CLINICAL PROFILES AND ANGIOGRAPHIC PATTERNS OF PATIENTS UNDERGOING CORONARY ANGIOGRAMS IN TWO HOSPITALS IN NAIROBI

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STUDENT'S DECLARATION

I declare that this dissertation is my original work and has not been published or presented for a degree in any other University.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS AND ACRONYMS

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ACS	Acute Coronary Syndrome
ACC	American College of Cardiology
AHA	American Heart Association
AMI	Acute Myocardial Infarction
AIDS	Acquired Immunodeficiency Syndrome
AV	Atrioventricular
BMI	Body Mass Index
CAD	Coronary Artery Disease
CABG	Coronary Artery Bypass Grafting
CAE	Coronary Artery Ectasia
CAG	Coronary Angiography
CCS	Canadian Cardiovascular Society Angina Classification
CHD	Coronary Heart Disease
COC	Corporate Outpatient Centre
CVD	Cardiovascular Disease
DALYs	

DVD	Double Vessel Disease
EQA	External Quality Assurance
HDL	High Density Lipoproteins
HIV	Human Immunodeficiency Syndrome
HRCA	High Risk Coronary Anatomy
IHD	Ischemic Heart Disease
IQC	Internal Quality Control
KNH	Kenyatta National Hospital
LAD	Left Anterior Descending Artery
LCX	Left Circumflex Artery
LDL	Low Density Lipoproteins
LMCA	Left Main Coronary Artery Disease
LV	Left Ventricle
MI	Myocardial Infarction
MS	Microsoft
N-STEMI	Non - St Segment Elevation Myocardial Infarct
NWH	Nairobi West Hospital
PCI	Percutaneous Coronary Intervention
PDA	Posterior Descending Artery
RCA	Right Coronary Artery
RA	Right Atrium
RV	Right Ventricle
SCAD	Spontaneous Coronary Artery Dissection
SSA	Sub-Saharan Africa
SPSS	Statistical Package For The Social Science
SVD	Single Vessel Disease
STEMI	St Segment Elevation Myocardial Infarct
TVD	Triple Vessel Disease
VLDL	Very Low Density Lipoprotein
WHO	World Health Organization

ABSTRACT

Background

An emerging principle threat in Africa is Coronary Artery Disease. Previous studies have focused on the analysis of risk factors of patient undergoing coronary angiography but no study has looked into the angiographic characteristic of this patient populations.

Study objective

The three primary objectives were first to determine the prevalence of angiographically confirmed CAD amongst patients undergoing coronary angiography. Secondly assess the risk factor profile of these patients with confirmed significant coronary artery disease and thirdly to determine the indications and describe the angiographic pattern of CAD in terms of vessel involvement (number and type) and severity of stenosis. The secondary objective was to determine a correlation between the risk factor burden (number of risk factors associated) and the severity of stenosis (number of vessel involved)

Methodology

A descriptive cross sectional study carried out in patients referred for coronary angiography in Kenyatta national Hospital and Nairobi West Hospital. Data on patient socio-demographics, risk factors and indication for coronary angiogram were collected from hospital records while the angiographic characteristics data was collected from analyzing images of coronary angiograms done each week under the expertise of two cardiologists.

Results

Ninety five patients who had been referred for diagnostic coronary angiography in Kenyatta National Hospital and Nairobi West hospital were screened for eligibility. A total of 90 patients were recruited; 44 of patients were from KNH and 46 from NWH. Of these 33(36%) were found to have normal epicardial vessels with no obstructive CAD while 57 (63%) had angiographically confirmed significant CAD with 1 or more obstructive lesion in the epicardial coronary arteries. The mean age of the patients with angiographically confirmed CAD was 57 years (SD 65.2) A male predominance was found with 64.9% of the participants being male resulting in a male to female ratio of 1.85:1. A great number of the participants resided in rural Kenya 39(43.9%) and had a primary level of education 25(43.9%). The prevalence of the risk factors evaluated in the study among patients with angiographically

confirmed obstructive CAD were as follows; Hypertension 50(87.7%), Diabetes 31 (54.4%), Dyslipidemia (56.1%), Smoking 19(33.3%), Obesity 16(28.1%) and family history of Premature CAD 2(3.5%). With respect to indications for coronary angiography, 36% of the patients had history of (ACS) STEMI/N-STEMI with 17.5% having stable angina (CCS class III/IV) and another 17.5% having unstable angina history. Angiographic analysis revealed that 35(61.4%) of the patients had single vessel disease, 15(23.3%) had double vessel disease, 7(12.3%) triple vessel disease and 8(7.2%) had left main disease. In relation to vessel involvement, left anterior descending (LAD) was the most common vessel diseased 40(36%) followed by left circumflex (LCX) 32(28.8%) and RCA 31(27.9%).

Conclusion

The most prevalent risk factor among patient with atherosclerotic CAD was found to be hypertension. Majority of the patients had single vessel disease with the most commonly involved epicardial vessel being LAD. A dose related response was seen where patients with more than three risk factors having more vessel involvement.

CHAPTER 1: INTRODUCTION

Atherosclerosis is an illness distinguished by accumulation of lipids, cholesterol, cellular debris and calcium within the intima of the large to medium sized vessels with associated vascular inflammation and endothelial dysfunction. Coronary artery atherosclerosis is the principal cause of mortality in men and women globally.(1) It is the primary cause of Coronary artery disease (CAD) which results in atherosclerotic changes within walls of the coronary arteries become with time become obstructive and lead to ischemia and infarction of the myocardium. Other rare causes of acute coronary events include coronary artery ectasia (CAE) sluggish blood flow due to aneurysmal CAD), endothelial dysfunction and spontaneous coronary artery dissection (SCAD) (2–4). CAD is a progressive condition whose onset develops in childhood but clinically becomes evident in middle to late adulthood.

Risk Factors

Various risk factors associated with atherosclerosis have been identified and their exact role in the pathophysiology well described. They can be classified based on whether they are modifiable or non-modifiable and include behavioral demographic, familial and physiological characteristics. The non-modifiable factors include age, male gender and a positive family history of premature CAD. Modifiable risk factors can be behavioral (sedentary lifestyle, cigarette smoking and poor diet-rich cholesterol and fat rich or physiological (dyslipidemia, diabetes, obesity, hypertension and post-menopausal status [in women]). The dramatic effectiveness of modifying risk factors as a means of preventing disease has been seen in some of the risk factors. For others, the relationship is less comprehended.

Coronary Angiography

Coronary angiography involves the injection of a radiopaque contrast media in order to visualize the coronary vessels radiographically using specialized intravascular catheters. The purpose of the procedure is to delineate the anatomy of the coronary vessels and the extent of luminal obstruction. The procedure is routinely used to verify existence and degree of obstructive lesions and to assess the eligibility of various management options such as percutaneous or surgical revascularization interventions.

American College of cardiology/American Heart Association Task Force (ACC/AHA) guidelines for coronary angiography is as follows (5)

Class I recommendation:

Acute Coronary Syndromes (STEMI/ NSTEMI: 24-72 hours)

Class I recommendation:

Incapacitating stable angina (Canadian Cardiology Society(CCS III-IV) unresponsive to medical management, unexplained heart failure, high-risk criteria on either clinical evaluation ornoninvasive testing, angina associated with heart failure, premature reoccurrence of angina after intervention, or pre-operative assessment prior to cardiac valve surgery in men older than 35 years; women older than 50 years).

Class II a:

Inability to undertake noninvasive testing, inconclusive stress testing results, and reassessment of recently performed procedures (high restenosis risk lesions, PCI to left main stem).

Class III: Benefit of CAG outweighed by risk of CAG(significant comorbidity) or CCS class I or II()mild angina) amenable to medical therapy

CHAPTER 2: LITERATURE REVIEW

Epidemiology of CAD

Cardiovascular disease (CVD) is the principle killer in adults responsible for over 17.3 million fatalities annually as of 2013 with this anticipated to rise to 23.6 million by the year 2030. (1) 7.3 million of the 17.3 million fatalities were due to coronary heart disease (CHD) while stroke attributed to 6.2 million. A disproportionate contribution by low to middle-income countries to the universal burden of CVD has been seen with 80% of CVD deaths occurring in these countries. With reference to adjusted years of life lost, developing countries have 2.8 times greater CVD prevalence compared to developed countries. (6)

The prevalence of CHD is encouraged by a high preponderance of cardiovascular (CV) risk factors, of note dyslipidemia, hypertension, diabetes, smoking and sedentary lifestyles. In the Middle East and Africa, patientswith myocardial infarction present at a younger average age, compared with patients in other regions. The predicted mortality burden from CHDthe Middle East and Africa is expected to overtake that seen in other regions. Essential in preventing this is, is promotion of healthier lifestyles in patients, albeit cultural and environmental barriers that still exist in the region. In addition, appropriate medical management is key in the curbing CVD. (6)

Developed countries have observed a decline in the CVD epidemic over the years as a result of these strategies. In addition, the major CV risk factors have been identified through landmark studies like Framingham and INTERHEART. As a result of these studies, effective control and treatment measures have been taken in individuals at high risk thus contributing to the fall of CVD mortality in most of these countries (7)

Sub Saharan Africa (SSA) countries, that are currently undergoing rapid epidemiological transitions, are however facing a twofold encumbrance of not only communicable but also non-communicable diseases. Increasing urbanization and change in lifestyle are two factors promoting this. It is therefore not surprising that there is a predicted increase in the age standardized mortality rate of IHD by 70% in men and 74% in women in Africa by the year 2030. (8)

In Kenya, non-communicable disease accounted for 27% of all mortality with CVD being the cause of 8% of all deaths.(9) According to WHO's May 2014 data, CHD deaths in Kenya were responsible for 2.74% of total deaths.(10)

Epidemiology of CAD risk factors

The Framingham Heart Study is one of the landmark studies that has been key in identification of the cardinal risk factors of CHD. INTERHEART study found nine modifiable risk factors were responsible for more than 90 percent of the population-attributable risk of an initial MI and that these factors do not differ between people of varying ethnic and geographical origin. These nine protective or risk factors were easily measured and included hypertension, diabetes, obesity, diet, exercise, current smoking, psychosocial factors, dyslipidemia (ApoB/apoA1 ratio) and alcohol consumption. Globally all nine risk factors were significantly associated with AMI except alcohol. (11)

Age and Gender

According to the Framingham Study, the incidence of all coronary events increases sharply with age, however they found that women lagged men by 10 years. This was like what the INTERHEART study found. (11) Men and women older than 40 years of age had the lifetime risk of 35% and 24% respectively. When compared, the incidence in persons aged 65 to 94 years vs 35 to 64 more than doubles in men and triples in women. (12)

A cause of concern other than the high CVD death burden in developing countries is the early age of the CVD compared to developed countries. INTERHEART Africa study found that the mean age of Myocardial infarction in Africa was 54.3 years; 3.8 years earlier than the overall INTERHEART study. It also found Acute myocardial infarction (AMI) risk increases with higher income and educational background in the black population. (11) A local study conducted by Ogeng'o et al supported this finding in our setup. The study found that 30% of the patients who had AMI were less than 50 years old. (13)

Hypertension

Hypertension is a major independent CAD risk factor that is progressively becoming a public health concern. In 2001, hypertension was approximated to have resulted in 7.6 million early fatalities (13.5% of the total) and accounted for 92 million disability adjusted life years.(14)Other than HIV/AIDS, the African union declared hypertension to be one of the

continent's most significant health challenges thus making it the most influential CV risk factor in Africa. The issue is worsened by unawareness, frequent under-diagnosis, sub-optimal control and the severity of its complications. In Africa, 40% of hypertensive patients are undiagnosed, less than 30% of those diagnosed are on treatment and less than 20% of those on treatment have optimal control (<140/<90 mmHg. (14) Various local studies conducted in Nairobi slums have found similar findings with high prevalence of hypertension compounded by low levels of awareness, treatment and control.(15–18) As a risk factor to myocardial infarction, the INTERHEART African study arm found that among the risk factors, hypertension played a bigger impact. Various local studies have found a similar finding in our set up. A study by Kimeu et al on assessment and outcomes of AMI patients in Nairobi Hospital found that among patients under study with STEMI and NSTEMI, hypertension was the leading risk factor at 71.9% (19)

Diabetes

Diabetes is an independent risk factor for CVD and contributed for about 60 per cent of all deaths in patients with diabetes. Diabetes confers two to three times more risk CV events with a disproportionately higher risk in women. (20) Worse still, when compared to people without diabetes, people with diabetes had poorer prognosis. (21)

In 2014, WHO estimated that, worldwide, 422 million adults (over 18 years) were diabetics. (22) In Africa, approximately 14.2 million people between the ages of 20-79 have diabetes translating to a 2.1-6.7% regional prevalence. Furthermore, with morethan two-thirds (66.7%) of people with diabetes unaware of their diagnosis, Africa has the highest proportion of undiagnosed diabetes. With improved life expectancy and increased urbanization in Africa, type II diabetes will present a constantly expanding threat. Worse still, the number of people living with diabetes in the regionis expected to be 34.2miilion by 2040 which is more than double the number estimated in 2015. (23)In Kenya, the prevalence of Diabetes ranges from 2.2% to 12.4% in urban populations. (24)

Tobacco Use

Worldwide, there are about 1 billion smokers currently. An estimated 10% of all CVD is due to smoking and the risk is higher in heavy smokers, female smokers and young men. (20) However, the risk of CAD is significantlydecreased within 2 years of quitting and after 15 years, the CVD risk reverts to that of a non-smoker. (25)

The prevalence of smoking in women in most sub-Saharan countries is below 2% with only Namibia and South Africa having higher rates of 5.9% and 5.5% respectively. Urbanization however has resulted in an increased trend in young women. Prevalence rates among men on the other hand is 20-50 times higher. (26)

In Kenya the prevalence of smoking is 13% (9) Its higher prevalence in men is similar to finding of studies in SSA. One study in Kenya conducted in a rural setting found that there were three times more men than women smokers.(27) It is the commonest risk factor for ACS in an Egyptian cohort of patients, (28) but was found to be the third most common risk factor at 35.9% in a study on ACS in Nairobi Hospital. (19)

Dyslipidemia

Risk of heart disease and strokes is increased by raised blood cholesterol. Worldwide, dyslipidemia accounts for a third of IHD (20) Hyperlipidemia especially a combination of increased very low-density lipoproteins (VLDL), LDL with associated decreased HDL promotes atherogenesis. Low HDL level is the most commonly found lipid abnormality found among Kenyan subjects. (24)

Obesity

According to Framingham Heart study, obesity was found to be a significant predictor of CVD particularly in women.(29) It is strongly associated to other principal CV risk factors.(20) Overall prevalence in Kenya is 4.2% (9) It has been observed, like in many other studies in SSA, that women in Kenya have a disproportionally higher prevalence than in men with almost 60% of them being either overweight or obese. (15)

Physical Inactivity

It is defined as participating in fewer than five times weekly moderate activity lasting 30 minutes, or less than three times weekly vigorous activity of 20 minute duration, or equivalent.(20) After adjusting for confounding effects of traditional risk factors studies have found insufficient physical activity to be an independent risk factor for CAD.(30) Its contribution to coronary artery disease is through various physiological mechanisms but mainly through its negative effects not only on glucose and lipid metabolism but also on blood pressure.

It is reported in Africa that men have higher levels of physical activity than women which is an observation that closely mirrors the reported prevalence of obesity.(8) In Kenya, no studies have been conducted on physical activity but with rising urbanization and increased automation, the prevalence is thought to be on the rise.

Unhealthy diet

Diet, which varies greatly in different parts of the world, is an important modifiable CVD risk factor with the increased risklinked to high intake of trans-fatty acids and saturated fats which when eliminated and replaced by polyunsaturated vegetable oil lowers it. In addition, diet rich in vegetables and fruits has been linked to reduced risk of CVD. (11)

Increased salt intake is acrucial causal factor of blood pressure level and general cardiovascular risk. World Health Organization's recommendation is<5grams/person/day to help prevent CVD. Furthermore, INTERHEART study found that intake of unhealthy diets heightens the risk of AMI globally and accounts for 30% of the population-attributable risk (11)No local data exists on the prevalence of dietary patterns and its effect on cardiovascular health

Family history of Premature Atherosclerosis

It is an independent risk factor for CAD, especially among younger persons.(31) The definition of which is a death from CHD or a myocardial infarction(MI) in a parent or sibling before to the age of 50 years in males and 60 years in females.(32) The significance of family history has been demonstrated in numerous large cohort studies and all revealed a history of premature CAD is linked to greater risk of developing CHD.[(11) (9)] A local study done by Kimeu et al found that 8% of the patients investigated for AMI, had a documented family history of premature coronary artery disease (19)

Pathophysiology of Coronary artery disease

CAD is largely caused by atheromatous plaque occlusion of the vessel. A mature plaque is made up of two components: a lipid core and a connective tissue matrix (CTM). The latter core consists mainly of cholesterol and cholesterol esters released from of necrotic foam cells (monocytes derived macrophages) that release ingested lipids. The CTM originates from smooth muscle cells, which like the macrophages movefrom the media to the intima where they form a protective fibrous capsule surrounding the lipid core.

Stable CAD results from blood flow reduction through the coronaries during physical activities(exertion). This is a consequence of a plaque producing a 50% or more stenosis or cross-sectional area reduction of75% or more. On the other hand, acute coronary events usually arise when a clot is formed following damage of the fibrous plaque with exposure of the thrombogenic matrix. Embolism of a thrombus embolism can result in micro infarcts downstream. (33)

Anatomy and function of the coronary vessels and the clinical significance of occlusion

Coronary arteries course through the epicardial surface of the heart to avoid compression by the cardiac muscle during contraction. The major epicardial vessels in the heart include the right and left coronary arteries. The left coronary system consists of the left main artery (LMCA) that divides in the left anterior descending (LAD) artery and the left circumflex artery (LCX).

Left Coronary System

1.6.1.1 Left Main Coronary Artery (LMCA)

The vessel originates from the left coronary cusp and bifurcates almost immediately into the LAD and LCX. It courses between the outflow tract of the right ventricle (RV) anteriorly and the left atrium (LA) posteriorly. A third branch arises, in 15% of cases, between LAD and LCX known as the Ramus Intermediate. Significant LMCA disease (defined as angiographic narrowing greater than 50%) is the highest-risk lesion subset amid the different types of anatomic obstructiveCAD and is found in 4 to 6 percent of all patients who have had

coronary arteriography. It is linked with worse outcomes compared with non-LMCA CAD and with multi-vessel coronary artery disease in about 70 percent of the time (34)

Left Anterior descending artery (LAD)

It runs anterior to the anterior interventricular (IV) groove, extends to the apex of the heart from the base, and gives rise to two sets of branches - the septal branches and the diagonal branches. Thediagonal branches course over the anterior aspect of the left ventricle and are numbered Diagonal 1(D1), Diagonal 2 (D2) onwards while the septal branches are numbered S1, S2 onwards, go and perforate the IV septum to supply the anterior two thirds of the septum. LAD at the apex anastomoses with the terminal branches of the posterior descending artery (PDA), which is usually a branch of the RCA.

Atherosclerosis of the LAD causes a myocardial infarction involving the apical, anterior and septalsegments of the heart muscles leading to deterioration of the cardiac function. Typically, such a lesion if not vascularized will compromise the left systolic function and reduce the overall Left Ventricular Ejection Fraction to at least 35-40% (35)

1.6.2.1 Left Circumflex Artery (LCX)

It rests in the left AV groove and supplies the lateral wall vessels of the left ventricle known as the obtuse marginals (M1, M2 and so forth) and are named so by virtue of supplying the lateral margin of the LV and branch off at an obtuse angle. In majority of cases, the LCX terminates as an obtuse marginal, but in 10% of the patients, theLCX also supplies the posterior descending artery (PDA)resulting in left dominant circulation. (36)

Right Coronary Artery

It emerges from the anterior sinus of the Valsalva and courses through the right atrioventricular (AV) groove to the inferior aspect of the septum. A sinus node artery arises as a second branch of the RCA, in 60% of cases. In the rest (40%), the sinus node branch originates from the LCX. Subsequent branches are diagonals that supply the anterior wall of the right ventricle's anterior wall. The RCA continues in the posterior aspect of the AV and gives off a branch to the AV node. The PDA, in sixty-five percent of cases, is a branch of the RCA. The PDA supplies the left ventricle's inferior wall and inferior part of the septum.

It provides the main blood supply to RV, RA and variable portion of the diaphragmatic surface of the left ventricle and the interventricular septum. (36)

Invasive Coronary Angiography

The gold standard modality used in CAD diagnosis is invasive coronary angiography. According to the 2015 ESC guidelines, its pivotal role is maintained in the management of NSTE-ACS. In this group of patients, it enables confirmation of diagnosis of ACSand therefore guide antithrombotic treatment. (37) It allows recognition of the culprit lesion(s) and determine the indication for revascularization (PCI or CABG). It finally allows stratification of patient's long term and short-term risk.

Pattern of CAD in patients with NSTE-ACS varied and range from normal coronaries to a coronary artery tree that is diffusely and severely diseased. As much as 20% of patients have no lesions or non- obstructive ones while 40-50% of those with obstructive CAD have multivessel diseases. (38)

Various angiographic studies undertaken have looked onto the pattern of CAD in varying population groups depending on age, gender and risk factor type and number associated to determine the prevalence, extent and severity of CAD based on the population under study.

1.7.1.1 Angiographic studies on age and the effect on the pattern of disease

In support of the Framingham study, one particular study conducted by Loaldi et al done on 2,234 patients with clinically suspected CAD but free of major modifiable risk factors, confirmed that coronary vessels remain prone to the aging effect in both genders even after adjusting for the influence of other risk factors.(39) In addition, it found that between the 4th to 8th decade of life, women had a significantly higher prevalence of normal angiogramshowever with aging, there was narrowing of the gender gap in triple-vessel disease, but did not disappear.

Another study done to compare the pattern of CAD among different age groups concluded that young age (<40 years) was associated with less extensive disease with relative scarcity of left main coronary involvement and high incidence of angiographically normal vessels. (40). In addition, a study done on a young adult population found that by and large the common risk factor in this age-group were obesity, dyslipidemia and smoking all of which are modifiable. Further, it found that the prevalence of SVD and STEMI presentation were higher amongst the young population. (41)

1.7.1.2 Gender differences in angiographic pattern of disease

Pertaining to gender, several studies have looked into the sex related differences in angiographic characteristics. A study on the gender differences in prevalence, severity and composition found that men had a disproportionately higher prevalence of any obstructive CAD compared to women. Similarly, another study found that women are more likely to present with non-significant stenosis (<50%) or angiographically normal coronaries. They also were more prone to having SVD while men were more prone to having double vessel disease (DVD).(42) Likewise, another study focusing on the pattern and prevalence of CAD in women found that elderly women had a higher prevalence of obstructive CAD especially DVD and TVD while the younger women had normal coronary angiographs. (43)

When gender, age and risk factors are considered, one study compared premenopausal to postmenopausal women and found that the former compared to the latter had less CV risk factors. However, premenopausal women had more frequent SVD involving proximal LAD and presented with more severe symptoms. (44) Postmenopausal women with diabetes were investigated for severity of CAD and the study concluded that these women develop more severe CAD compared to nondiabetic women. The associated was independent of other risk factors and suggested an independent effect of Type II diabetes on the atherosclerotic process.

1.7.1.3 Angiographic studies correlating risk factors number and pattern of disease

One angiographic study sought out to determine the correlation of risk factor number and the angiographic finding and the results were that increasing cardiovascular risk factors were associated with a higher prevalence, extent and severity of CAD with persons with more than three risk factors manifesting a dose response increase.(45)

1.7.1.4 Effect of diabetes, obesity and family history of premature CAD on the angiographic pattern

Relating to the association of specific risk factors with the pattern of CAD on angiographic studies the most common risk factor studied is Diabetes. The overwhelming finding is that diabetes has been found to be an independent risk factor to severe CAD in which case it confers multiple vessel involvement, more left main CAD and significant artery stenosis(39,46) With reference to Obesity, it has been found that after adjustment for comorbidity, it is not an independent predictor of severity of CAD.(47) In fact, another study looking at the relationship between BMI(obesity) and high risk coronary anatomy(HRCA)

(defined as Left Main coronary artery disease stenosis >50% and/or significant CAD in other epicardial vessels) and disease extent found that obese patients were younger and had greater prevalence of diabetes, dyslipidemia and hypertension. Interestingly, patients with obesity had had less HRCA. (48) In addition, obese patients are sent for Coronary angiograms at an earlier age and thus have a lower CAD burden. Family history of premature CAD has been found to display some heritability pattern regarding proximal stenosis of vessels, particularly left main CAD. The investigators concluded that advancing age, male gender, diabetes mellitus and hyperlipidemia were independent predictors of HRCA. (49)

Various local and international studies have described the risk factors of patients with coronary artery disease. (39) In our setup, however no study has addressed the clinical profile and angiographic characteristic of this patient population. What we aimed with this study is to profile the patients with CADwith respect to socio-demographics, risk factors and angiographic characteristics.

CHAPTER 3: STUDY JUSTIFICATION

Coronary angiography remains the gold standard test in confirming CAD. More patients are now able to have the procedure done due to improvement in accessibility as well as affordability. Several studies conducted locally have identified cardiovascular risk factors profile in our population, but no study has focused on the angiographic characteristics of CAD, particularly the severity. Severity of CAD has an impact on the patient prognosis; affect the type of intervention offered and can contribute to technical difficulties during the procedures. This study aimed to determine the prevalence of, and risk factor associated with coronary artery disease amongst patients who have had coronary angiography, determine the severity of CAD and correlate the angiographic characteristics with the risk factor burden in our population. This knowledge can then be used to inform policy on need for aggressive preventative strategies of CAD by proper prevention and management of the diseases that predispose to it. Furthermore, drive the agenda for increasing the number of hospitals proficient in the diagnosis of CAD and its management.

CHAPTER 4: STUDY METHODOLGY

Research Question and Hypothesis

I. What is the risk factor profile and severity of Coronary artery disease amongst our patient population?

Objectives

Primary objectives

I. To determine the prevalence of angiographically confirmed CAD amongst patients undergoing coronary catheterization in KNH and Nairobi West hospitals.

II. To determine the prevalence of risk factors of patients with angiographically confirmed CAD

III. To determine the angiographic characteristics (vessel involvement and severity of obstruction) of patients with angiographically confirmed CAD

Secondary objective

Correlate the risk factor burden (number of associated risk factors) with the severity of the CAD with regard to severity of stenosis (single vessel, double vessel and triple vessel disease)

Study design

A descriptive cross- sectional study

Study setting

The study was conducted in two centers simultaneously, the Kenyatta National Hospital (KNH) and Nairobi West Hospital (NWH) catheterization laboratories in Nairobi. KNH is the largest referral facility in Kenya with an 1800-bed capacity and a teaching hospital for the University of Nairobi. NWH is a privately-owned facility that has a 200-bed capacity. The KNH catheterization laboratory is part of the Cardiology department and has one catheterization suite shared between the adult and pediatric patients. The two laboratories receive their adult patients referred for the procedure from outpatient cardiac clinic and he medical wards. The cardiac clinic every Tuesday morning in both KNH and NWH. On

average 5-7 patients, undergo the procedure each week in KNH while in NWH the average is 10-12. Personnel in both laboratories is similar with physicians in charge of the procedure (interventional cardiologists), catheterization laboratory trained registered nurses that administer medication and monitor patients before and after the procedure, a radiologic technician who is responsible for the equipment. The major pieces of equipment in the laboratories are for three integral functions: monitoring, imaging, and data archival. An oscilloscope used for monitoring heart rhythm and other vital physiologic events like blood pressure. Under imaging, image intensifiers that always allow adequate visualization of the catheters and patients, connected to a monitor to allow other staff to monitor the course of the catheters during the procedure. Contrast angiocardiography that permits rapid injection of the contrast media as well as simultaneous filming of the events to allow rapid playback of the procedure. Computers with data/image archival systems are also available in both laboratories that allow storage of images as well as printing of the same in CDs in addition to report writing for the findings of the procedure.

Study population

Adult patients referred for coronary catheterization in KNH and Nairobi West hospital.

Inclusion criteria

The participant must fulfil the following criteria: -

- Have undergone coronary angiography
- Age >35 years of age
- Provide an informed consent

Exclusion criteria

- Age < 35 years of age
- Patients without informed consent

Sample size calculation

The sample for this study was drawn from a population accessible to the investigator in the 6 months of the study. A review of the hospital records prior to the study showed an estimated number of 10-15 eligible patients per month in both hospitals. Therefore, if 90 eligible

patients will be accessible in 6 months, the sample size was determined using a sample size formula for cross sectional studies with finite population correction (Arya, Antonisamy, & Kumar, 2012).

$$n' = \frac{N(z^2)P(1-P)}{(d^2)(N-1)+(z^2)P(1-P)}$$

Where:

n' = Sample size

N = Estimated number of accessible populations = 90

Z = Z value (1.96 at 5 % type 1 error [P < 0.05] at 95% confidence level)

P = Expected proportion of angiographic findings in patients undergoing coronary angiography 45%. (50)

d = Desired margin of error = 5 %

Substitution into the formula gives the sample size as 73.

Sampling Method

Consecutive sampling was done until a sample of 90 was reached

Screening, Recruitment and Study Activities

Patients referred for coronary angiography at KNH and NWH were screened for eligibility. Persons above the age of 35 undergoing coronary angiography were taken through the process of informed consent by the research assistants and/ or the primary investigator. Once consent was granted, patients were recruited into the study.

Socio-demographic and Risk Factor Assessment

Baseline socio-demographics and risk factors data was collected in a data collection sheet from the patient's files. Conventional risk factors of interest in the study will include hypertension, diabetes mellitus,obesity, smoking dyslipidemia and family history of premature CAD as defined by operational definitions were assessed. To assure accuracy in assessment of risk factors, certain procedures were undertaken in addition to the vital signs

done before the procedure. Anthropometric measurements of weight and height were taken using a weighing scale and a measuring stick respectively to assess Body mass index (BMI). A fasting blood sugar was taken, and assessment of lipid profiles done in reputable laboratories that had been done within 2 weeks of the procedure was assessed in patients who were not on statins therapy were deemed acceptable. Once their risk factors were established, patients were stratified into three groups according to the number of risk factors associated [risk factor burden (zero to one, two to three and four or more)]. This was then used to correlate the risk factor burden with severity of CAD regarding severity of stenosis.

Coronary angiography

Indications for the coronary angiography of interest in the study were classified as stable angina, unstable angina and myocardial infarction. The procedure was performed under local anesthesia by trained cardiologists whereby a catheter was inserted in the femoral or radial artery depending on cardiologist's preference using the Seldinger approach. The tip of the catheter advanced to the aortic sinus cusp and the contrast dye injected with images of the transient distribution of the radio-contrast within the coronary arteries done to visualize the arterial tree.

Coronary Angiogram Reporting

Images saved from the weeks' procedures were visually assessed by two trained cardiologists independently and the primary investigator. Obstructive CAD was defined as a stenosis of at least 50% of LMCA or at least 70% of at least one of the major epicardial coronary arteries. Non-significant lesion was defined as stenosis of less than 30%of any epicardial artery. Intermediate lesion was defined as a stenosis of 30–50% of LMCA, or 30–70% of one of the major epicardial arteries. Classification as SVD, DVD and TVD dependingon the number of major epicardial arteries involved was done. LMD was defined as at least 50% stenosis of luminal diameter of LMCA. Diagnosis of CAD will be made in those with >50% stenosis inmore than one epicardial coronary segments. Once CAD diagnosis was made, patients were categorized as havingSVD, DVD or TVD according to the number of vessels involved. Stenosis of the vessel (degree of obstruction) was estimated as a percentage of the arterial lumen narrowed compared to an adjacent normal artery and will be categorized as mild (<50%), moderate (50-69%) and severe (>70%). Differences in the angiographic reports made independently by each cardiologist was resolved by consensus.

Study Variables

Risk factors

Non-modifiable risk factors

Age and Gender: Age >45 years for males and > 55 years in women (12)

Family history of premature heart disease: defined as Ischemic heart disease in the father or brother diagnosed before the age of 55 years and in the mother or a sister diagnosed before the age of 65 years. (32)

Modifiable risk factors

Hypertension: defined as long-term use of anti-hypertensive medication or a previously recorded blood pressure reading >140/90 mmHg (51)

Diabetes: defined as long-term use of antidiabetic medication or previously recorded diagnosis from medical files or confirmed during an admission by fasting blood glucose estimations to be > 7mmol/L or random blood glucose estimation >11.1mmol/L (52)

Smoking*:*

According to the CDC (53) the smoking status definitions as follows: -

- **Current smoker:** An adult who in his or her lifetime has smoked 100 cigarettesand who currently smokes cigarettes.
- **Never smoker:** An adult who in his or her lifetime has never smoked or who has smoked less than 100 cigarettes.
- **Former smoker:** An adult who in his or her lifetime has smoked at least 100 cigarettes but who had quit smoking at the time of interview.

Dyslipidemia: defined as patients who were taking lipid-lowering medication or total cholesterol (TC) ≥6.20 mmol/L), Low density lipoprotein (LDL-C) ≥4.15mmol/L or High-density lipoprotein (HDL) ≤0.90 mmol/L (54).

Obesity: Defined by WHO as a BMI greater than or equal to 30kgs/m^2 (55)

Quality Control and Assurance

The primary investigator and research assistants recruited the study population from the catheterization laboratories in the two hospitals. Subsequently, in addition to baseline vitals, anthropometric measurements were carried out by the primary investigator and research assistant in all patients. The lipid profiles from the patient files were deemed acceptable if they had been done within 2 weeks of the procedure and assessed in biochemistry laboratory of either Kenyatta National Hospital or Nairobi West hospital for standardization.

Quality assurance of the biochemistry laboratories in KNH and NWH is usually done with an intention to achieve reliable results by accuracy and precision. The quality assurance programme involves external quality control and internal quality control (IQC). IQC checks were performed daily in both laboratories to ensure precision of the laboratory lab work. It includes measurement on specially prepared materials and repeated measurements on routine specimens. There is also Inter-laboratory quality assurance that is done on a biweekly basis between Renal, Corporate Outpatient Centre (COC) and lab number 16). On a monthly basis, External Quality control and is done by International accredited Quality assurance body based in United Kingdom and is involved with the analytical part of the test.

The primary investigator and the two cardiologists independently visually assessed the coronary angiograms images saved to assess the characteristics. Any controversial diagnosis or characteristics was discussed by the two cardiologists and based on consensus a final decision was made.

Data Management and Analysis

Data was keyed into two tools

- A hard copy Study Pro-forma.
- Keyed into a MS access database.

Data captured forms was stored and shall remain available for scrutiny. Double data entry technique was used to enter data into MS Access. Data verification, cleaning and validation was done in MS Excel. Copies of all data are archived, and the data analysis was done using Statistical Package for the Social Sciences (SPSS) version 21.0.

Statistical Analysis

The study population was described using demographic characteristics by summarizing categorical variables such as gender into percentages and continuous data such as age into means with standard deviations. Prevalence of CAD risk factors were analyzed and presented as percentages with 95% confidence interval. Indications of angiography and angiographic characteristics were presented using percentages. Number of Risk factors associated to each patient were associated with the patterns of angiographic characteristics using chi square test. Odds ratios were presented as estimates of risk ratios associated with the risk factors. All statistical tests were interpreted at 5% level of significance (p value equal to or less than 0.05).

The study findings were organized into graphs and tables where necessary.

Ethical Consideration

The Department of Clinical Medicine and Therapeutics and the Kenyatta National Hospital / University of Nairobi Ethics and Research Committee will undertake this study only after approval. Enrolment into the study will be voluntary after obtaining written informed consent (Appendix 1 and 2). Participants then were assigned a study number at enrollment for anonymity and this was used to identify them for all matters relating to the study. Information gathered from the study participants including data forms were kept confidential. All the raw data forms such as the study pro-forma are being stored under lock and key, with the principal investigator being the chief custodian.

The patients recruited in the study were the ones already scheduled for coronary angiography testing. Therefore, no additional risk was imposed on the patients other than RBS and lipid profile blood sampling were done under the WHO guidelines on drawing blood (56)

CHAPTER 5: RESULTS

Between May to October 2018, 95 patients of the patients referred for diagnostic coronary angiography in Kenyatta National Hospital and Nairobi West hospital were screened for eligibility into the study. A total of 90 patients were recruited with 44 of patients from KNH and 46 from NWH. Of these 33(36%) of the patients were found to have normal epicardial vessels with no obstructive CAD while 57 (63%) had angiographically confirmed CAD with 1 or more obstructive lesion in the epicardial coronary arteries.

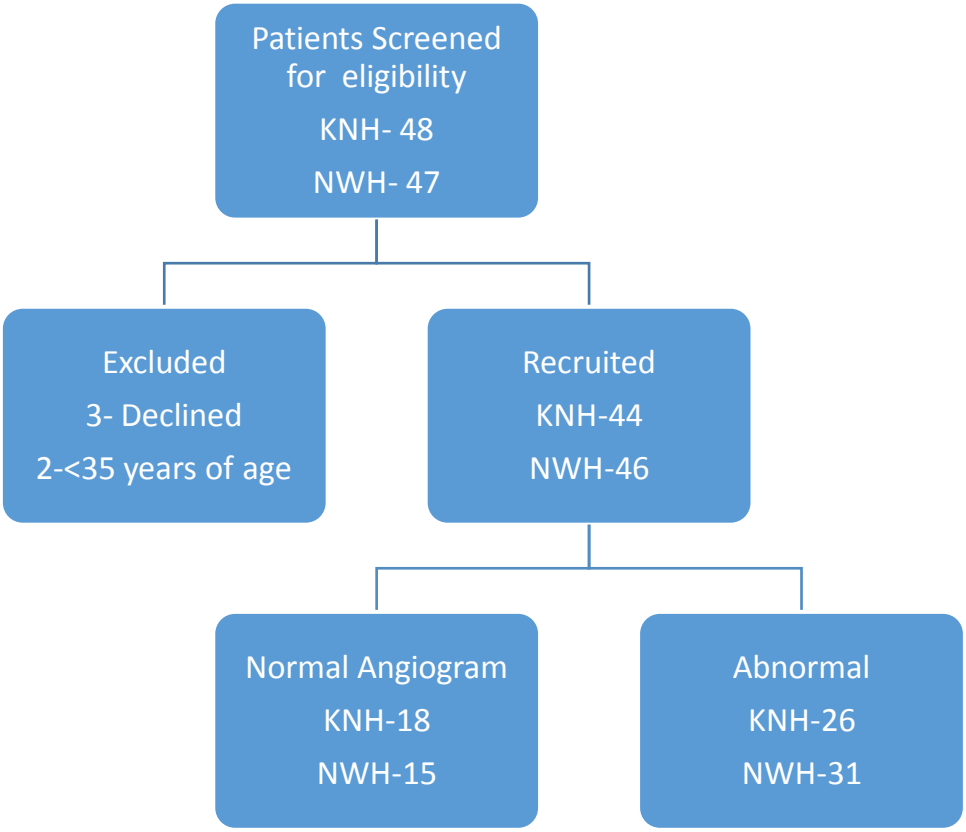

Figure 1: Flow chart of patient screening

2

Patient Demographics

The mean age of the patients with angiographically confirmed CAD was 57 years (SD 65.2) with the youngest participant aged 37 years while the oldest was 89 years. Majority, (29.8%), of the patients were in the 6th decade followed closely by the patients in the 8th and 7th at 28.1% and 26.1% as depicted in Figure 2 below. There was male predominance of 64.9 of the participants, resulting in afemale to male ratio of 1:1.85. A great number of the participants resided in rural Kenya 39(43.9%) and had a primary level of education 25(43.9%). Baseline characteristics of those with angiographically confirmed CAD are summarised in table 1.

Table 1: Demographic characteristics of patients with angiographically confirmed coronary artery disease (CAD)

Variable	Frequency n (%)
Mean age(SD)	57(65.2)
Gender	
Male	37 (64.9)
Female	20 (35.1)
Level of Education	
Primary	25 (43.9)
Secondary	20 (35.1)
Tertiary	12 (21.1)
Residence	
Urban	18 (31.6)
Rural	39 (68.4)

3

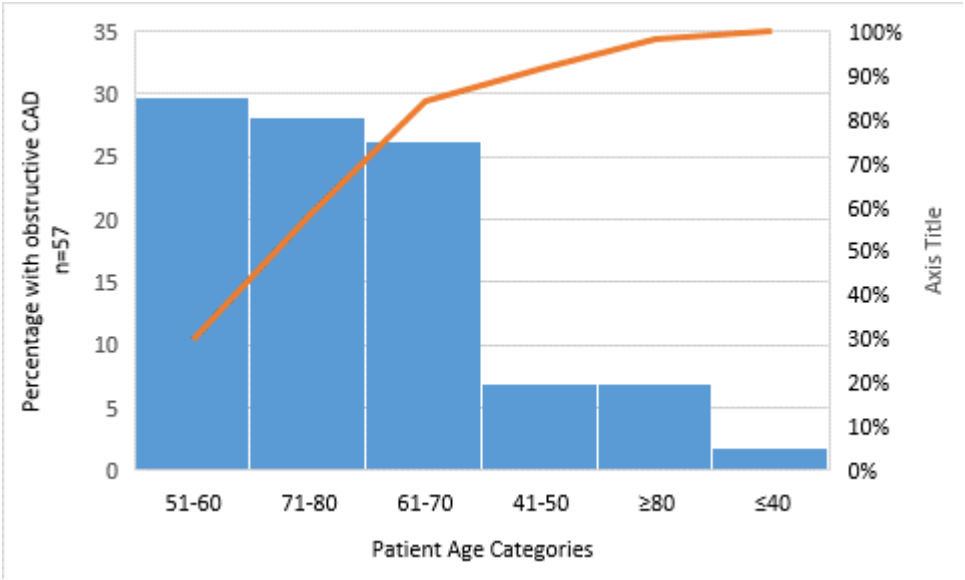

Figure 2: Age distribution of significant obstructive CAD

Risk Factors

The prevalence of the risk factors evaluated in the study among patients with angiographically confirmed obstructive CAD were as follows; Hypertension 50(87.7%), Diabetes 31 (54.4%), Dyslipidemia (56.1%), Smoking 19(33.3%), Obesity 16(28.1%) and family history of Premature CAD 2(3.5%). A summary of the above figures are as seen below in table 2.

Table 2: Prevalence of risk factors amongst patients with angiographically confirmed Coronary artery Disease (CAD)

Risk Factor	Frequency n (%)
History of PCAD	2(3.5)
Smoking	19(33.3)
Hypertension	50(87.7)
Diabetic	31(54.4)
Dyslipidemia	32(56.1)
Obesity	16(28.1)

Angiographic characteristics

The prevalence of obstructive CAD is 63.3%% of the patients undergoing coronary procedure in our study. With respect to indications for coronary angiography, 36% of the referred patients had history of STEMI/N-STEMI with 17.5% having stable angina and another 17.5% having unstable angina. Angiographic analysis revealed that 35(61.4%) of the study patients had single vessel disease, 15(23.3%) had double vessel disease and seven (12.3%) had triple vessel disease. Left Main Disease which was defined to be significant >50% was present in 8(7.2%) of our study population. In relation to vessel involvement, left anterior descending (LAD) was the most common vessel diseased 40(36%) followed by left circumflex (LCX) 32(28.8%) and RCA 31(27.9%).

Table 3: Angiographic characteristics of patients with angiographically confirmed Coronary artery disease (CAD)

Indication for coronary angiography		**Number (%)**
	Stable Angina	10(17.5)
	Unstable Angina	10(17.5)
	Myocardial Infarction	36(63.2)
	Others	1(1.8)
Angiographic Findings	Single Vessel Disease	35(61.4)
	Double Vessel Disease	15(23.3)
	Triple Vessel Disease	7(12.3)
	Left Main Coronary Artery	8(7.2)
Stenosis categories	Mild (<50%)	4(4.1%)
	Moderate (50-69%)	17(17.3%)
	Severe (>70%)	77(78.6%)
	Mean stenosis(SD)	82(18.7%)

Patients were classified according to the number of cardiovascular risk factors they had into groups of 0-1, 2-3 and >3 risk factors. Most of the patients had 2-3 risk factors 28 (49.1%). Amongst the lesions the Triple vessel disease was seen mostly in patients with more than 3 risk factors at a prevalence of (71.4%).

Table 4: Correlation between the number of risk factors and severity of CAD (number of vessel involved)

Risk factor stratification(no. of risk factors associated)	Single vessel disease (SVD)	Double vessel disease (DVD)	Triple vessel disease (TVD)	P Value
0-1	2(100.0)	0(0.0)	0(0.0)	0.014
2-3	23(82.1)	3(10.7)	2(7.1)	
>3	11(40.7)	11(40.7)	5(18.5)	

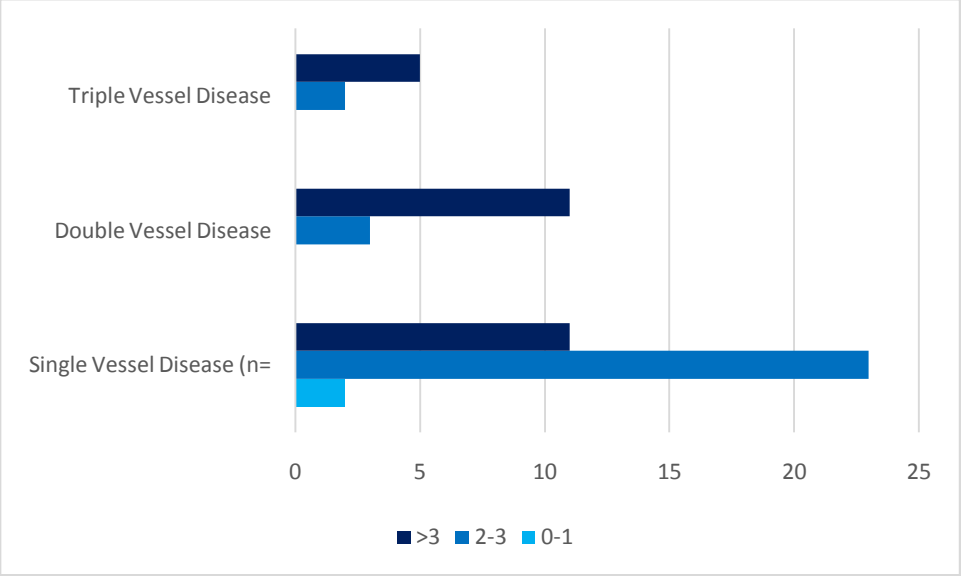

Figure 3: Relationship between number of risk factors and the severity of CAD (number of vessels involved)

CHAPTER 6: DISCUSSION

Cardiovascular disease (CVD) is the principle cause of death in adults acc for responsible for over 17.3 million fatalities annually as of 2013 with this predicted to rise to 23.6 million by 2030.(1) A disproportionate contribution by low to middle-income countries to the global CVD burden has been seen with 80% of CVD deaths occurring in these countries. (6)

A cause of concern other than the high burden of CVD death in developing countries is the early age of the CVD compared to developed countries. The mean age of the patients with angiographically confirmed CAD in our study was found to be 57 years (SD 65.2). This is comparable with a study on black Africans undergoing coronary angiography in Nairobi Hospital by Kamotho et al which found the mean age of the population under study was at 54.4years.(57) Similarly INTERHEART Africa study which was conducted in fifty two countries worldwide, looked into nine modifiable risk factors of MI found the mean age at 54.3 years.(52)

in our study with a male to female ratio of 1.85:1 compared to 5.5:1 amongst patient with confirmed On the contrary, to the observations of by Kamotho et al, a slight male predominance was seen CAD. With an average age in the fifties in both studies, a possible explanation could be that with time more women have adopted an urban western lifestyle with the previously skewed gender different exposure to cardiovascular risk factors becoming more similar.

Hypertension that was once considered a rare disease in African is now more frequently observed in our patient populations and is arguably the most powerful risk factor for CAD in the African context. (8)Indeed, hypertension was found to be the leading risk factor at 87% amongst our study participants. Similarly Kimeu et al who conducted a study on patients with acute MI undergoing coronary angiography in Nairobi Hospital found a prevalence of hypertension at 71.1% as the leading risk factor.(19) It is a well-known major and independent risk factor for CAD and a significant health concern in our continent with less than 40% of hypertensive patients being undiagnosed, less than 30% of those diagnosed not on treatment and less than 20% of those on treatment not having optimal control (<140/<90 mmHg. (14). INTERHEART African arm found hypertension to be of great importance since it was reported that a history of hypertension was considerably stronger in the total African group in comparison to the global INTERHEART population.(58) Our efforts towards

curbing coronary artery disease must then be focused towards ensuring more awareness, diagnosis and treatment of hypertension as well as better control of those on treatment.

Our data found Diabetes to be the third most prevalent risk factor in the study population (31) 54.4%. This is higher than the prevalence seen by other similar studies done by Kamotho et al where a prevalence of 38.5% while Kimeu et al found the prevalence at 25%. In addition, the study showed that patients referred for CAD in KNH and NWH had significantly higher prevalence of Hypertension and diabetes compared to patients in the INTERHEART African study with prevalence of 42.3%and 23.6% respectively.

Dyslipidemia, which accounts for one third of the Ischemic heart disease was the second most prevalent risk factor at 32(56.1%) in our study. This is comparable to the findings of Kamotho et al whereby a prevalence of 67.3% was seen. Interestingly, smoking previously found to be low at 15.4% by Kamotho et al, was found to be much higher at 33.3% of which all the smokers in the study were male. This was comparable to Kimeu et al prevalence rate of 35.9% amongst patients with acute MI at the Nairobi Hospital.

Patients, in our study, were characterized by the presence of multiple risk factors. Hypertension, dyslipidemia and diabetes were the most commonly observed risk factors with a good number of the patients (47.4%) having more than three risk factors These results are consistent with the INTERHEART African study and confirm that people exposed to known major CAD risk factors are at risk of developing atherosclerotic CAD as are people across the globe.

Obstructive CAD is defined as a stenosis more than 50% occlusion of a major coronary artery with significant stenosis more than 70% for all the epicardial vessels except LMCA. Our study found the mean luminal stenosis was 87.0 (SD18.7). This means that majority of the patients presented with advanced CAD with almost near critical stenosis at 90%. SVD was the most prevalent at 54.1%, with LAD being the most commonly diseased vessel. 36%). Not surprising as literature confirms that LAD is indeed the most common site of clinically significant atherosclerosis within the heart. Following closely after LAD was LCX and RCA at 25.8% and 27.9% respectively. Preponderance of LAD involvement was also found in a similar study done by Ibrahim et al in Lady Reading Hospital in Pakistan. (50). LMCA disease is a relatively infrequent but important cause of symptomatic CAD. Acute MI involving the Left Main artery has been associated with worse outcomes compared to MI involving other coronary arteries. (53-54)

In determining whether there is a correlation between the number of risk factor a patient has and the angiographic findings, the results of our study demonstrated that increasing cardiovascular risk factors were associated with a higher prevalence as well as extent and severity of CAD with persons with more than three risk factors manifesting a dose response increase.(45)

Amid the patients with normal angiographic findings who presented with classic symptoms suggestive of CAD, that warranted invasive coronary angiography, it is worth mentioning other possible causes of coronary artery disease that are not obstructive but still cause morbidity. These includes endothelial dysfunction, coronary aneurysms and dissections, ectactic coronary blood flow, congenital anomalies and myocardial bridge. These highlight the limitation of visual invasive coronary angiography as compared to other physiological studies like cardiac Magnetic Resonance Imaging. In addition, the lesions classified as non-significant stenosis, have a prognostic implication which newer modalities of assessing coronary stenosis including fractional flow reserve and intravascular ultrasound technique have been developed. A study by Park el at found thatlesions classified as multi-vessel moderate CAD on FFR but regarded non-significant on coronary angiography had ahigher risk of 2-yearmajor adverse cardiac events (MACE) (34)

CONCLUSION

The most prevalent risk factor among patient with atherosclerotic CAD in our study was hypertension. Most of the patients had SVD with LAD being the most commonly involved epicardial coronary vessel. A dose related response was seen where patients with more than three risk factors having more vessel involvement.

RECOMMENDATIONS

We emphasize the need for early diagnosis and management of modifiable cardiovascular risk factor particularly hypertension (arguably is the most powerful risk factor of CAD in our setup) to prevent the occurrence of CAD in our patients. Patient with multiple cardiovascular risk factors need aggressive control of each to prevent the development of severe CAD. Future studies can look into the treatment options andpatientsoutcomes with angiographically

confirmed coronary artery disease and possibly establish specific associations between angiographic characteristics and patient outcomes.

LIMITATIONS

Potential limitations of the study that merit considerations. Coronary angiography was only done in those who could afford the procedure or had insurance to cover for it and so selection bias was encountered. Another limitation is that during coronary angiography, visual estimation of the Coronary artery stenosis severity was done which has inter-observer and intra-observer variation.

TIMELINE

EVENT/MONTH	SEPTEMBER 2017	JANUARY 2018 – APRIL 2018	MAY 2018 - OCTOBER2018	NOVEMBER 2018
PROTOCOL PRESENTTION	•	•	•	•
ETHICAL APPROVAL	•	•	•	•
DATA COLLECTION	•	•	•	•
RESULTS	•	•	•	•

Figure 4: Study Timeline

STUDY BUDGET

Table 5: Study Budget

ITEM	COST(KSH)
STATIONERY AND PRINTING	**10,000**
STATISTICIAN	**30,000**
RESEARCH ASSISTANTS (2 research assistant in each study setting to be paid 60,000 each at the end of the study)	**120,000**
LABORATORY- RBS AND LIPID PROFILE	**70,000**
CONTINGENCY /MISCELENIOUS	**20,000**
TOTAL	**250,000**

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APPENDICES

4 Appendix I: Consent Explanation (English)

INFORMATION SHEET

Introduction

I, Dr. Patricia Mumbua Wambua, am a postgraduate student at the University of Nairobi, currently doing a Masters' degree in Internal medicine. I am conducting my research project for which I request your participation. You may seek clarification or ask question on things that you do not understand as you go through this form.

Purpose and benefits of the study

I am carrying out a study on the clinical profile of patients who have been diagnosed to have coronary artery disease by angiography as well as the angiographic characteristics seen during the procedure. The clinical profile entails the indication (reason) for which the angiography was requested for as well as the socio-demographic details that include age and gender. The risk factors are disease conditions that have predisposed you to coronary artery disease and include hypertension, diabetes, high cholesterol and obesity. As part of the study, we will ensure thorough assessment of your cardiovascular risk factors, which will inform on your management of your Coronary artery disease if diagnosed. Lifestyle modification advice will be given to the participants for control of the existing cardiovascular risk factors as well as prevention of development of others. This study is part of my university requirements but the results of the study will be used to inform health care workers and the public on the severity of coronary artery disease and the effects of risk factor burden on the same.

Procedures to be followed in the study

Once you agree to participate in the study, data from your file will be used to fill in the sociodemographic and risk factor profile as indicated in the data collection sheet seen below. A blood sample will be drawn after a period of overnight fast to ensure thorough workup of the patients and that the risk factors under study are not missed in any patient. Thereafter, an

interventional cardiologist and I will go through the angiographic images from your study and classify according to severity and vessel involvement.

Confidentiality

All the information you provide will be handled in a confidential manner and will not be divulged to any other person without your consent. Your individual responses will be stored in a locked place under my control and will only be seen by my statistician and I.

Voluntariness of participation

Your participation in this research is voluntary and in the event that you refuse to participate in this study, your treatment will not be affected. If you choose to participate and not answer certain questions, you are free to do so. You are free to terminate the interview and withdraw from the study at any time. You are free to ask questions before signing the consent form.

Rights

You may choose to withdraw from the study at any time whatsoever with no consequences to your treatment.

If you have any questions regarding the study, contact any of the following persons:

Dr. Patricia Mumbua Wambua (Principle Investigator)

Mobile Number 0724894235

OR

Professor E. N. Ogola

Mobile Number 0722737944 (Lead Supervisor)

In case of any ethical concerns, please contact:

The Secretary,

KNH-UoN Ethic Research Committee,

P.O. BOX 20723-00202, Nairobi.

Telephone number (+254-020) 27263003 ext 44355

Email: uonknh_erc@uonbi.ac.ke

CONSENT FORM

I _____having been explained to the nature of the study being carried out by Dr. Patricia Leila Mumbua Wambua, do voluntarily agree to take part in the research on *Clinical Profile, Risk Factors and Angiographic Characteristics of patients undergoing coronary artery disease in Kenyatta National Hospital.* I understand that I am free to participateor not in it and failure to do so will not in any way affect the appropriate treatment I have been receiving or will continue to receive.

Signed: _____

Witnessed: _____

Dated: _____

5 Appendix II: Consent Explanation (Swahili)

FOMU YA MAELEZO YA UTAFITI

Utangulizi

Mimi, Dk. PatriciaMumbuaWambua ,nimwanafunziwa Chuo Kikuu cha Nairobi. Ninafanya shahada ya Masters katikautaalamuwadawa za ndani. Ninafanyamradiwanguwautafitiwaugonjwawamoyoambaoningependauhusikenanaombaomila kokabla. Fomuhiiniyamaelezo yote utakayohitajiukiamuakamautajiunganautafitihuu. Unapoisomanabaadayakusomafomuhii, ukohurukuulizamaswaliyoyotekamakunasehemuhujaelewavyema.

Kusudi la utafiti

Ninafanyautafitijuuyakueneakwawagonjwawaliyonaugonjwawamishipayamoyoiliyothibitish wanaangiografiamiongonimwawaliofanyiwaangiografiayamishipayamoyo. Tutachunguzaumri, jinsia, kiwango cha elimunamakazi (vijijinidhidiyamijini) yawaliopatikananaugonjwahuu. Sababuambayo angiography iliombwapamojanasababumbalimbaliyalioongezeauwezekanowamtukupataugonjwahuuwami shipayamoyo pia utachunguzwa. Hatimayekwamsaadawa cardiologists wawiliwenyeujuzi, tutachunguzapicha za utaratibuwakowaangiografia. Utafitihuunisehemuyamahitajiyanguyachuokikuulakinimatokeoyautafitihuuutatumikakuwajul ishawafanyakaziwaafyanaummazaidijuuyaugonjwahuunchinikenya.

Utaratibuwautafiti:

Baadayakupatakibali cha kushirikinautafitihuu, data kutokafailiyakoitatumikakujazafomuyakukusanya data iliyoonekanachini. Sampuliyadamuitachukuliwakupima cholesterol nakipimo cha sukariitafanywailikudhibitishwauweponaukosefuwamagonjwahaya .Baadaye, mwanadamuwamoyonamiminitapitiapicha za angiografiazilizohifadhiwakutokakwenyeutafitiwakonakugawakulingananaukalinauingizajiw achombo.

Hatarinagharamainayohusika

Unawezahisiuchungukidogodamuinapoondolewa.

Mahaliunapodungwapanawezakufurakidogo, lakiniitaishayenyewebaadayasikuchache.

Damuitakayoondolewanikidogonahaitakudhuru.

Hakizako

Kujiunganautafitihuunikwahiariyako. Hutabaguliwakimatibabuukikataakujiunganautafitihuu. Ukijiunganautafitihuunaushindwekujibumojawapo au maswalimenginetutakayouliza, nisawa. Una uhuruwakutokakwenyemahojianonakujitoakwautafitihuuwakatiwowote. Una uhuruwakuulizamaswaliyoyoteuliyonayokablayakutiasahihifomuyamakubaliano. Maelezoyako yote yatawekwapahalipasiri. Ni mtafitimkuunamwanatakwimu wake pekeeambaowataangaliamaelezoyako.

Manufaayautafitihuu

Kujiunganautafitihuunavipimovyamaabaravitatumikakwamanufaayako. Matokeoyautafitiyatasaidiawauguzikatikahospitaliya Kenyatta**.**

Ikiwa una maswaliyoyotekuhusuutafitihuu, wasilianawafuatao:-

Dk.Wambua 0724894235 (Mchunguzimkuu)

Profesa E. N. Ogola 0722737944 (MsimamiziMkuu)

Ikiwa una maswaliyeyotekuhusunjia za utafitihuu, wasilianana

Katibu,

KNH-UoN- Kitengo cha utafiti,

S.L.P 20723-00202, Nairobi.

Simu nambari: (+254-020) 27263003 ext 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

FomuYaIdhini

Mimi ……. kutoka ……..Nimekubali/kataakujiunganautafitihuuambaoumeelezwakw

aukamilifukwangu.Nimesomanakuelewamaelezo yote. Maswaliyangu yote yamejibiwakwaukamilifunamtafiti.

Sahihi/Alamayakidolegumba cha kushoto.……....

Tarehe ……

Shahidi……

Tarehe……..

Appendix III: Data Collection Sheet

DATA COLLECTION SHEET	
STUDY NUMBER:	
SURNAME: OTHERNAMES:	
AGE: D.O.B:	GENDER: MALE □ FEMALE □ RESIDENCE: URBAN □ RURAL □
LEVEL OF EDUCATION: PRIMARY: SECONDARY: TERTIARY:	
FAMILY HISTORY OF PCAD: YES□ NO□	
SMOKING: YES □ PACK YEARS _____ NO □	
HYPERTENSIVE: YES □ NO□	
DIABETIC STATUS: DIABETIC□ NON DIABETIC□	
DYSLIPIDEMIA : Current use of lipid lowering agents: YES □ NO□ HDL level (mmol/L): LDL level (mmol/L): Total Cholesterol (mmol/L):	
OBESITY: BMI: Abdominal Circumference : YES□ NO	
DATE OF CORONARY ANGIOGRAM:	
INDICATION FOR CORONARY ANGIOGRAM STABLE ANGINA: UNSTABLE ANGINA: NSTEMI: STEMI: OTHERS:	
ANGIOGRAPHIC FEATURES:	

NORMAL □	
ABNORMAL □ (if yes fill in name and number of vessel involved)	
VESSEL	STENOSIS (%)
LMCA □	
LCX □	
LAD □	
RCA □	
OTHER FINDINGS: Please specify_____ _____ _____ _____	