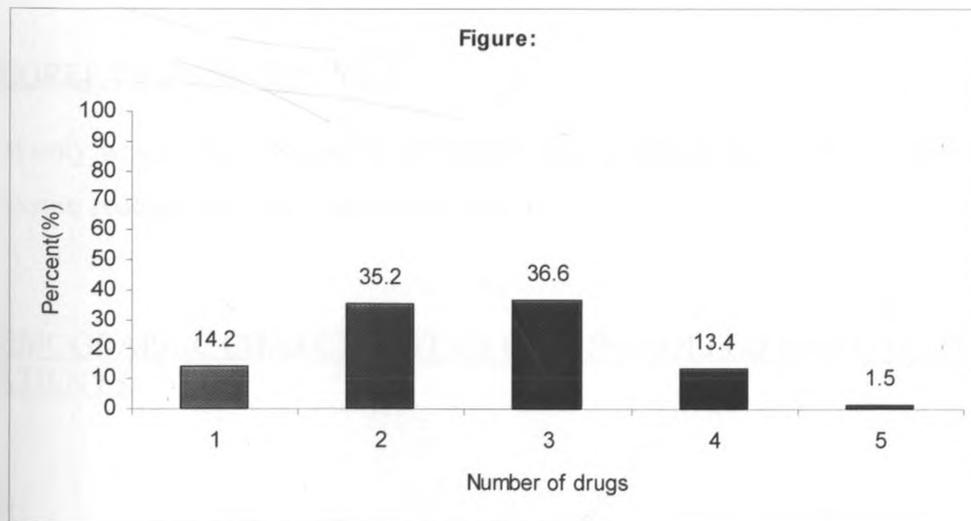
PROPORTION OF HYPERTENSIVE PATIENTS WITH ADEQUATE BLOOD PRESSURE CONTROL

The mean systolic blood pressure was 148.3mmHg with a range of 90-240mmHg. The mean diastolic blood pressure was 92mmHg with a range of 50-160mmHg. 26% of the patients (68) were adequately controlled with 74% of patients (194) not controlled.

Figure 3: ADEQUACY OF BLOOD PRESSURE CONTROL

BP CONTROL

N=264

- ■ <140/90
- ▦ 140/90-159/99
- ■ 169/100-179/109
- ■ >180/110
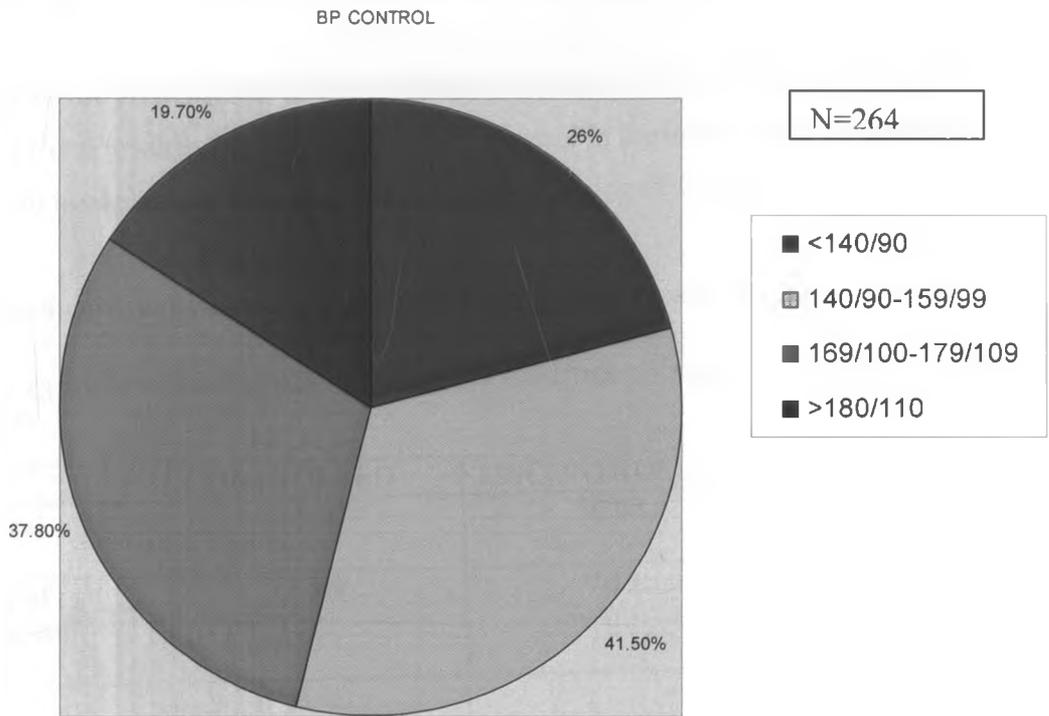
DEGREE OF POOR CONTROL

Not only was a large proportion of patients uncontrolled, but, 57.5% of these had blood pressure reading of ≥ 160/100mmHg (fig 3

DEMOGRAPHIC CHARCTERISTICS OF CONTROLLED AND UNCONTROLLED PATIENTS

DEMOGRAPHIC CHARCTERISTICS OF CONTROLLED AND UNCONTROLLED PATIENTS

There were no statistically significant differences in the demographic characteristics of the patients with controlled blood pressure and those whose BP was not controlled.

There was a trend towards poor blood pressure control in those with longer duration of hypertension, however, this was not statistically significant (P = 0.06).

Knowledge of life style measures did not influence control of blood pressure, however, there was a trend towards better blood pressure control in those who had knowledge of reducing salt intake as part of management of hypertension (P 0.08).

Weight was significantly associated with BP control as is shown below.

Table 4: CHARACTERISITICS OF PATIENTS BY CONTROLLED AND UNCONTROLLED BP STATUS

	CONTROLLED	UNCONTROLLED	P-VALUE
Age (years)	59.07	56.62	0.4
Duration of hypertension (years)	5.49	7.19	0.06
BMI% Normal Overweight Obese	31.9 37.7 30.4	17.9 38.4 43.7	0.03
Gender Male Female	24 (28.2%) 45 (25.4%)	61 (71.8%) 132 (74.6%)	0.629
Knowledge of Weight loss Yes No	36 (27.7%) 32 (25%)	94 (72.3%) 96 (75%)	0.624
Knowledge of reduced salt intake Yes No	60 (28.7%) 9 (17%)	149 (71.3%) 44 (83%)	0.083

	CONTROLLED	UNCONTROLLED	P-VALUE
Knowledge of exercise			
Yes	38 (26.8%)	104 (73.2%)	0.897
No	31 (26.1%)	88 (73.9%)	
Knowledge of dietary changes			
Yes	39 (28.1%)	100 (71.9%)	0.501
No	30 (24.4%)	93 (75.6%)	
Level of education			
None	33.3	66.7	0.235
Primary	22.2	77.8	
Secondary	28.9	71.1	
Tertiary	14.8	85.2	
Occupation			
Farming	30.9	69.1	0.540
Business	23.3	76.7	
Formal employment	11.4	88.6	
Marital status			
Married	26.8	73.2	0.591
Single	25	75	
Widowed	28.6	71.4	
Divorce	0	100	
Who buys medication	26.4	73.6	0.547
Self	28.4	71.6	
Child	0	100	
Employer/insurance			

WEIGHT (BMI) AND BLOOD PRESSURE CONTROL

Of the patients with good blood pressure control, 31.9 % had normal BMI, 37.7% were overweight and 30.4% were obese, whereas, of those with poor control, 17.9% had normal BMI, 38.4% were overweight and 43.7% were obese. Increasing BMI was associated with poor BP control (p=0.03).

Normal BMI was associated with good blood pressure control, OR 2.15 (CI 1.09-4.29, p=0.02).

The mean systolic and diastolic blood pressures rose with increasing number of antihypertensive drugs (ANOVA p=0.012 for systolic and 0.038 for diastolic). This may have been a reflection of the difficulty of BP control

Figure 4: Relationship between number of drugs and average diastolic blood pressure

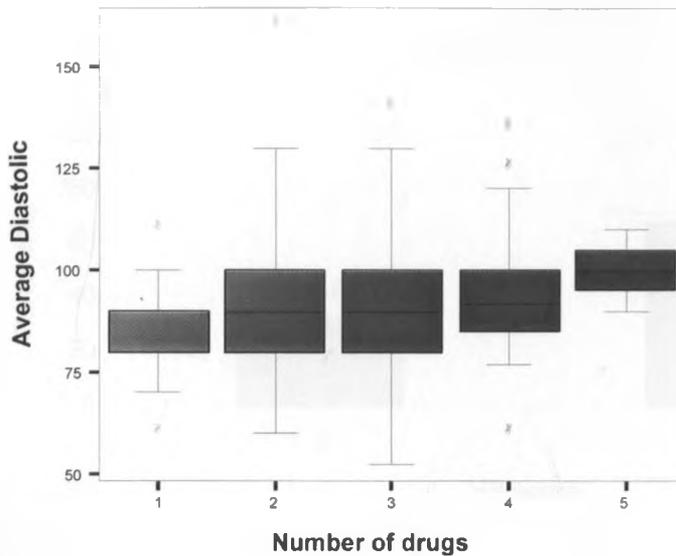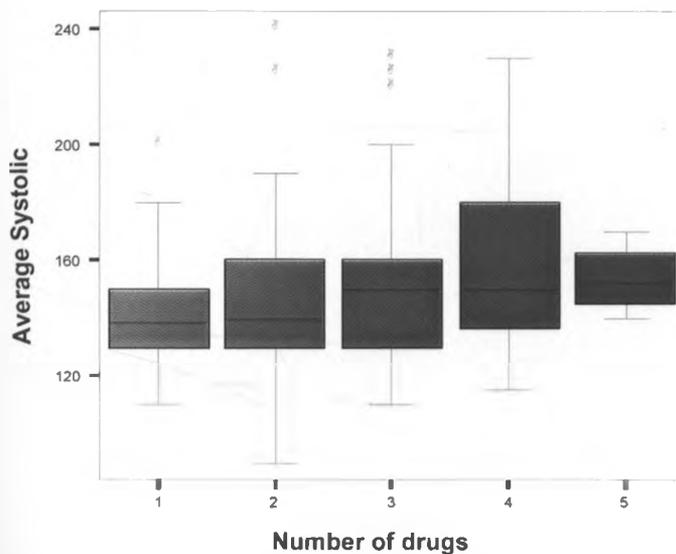

Figure 5: Relationship between number of drugs and average systolic blood pressure

PROPORTION OF PATIENTS ADHERENT TO PHARMACOLOGIC THERAPY AS DEFINED BY THE HILL BONE QUESTIONNAIRE

31.8% of the patients were found to have a score of 8 on the Hill-Bone scale representing the highest levels of adherence.

Figure 6: NUMBER OF PATIENTS (%) ADHERENT AND NON ADHERENT AS PER THE HILL BONE SCORE
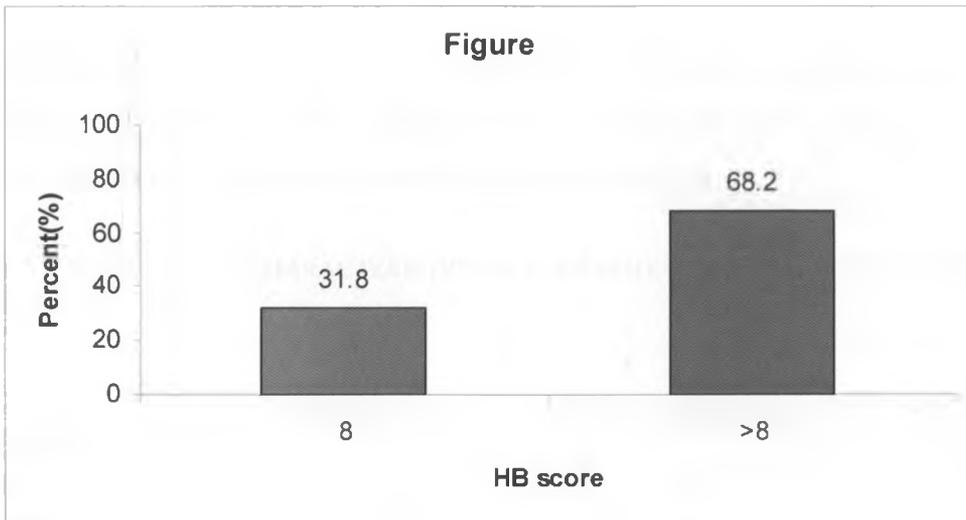
SOCIODEMOGRAPHIC CHARACTERISTICS OF NON ADHERENT PATIENTS

There were no statistically significant differences in demographic or socioeconomic characteristics of the adherent and non adherent patients.

There was a trend towards higher adherence among patients who attained tertiary education compared to the others, however, below tertiary education, the level of adherence did not increase with increasing level of education.

Table 5: DEMOGRAPHIC CHARACTERISTICS OF ADHERENT COMPARED TO NON ADHERENT PATIENTS

	ADHERENT	NON ADHERENT	P-VALUE
Gender (%)			
Male	30	70	0.52
Female	25.6	74.4	
Mean Age (years)	57.9	57.0	0.385
Marital Status (%)			
Single	36.4	63.6	0.86
Married	27.2	72.8	
Divorced/separated	20.0	80	
Widowed	24.0	76	
Occupation (%)			
Formal employment	14	24	0.3
Business	13	43	
Farming	17	40	
Other	8	33	
Level of education (%)			
None	5	27	0.09
Primary	25	60	
Secondary	10	43	
Tertiary	12	11	
Who buys medication (%)			
Self	28.1	71.9	0.839
Emloyer/insurance	42.9	57.1	
Parent	0	100	
Child	24.1	75.9	
Other	0	100	
Duration of hypertension (years)	6.44	6.91	0.622

PROPORTION OF PATIENTS WITH ADEQUATE BLOOD PRESSURE CONTROL IN THE ADHERENT AND NON ADHERENT GROUPS

37.3% of the patients who were adherent had adequately controlled BP as compared to 20.8% of those who were non adherent. (p=0.005)

62% of uncontrolled patients were adherent as compared to 72.9% of the non adherent patients, statistically significant differences (P 0.005)

20.8% of non-adherent patients were controlled, and 26.9% of uncontrolled patients were adherent with their medication

Figure 7: CORRELATION BETWEEN ADHERENCE AND BLOOD PRESSURE CONTROL
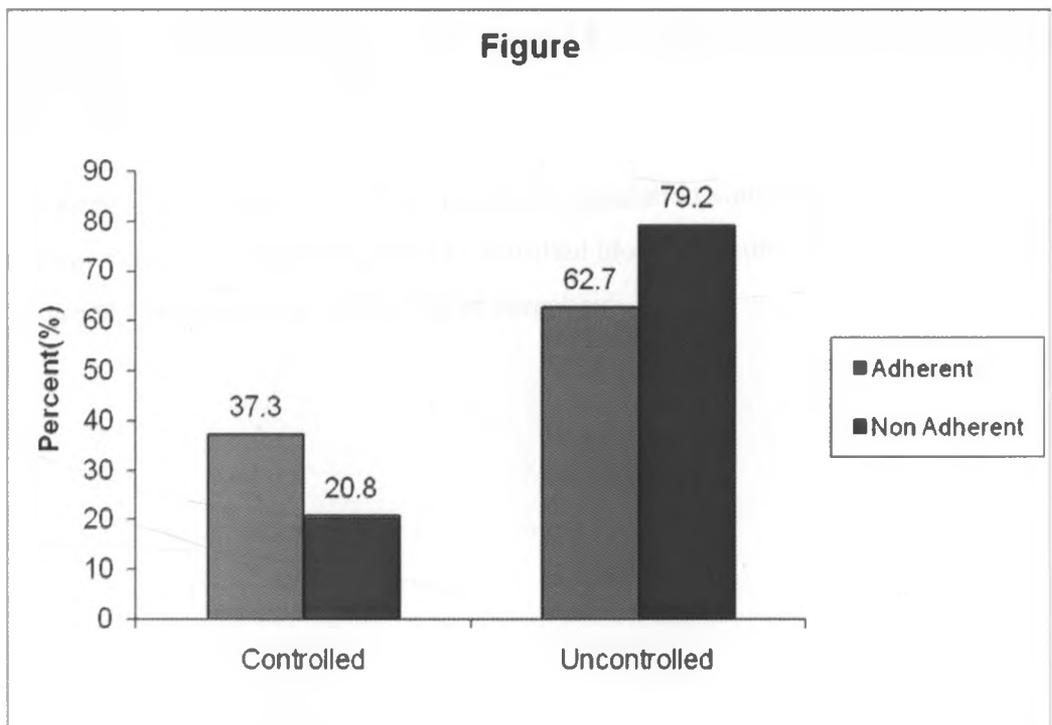
PATIENTS WHO WERE ADHERENT TO MEDICATION YET HAD UNCONTROLLED BLOOD PRESSURE

51 patients representing 19.3% of the study population were found to be adherent to medical therapy but had poor blood pressure control.

49% of the patients were on 3 drugs, 25.5% on 2 drugs, 15.7% on 1 drug and 9.8% on 4 drugs. However, of these, only 7 patients were on maximal doses of three drugs including a diuretic

37.2% of the patients were not on a diuretic agent. 86.3% of the patients were on suboptimal dosing of one or more agents

PATIENTS WHO WERE NON ADHERENT YET HAD CONTROLLED BLOOD PRESSURE

35 patients representing 13.25% of the study population were not adherent to antihypertensive medication yet had controlled blood pressure. 82% of these patients had grade I hypertension at the time of diagnosis.

CORRELATION BETWEEN BLOOD PRESSURE AND LEVEL OF NON ADHERENCE

Increasing levels of non adherence as assessed by the Hill Bone score were significantly associated with increasing blood pressure levels.

Analysis by Spearman's rank found a positive correlation of 0.6 between higher adherence scores on the Hill Bone scale and higher systolic blood pressure levels (p=0.067) and 0.77 between HB score and diastolic blood pressure (p=0.009).

When the adherence total score was analysed as a continuous variable, there was a positive correlation between non adherence and increasing BP. The Pearson correlation for systolic BP was 0.736 (p=0.015), and for diastolic BP was 0.796 (p=0.006).

On linear regression, every unit increase in HB score was associated with a 4mm rise in systolic blood pressure, R-square = 0.54 (Figure 10), and a 3mm rise in diastolic blood pressure R-square =0.63 (Figure 11).

Figure 8: LINEAR REGRESSION OF HB SCORE AND AVERAGE SYSTOLIC BP
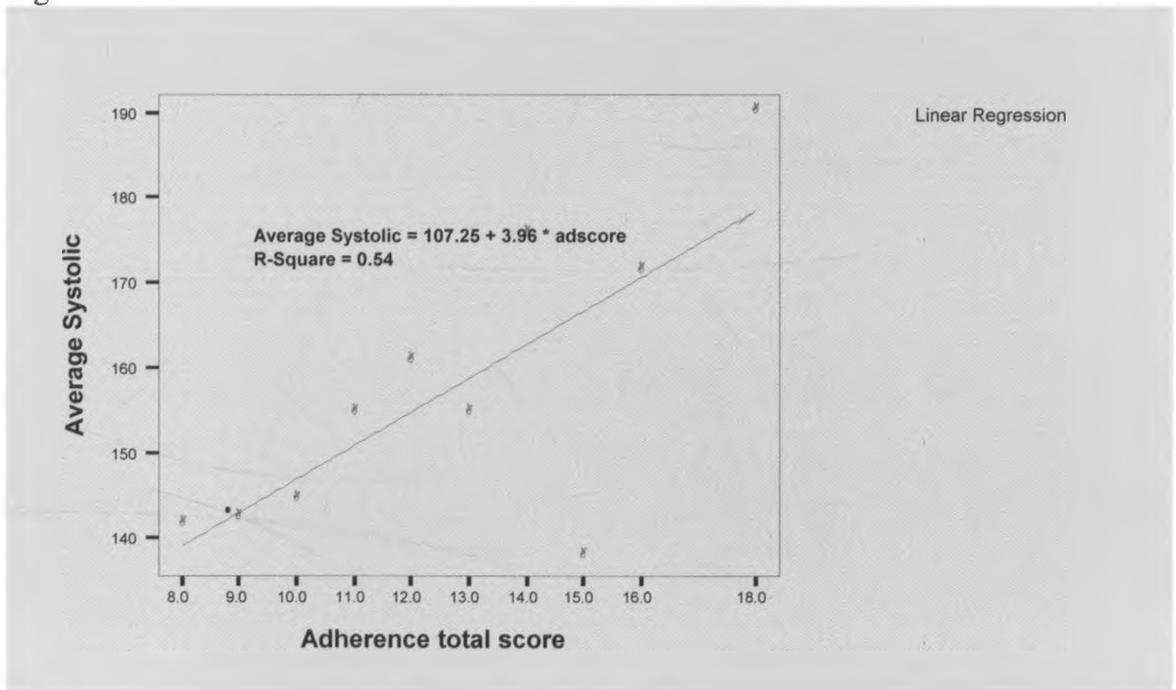
Figure 9: LINEAR REGRESSION OF HB SCORE AND AVERAGE DIASTOLIC BP

Linear Regression

avdiastolic_mean = 59.68 + 3.10 * adscore
R-Square = 0.63
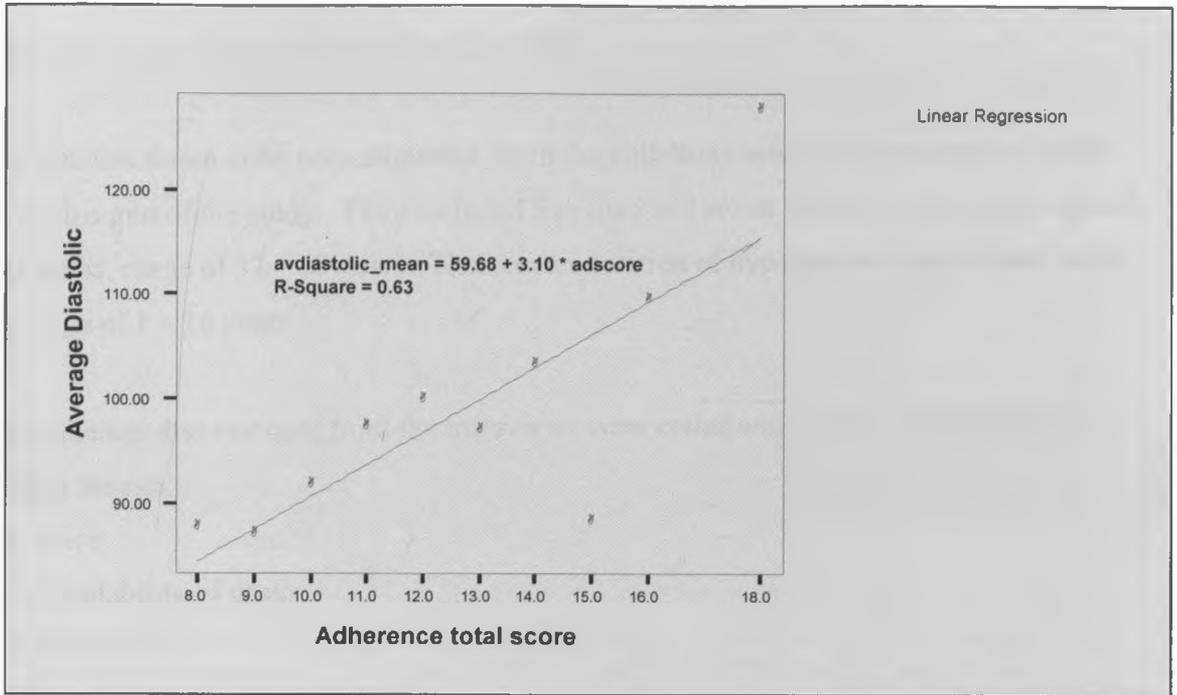
RESULTS OF THE INDEPTH INTERVIEW

12 patients found to be non-adherents from the Hill-Bone questionnaire were recruited into this part of the study. They included five men and seven women, with a mean age of 48 years, range of 32 – 69 years. Their mean duration of hypertension was 7 years, with a range of 1 – 16 years.

The themes that emerged from the interviews were coded and the data analysed under these themes.
1. Price
2. Availability of drugs
3. Side effects
4. Competing alternative therapies
5. Convenience
6. Lack of knowledge

1) Price – This was mentioned by 8 of the patients as a reason for not adhering to medication. Patients' concerns included either the high cost of medication or lack of money to buy even the cheaper drugs.

Excerpt 1 – 39 year old lady from Kawangware in Nairobi on Losartan, Hydrochlorothiazide, Nifedipine, atenolol and aldomet. BP at time of interview was 190/110 mmHg.

"…..Sometimes I do not have money to buy the medicines, and recently I was given Losartan, and that is expensive – it is 25Kshs, though a little cheaper at the KNH pharmacy. Many times I only buy atenolol and aldomet, those are ok…"

2) **Availability** – This was mentioned by 3 patients as the reason for non adherence. Some of the drugs prescribed were not available in some areas

Excerpt 2 – 65 year old lady from Makindu on prescription of HCTZ, enalapril and Nifedipine. BP at time of interview 160/100

".....The drugs are not found where I stay in Makindu so when I go to buy, they tell me they don't have and give me something different...." She is mostly on Captopril 25mg twice a day.

3) **Side effects** – Mentioned by 2 patients as their reason for non adherence. Some of he side effects mentioned included dizziness and excessive fatigue. These patients had not been warned about the possibility of these side effects neither had they mentioned this to their primary doctor.

Excerpt 3 – 48 year old teacher from Machakos, on HCTZ, Enalapril and Nifedipine. BP at time of interview 150/100.

"...When I take this medicine called Nifelat in the morning, I feel very dizzy the whole day, so I decided to take it only at night and not to take the one for morning, so I do not feel so bad..."

4) **Competing alternative therapies**

i) Herbal therapy – Four patients mentioned having taken herbs and stopped the prescribed medication.

Excerpt 4 – When asked about knowledge of other treatment for hypertension
P: "Some of these medicines from South Africa, I have heard of them but I haven't followed them up so keenly..."
Q: "Have you ever used them?"

P: "No I haven't, but I have used the ones from Subukia, here in Nakuru........It is a black powder that I used to take twice a day. "

Excerpt 5 – This patient had tried some herbal medication

".....It is called Ghetto, some one told me about it and I went to buy it......There is a time I used three packets and the pressure reduced a little....."

ii) Prayer therapy – This was mentioned by 3 patients

Excerpt 6

Q: "What else causes you not to take the medicines?"
P: "Forgetting and ignoring.....I just decide not to take, I say Jesus heal me, there are times I am prayed for and I stop the medicine...."

5) **Convenience** – Dosing schedules that did not fit in with the patient's lifestyle. This was a concern for those who went to work early and forgot their morning dose or were not able to carry their medicines to work.

Excerpt 7

P: "You see in my work, I leave the house very early, so when I forget the medicine, I can't go back home to take"
Q: "Can you carry your medicine with you to work?"
P: "That will be too much...."

6) Lack of Knowledge

i) Relief of symptoms

Excerpt 8 – 56 year old man, hypertensive for 3 years, on Nifedipine and enalapril, BP at time of interview 148/92mmHg

"Before the doctors discovered my problem, I always used to have headaches and in the clinics they were treating me for malaria and typhoid, then when I started taking the medicine the headache went and I felt better so I stopped taking the medicine, but when I have the headache I take them again…"

ii) Fear of very low blood pressure

Except 9 – 43 year old man, hypertensive for 6 years, on HCTZ and atenolol. BP at time of interview 130/96mmHg

"You see there are times I feel very well, and I see that if I continue taking the medicines, then the pressure will go too low, and that can bring me problems so I give it a break for some time…."

iii) Conflicting information from health care providers. There are patients who visit other clinics other than the one at KNH, here they may be seen by nurses, clinical officers or even other doctors.

Excerpt 10 – 47 year old man, hypertensive for 3 years, on Nifedipine, enlapril, HCTZ, BP at time of interview 150/90mmHg

"I do not even know why my pressure is high today, you see the other day (2 months prior to this visit), I went to a clinic near home and they took blood pressure and they found it to be low, you see the upper one was 120 and the lower one was 70, so they said that I should not take all the medicine, they told me to stop nifedipine…."

iv) On going symptoms, this was a reason for non adherence in patients who did not understand the course of hypertension or the expected outcomes with treatment

Excerpt 11 – 48 year old lady, hypertensive for seven years, on HCTZ, Nifedipine and atenolol. BP at time of interview 160/90mmHg

"There are times I feel tired and I keep taking the medicine but I see I am not feeling better and I have been taking medicine for a long time….and I think these medicines they are too may, they can cause your body problems, and I don't know if I am going to take these medicines for ever…"

DISCUSSION

This study was carried out in a medical out patient clinic at a tertiary referral hospital. The clinics are run by physicians and medical residents. There are no standard protocols for use in this setting and management of hypertension is based on guidelines from western countries.

The demographic characteristics of our patient did not differ significantly from other populations, however, most African studies are population based rather than hospital based. (8). More females in our study is a reflection of MOPC attendance, it is not clear why this is so, though it is thought that this may be due to better health seeking habits by females. This was not expected to impact on the study results.

BLOOD PRESSURE CONTROL:

Our level of BP control was 26%. This falls below the WHO recommended 'rule of halves' for community control, where, in the community, half of all patients with hypertension should be detected, half of those detected should be treated and of these, half should be controlled (37). This is also way below what has been achieved in the setting of clinical trials of up to 60% control of systolic BP and 90% control of diastolic BP as seen in HOT, ALLHAT, CONVINCE. (27, 54, 55).

Singer and others in a hypertension specialist clinic achieved adequate BP control in 59% of their patients with 63% at systolic BP goal and 86% at diastolic BP goal (56). This compared favourably with that achieved in clinical trials. This figure is considerably higher than that found in our study, this may be due to the fact that this was a hypertension specialist clinic, but also due to the fact that they followed hypertension management guidelines and tried to simulate a clinical trial setting.

In the United States, control rates of as high as 59% have been reported (23). In an Italian study, looking at 7626 hypertensive patients managed by general practitioners,

48.1% achieved BP levels <140/90mmHg (57). This figure is higher than ours and this may be due to the much higher adherence levels reported in their study of 75%.

African data is scarce and mainly population based. An Egyptian study in 1995 found 8% BP control (58), in Tanzania a study carried out in 1999 found 13% control (8), South African study found 16% control (59), a study in Ghana in 2006 found 6.2% to have good BP control (60). In a study of cardiovascular risk factors among hypertensive patients at Kenyatta National Hospital, Mohammed I found 21.5% of his study population to have well controlled hypertension (21), a figure that has barely changed in the five years since that study was carried out.

Our figure of 26% is higher than that in other African studies, this may be due to the fact that this study was carried out at a tertiary referral hospital, it is to be expected that population based studies would find much lower BP control.

Of the patients who had poor control, 57.5% had blood pressure of $\geq$ 160/100mmHg, this reflects the very poor control achieved in our population and the high cardiovascular risk of most of our patients. In a study on hypertension control in 1999, Borzecki et al found 43% BP control, of those who were uncontrolled, 18% had BP of $\geq$160/100mmHg. (61).

The very poor BP control in our population, in the face of high prevalence of hypertension, underlies the growing public health challenge of hypertension and the expected epidemic of morbidity and mortality from cardiovascular and renal complications. Cost effective strategies for primary prevention and treatment of hypertension are urgently needed to curb this problem.

<u>Reasons for poor BP control in our study included</u>:

Non adherence to medication was significantly associated with poor blood pressure control in our population. This has also been shown in other studies. Ross et al found diastolic BP to be associated with adherence: Mean diastolic BP in adherent group was 85mmHg and 91mmHg in poor adherent, a statistically significant difference (P=0.001). Nelson et al found that adherence was associated with significantly lower systolic blood pressure. (47).

Obesity was found to contribute to poor BP control. 74.8% of our study population was either overweight or obese. Overweight and obesity was found to be significantly associated with poor BP control. It is already known that maintaining a normal BMI leads to approximately 5-20 mmHg drop in SBP (24). There is conclusive evidence that weight reduction lowers BP in obese patients. In a meta-analysis of available studies, the mean systolic and diastolic BP reductions associated with average weight loss of 5.1kg were 4.4 and 3.6 mmHg respectively. (62). Weight loss measures should be part of hypertension management in our clinics.

Lack of lifestyle modification may have contributed to poor BP control. This study assessed patient's knowledge of lifestyle measures in treatment of hypertension and found that just about 50% of the patients knew about weight loss, exercise and dietary changes. More patients were aware of the need to reduce salt intake (79.8%). It has already been shown in multiple studies that lifestyle measures contribute to BP reduction (24, 25). The failure of the knowledge of lifestyle measures to translate into better BP control may be due to non adherence with the lifestyle measures. However, this was not assessed in this study.

Sub optimal therapy was found to be a cause of poor BP control. Inadequate drug combinations or failure to achieve optimal doses may have accounted for lack of control in patients who were otherwise adherent to therapy. It was noted in our study that 55.7% of the patients were on β-blockers, mainly atenolol. This may need to be

reviewed in light of recent literature indicating that atenolol may not be optimal treatment for hypertension management. (63). Suboptimal therapy may also be due to therapeutic inertia, which has been described in other studies and the failure of providers to begin new medications or increase dosages of existing medications when an abnormal clinical parameter is recorded. (64).

Resistant hypertension accounted for a very small percentage of poor BP control. Resistant or refractory hypertension is defined by a blood pressure of at least 140/90 mmHg or 130/80mmHg in diabetes or renal disease, despite adherence with full doses of at least three antihypertensive medications, including a diuretic (23). From our study, only 7 patients (2.6% of the total population) would be considered to have resistant hypertension.

It was noted that there was a group of patients who had good BP control despite being non adherent to medication. Most of these patients had grade I hypertension at the time of diagnosis. The reason for their BP control may be that this was a group of patients that did not require drug therapy, either because they were misclassified as hypertensive or could have achieved control by lifestyle measures only.

ADHERENCE

We found low levels of adherence, with only 31.8% of the study population adherent to medication. There are no regional studies for comparison. Western countries have reported high levels of adherence. In an Australian study, Nelson et al using the Morisky score to assess level of adherence found 55.2% of the hypertensive patients studied to be adherent (47). Siegel and others found adherence rates of 78.3% in the department of veteran affairs in the United States (65).

In the western countries, assessment of adherence was done in groups of patients who had access to medication for free and this may account for some of the differences in level of adherence seen in our population.

There were no clear predictors of non adherence in our population, however there was a trend towards poorer adherence with increasing number of medications, this did not reach statistical significance. Non adherence was not significantly associated with any demographic factors. Poor adherence in other populations has been associated with black race, lower income, younger age and fewer medications.

Ross et al found that older patients were more likely to be adherent than young patients. Patients with lower education were more likely to believe that medicines were necessary. However, number of medications was not associated with adherence. (43).

The failure to demonstrate a difference in demographic factors may be due to the fact that our population was fairly homogeneous in terms of their demographics and social status.

REASONS FOR NON ADHERENCE

A qualitative method (in depth interview) was used to assess the patient perceived reasons for non adherence. This method has been used by others. (66).

Reasons for non adherence in our population included cost and availability of drugs, side effects, lack of knowledge, alternative therapies such as herbal therapy and prayer.

In a study assessing reasons for non adherence with antihypertensive medication, Svensson et al found adherence rates of 58%, the reasons for non adherence in their population included: side effects, general dislike of drugs, lack of symptoms, those who did not think therapy was necessary or assumed BP was normal and forgetting to take medication.

Our population is different from theirs in that our patients had to buy their medication hence cost and availability of drugs seemed to play a bigger role.

Patients mentioned that they stopped medication due to relief of symptoms or due to fear of low blood pressure once they achieved adequate control. This shows that patients regard hypertension as an intermittent condition that only needs treatment in the presence of symptoms. This may be due to lack of information or patients' idiosyncratic interpretation of information from health care givers and may be reinforced by input from friends, family or media. This highlights the necessity for adequate communication between patients and physicians.

The issue of conflicting information from health care providers highlights the need for continuing medical education for all those involved in care of patients with hypertension and the need to adopt guidelines in the management of hypertension.

Better patient education on the course of hypertension, treatment modalities and expected outcomes is needed to prevent discontinuation of therapy due to alternative therapies. Availability and use of herbal medication should be regulated.

Regular assessment of patients' medication and education on any expected side effects should be made part of the each clinic visit, change of regimen may be necessary in those experiencing untoward effects of medication.

A number of patients mentioned cost of drugs as a hindrance to adherence. However, it was also noted that even patients who had the drugs provided for them, either by their children, employer or insurance, were not more adherent than those who bought their own medication. This has also been noted in other studies in which patients were non adherent despite having free medication. This is a pointer that there may be underlying attitudes towards hypertension or its treatment that affect adherence.

CONCLUSIONS

The majority of patients in this study population had poor blood pressure control

The majority of patients were non adherent with therapy.

Reasons for the poor control included:

- Non adherence to pharmacologic therapy – increasing level of non adherence was found to positively correlate with higher BP levels
- Obesity and lack of lifestyle modification– obesity was significantly associated with poor blood pressure control. Knowledge of lifestyle measures did not translate to better BP control, this was thought to be due to non adherence to the same.
- Sub optimal therapy – failure on the part of the physicians, with inadequate drug combinations and failure to achieve optimal dosing of drugs in patients with poor BP control.
- Resistant hypertension accounted for a minority of poor BP control.

Reasons given by patients for non adherence included: high cost, unavailability of drugs, side effects of drugs, use of alternative therapies and lack of patients' knowledge on the nature of their illness and necessity of medication which led to discontinuation of medication due to relief of symptoms, lack of relief of symptoms, or fear of low blood pressure.

LIMITATIONS

Patient self report may overestimate level of adherence; however in our population adherence was low in spite of this.

RECOMMENDATIONS

There is need to put in place modalities to improve blood pressure control and patient adherence to therapy, some of these modalities include:

1. Adequate patient education needs to be carried out for all our patients with hypertension.
2. Weight loss programs should be incorporated in management of patients with hypertension.
3. We need to set up hypertension management guidelines (standards of practice) for use in our clinics.
4. There needs to be on going education of clinicians on current hypertension treatment guidelines with the aim of improving prescription patterns in the clinics.
5. The in depth interview revealed many issues that lead to non adherence, a further study needs to be carried out to find out the importance of these issues in our population.
6. A further study is required to find out the underlying attitudes that affect patients perception of hypertension and its treatment.

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APPENDIX I - PROFORMA

Date

Name

1. Study Number

2. OP Number

3. DOB (month, year)

4. Age (years)

5. Date of diagnosis of hypertension
   (month/year)

6. Duration of hypertension (months/years)

DEMOGRAPHICS

1. Gender   1=M / 2=F

2. Marital Status
             1=Single
             2 Married
             3=Divorced/separated
             4=Widowed

3. Usual residence (*district*)

4. Occupation
             1=Formal employment
             2=Business
             3=Farming
             4=Other (*specify*)

5. Level of formal education
             1=None
             2=Primary level
             3=Secondary level
             4=Tertiary level
             5=Other (*specify*)

6. Who buys your medication
                1=self
                2=Employer/insurance
                3=Parent
                4=Child
                5=Other (*specify*)

7. Have you ever been told about any of the following? (1 = Yes/ 2 = No)
                Weight loss
                Reduced salt intake
                Exercise
                Dietary changes

BP (mmHg) - 1st reading _____
                2nd reading_____

                Average of two readings _____
Weight _____
Height _____

                BMI _____

Waist circumference
Hip Circumference _____

                WHR _____

PATIENT'S MEDICATION

(Specify drug)	yes	dose	frequency
Thiazide diuretics			
β-blocker			
Calcium channel blocker			
Angiotensin converting enzyme Inhibitor			
Angiotensin receptor blocker			
α-methyl dopa			
Fixed drug combination			
Other			

Total

APPENDIX II - Table I. Hill-Bone HBP Compliance Scale

No.	Item	Response
		1. None of the Time
		2. Some of the Time
		3. Most of the Time
		4. All of the Time
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 shake salt on your food before you eat it?	
5	How often do you eat fast food?	
6	How often do you make the next appointment before you leave the doctor's office?*	
7	How often do you miss scheduled appointments?	
8	How often do you forget to get prescriptions filled?	
9	How often do you run out of HBP pills?	
10	How often do you skip your HBP medicine before you go to the doctor?	
11	How often do you miss taking your HBP pills when you feel better?	
12	How often do you miss taking your HBP pills when you feel sick?	
13	How often do you take someone else's HBP pills?	
14	How often do you miss taking your HBP pills when you are careless?	

HBP=high blood pressure.

* Reverse coding.

For the purposes of this study, the 8-item medication taking behaviour subscale will be used. This includes items 1, 2, 9-14.

APPENDIX II - Table II Hill-Bone HBP Compliance Scale – medication taking subscale

No.	Item	Response
		1. None of the Time
		2. Some of the Time
		3. Most of the Time
		4. All of the Time
1	How often do you forget to take your HBP medicine?	
2	How often do you decide not to take your HBP medicine?	
9	How often do you run out of HBP pills?	
10	How often do you skip your HBP medicine before you go to the doctor?	
11	How often do you miss taking your HBP pills when you feel better?	
12	How often do you miss taking your HBP pills when you feel sick?	
13	How often do you take someone else's HBP pills?	
14	How often do you miss taking your HBP for no particular reason?	

HBP=high blood pressure.

APPENDIX III

QUESTIONNAIRE ON REASONS FOR NON –ADHERENCE

1. What do you understand by high blood pressure?

      Probes: How does high blood pressure affect you?

            What do you think is the cause of high blood pressure?

2. What does taking drugs mean to you?

      Probes: How long do you have to take the drugs?

            Are the drugs beneficial?

3. We understand that there are times when one is not able to take their drugs for various reasons. What are some of the reasons for not having taken your drugs from time to time?

      Probes: Side effects

            Cost

            Availabillity

            Convenience

            Relief of symptoms

            Worsening of symptoms

            Pill burden

4. What would help you take your drugs?

5. There are other treatments that are used for high blood pressure. do you know of any and have you used any of these?

I'm Dr Loice Achieng, a post-graduate student in the Department of Medicine, University of Nairobi.

We are conducting a study at the Kenyatta National Hospital to assess the control of blood pressure in patients with hypertension and to evaluate the level of adherence with antihypertensive drugs. We acknowledge that patients may fail to take their medication from time to time and as part of this study we shall be evaluating the reasons for this.

The purpose of this study is to generate information that will help us improve the management of hypertensive patients at this hospital.

You will be required to answer a number of questions regarding your medication and some of the reasons that may cause you not to take your medication sometimes. We will also ask you a few questions about yourself. We will record your blood pressure, weight, height, hip and waist circumference. We may require to tape record some of the answers you give us, all such recordings will be destroyed after the information is transferred into text.

The results obtained from this study will be entered into your file and will also be made known to you. During analysis of the results, your name will not be revealed and all information will remain confidential.

We would appreciate your participation in this study. Should you choose not to participate in the study, you will receive your care as usual and will not be discriminated against in any way.

Dr Loice Achieng (Principal Investigator)
Tel 0722 576984.

APPENDIX V – CONSENT FORM:

I _____ after having read the consent explanation form and been explained to, do voluntarily agree to take part in this study on **adequacy of BP control, level of adherence and reasons for non-adherence to pharmacologic therapy in hypertensive patients seen at KNH**. I am also aware that I can withdraw from this study without losing any benefits or quality of management of my problem being affected.

Signed _____

Witnessed _____

Dated _____