The Relationship between Type II Diabetes and Selected Modifiable Lifestyle Factors: A Case-Control Study at the Out-Patient Department of the St. Mary's Mission Hospital, Langata, Nairobi.

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Approval

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Dedication

To my beloved wife Anna, my loving Mum and my friends for life; Alex, Joe and Ernest, I couldn't have achieved the much that I have without your ever-present support.

Table of Contents

List of Figures

List of Abbreviations and Acronyms

ADA – American Diabetes Association

BMI - Body Mass Index

CHD – Coronary Heart Disease

DM – Diabetes Mellitus

DMI – Diabetes Management Institute

IDF – International Diabetes Federation

NCDs – Non Communicable Diseases

NIDDM - Non-insulin Dependent Diabetes Mellitus

OR – Odds Ratio

RR – Relative Risk

STEPS - WHO STEPwise approach to chronic disease risk factor surveillance

USD – US Dollars

WDF - World Diabetes Federation

WHO – World Health Organization

Operational Definition of Terms

Body Mass Index - A statistical measure of body weight based on a person's weight and height used to estimate a healthy body weight. BMI = Mass (kg)/ (height (m)) ^{2}

Disability-Adjusted Life Years – A measure of the overall disease burden in a population, expressed as the number of years lost due to ill-health, disability or early death. It is calculated as the sum of the years of life lost due to premature mortality and the years lost due to disability for incident cases of the health condition in the population.

Glycemic Index- A measure of the effects of ingested carbohydrates on blood sugar levels. The smaller the index, the smaller the change in blood sugar levels after ingestion of a particular carbohydrate. A lower glycemic index suggests slower rates of digestion and absorption and vice versa.

Pack-years – Quantification of the amount a person has smoked over a period of time calculated by multiplying the number of packs of cigarettes smoked per day by the number of years the person has smoked.

Selected modifiable lifestyle factors - Obesity, alcohol intake, cigarette smoking, physical inactivity and unhealthy diet.

WHO criteria for diagnosis of diabetes: Diabetes symptoms of polyuria, polydipsia and unexplained weight loss plus a random venous plasma glucose concentration of 11.1 mmol/l or a fasting plasma glucose concentration of 7.0 mmol/l (6.1mmol/l if whole blood), plasma glucose concentration of 11.1 mmol/l two hours after 75g anhydrous glucose in an oral glucose tolerance test (OGTT).

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Abstract

Type 2 diabetes is a chronic non-communicable disease that is associated with high levels of morbidity, mortality and economic burden both at individual and national levels. However it is also a highly preventable disease with research indicating that up to 80% of all cases of this disease can be prevented through lifestyle modification. Obesity, alcohol intake, cigarette smoking, physical inactivity and low fiber diet have been linked by many studies to type 2 diabetes as modifiable risk factors (WHO, 2010).

Primary prevention of type 2 diabetes would involve parallel public health programs, in respect to each of the modifiable lifestyle factors, aimed at modifying these factors in the general population. Since such programs would require substantial resources, prioritization would be imperative especially in resource-poor countries to ensure that resources are allocated to each of these programs commensurate or proportionate to their expected impact in terms of reduction of type 2 diabetes in the general population. This requires scientific studies to establish how strongly each of these modifiable lifestyle factors is a risk factor for type 2 diabetes.

This study therefore sought to find out the relationship between each of the five modifiable lifestyle factors and having type 2 diabetes. The study was a matched case-control study at the out-patient department at the St Mary's Mission Hospital, Langata in Nairobi. The dependent variable was the presence of type II diabetes while the predictor variables were Body Mass Index (BMI), number of pack-years smoked, type of diet, level of physical activity and the level of alcohol consumption with the possible confounding variables being age, sex, level of education and work status. The sample size was 132 cases with one control for each case.

A case was defined as any patient who was seen at the diabetic clinic at the hospital, was newly diagnosed with type 2 diabetes as per the WHO criteria and gave fully informed written consent for inclusion into the study. A control was defined as any adult out-patient who was seen at the general out-patient clinic at the hospital for any disease other than diabetes, hypertension, cancer, chronic respiratory disease or any chronic cardio-

vascular or cerebro-vascular disease, who matched a particular case for age and gender and who gave a fully informed written consent for inclusion into the study. Cases were selected as they become available while controls were purposively selected to match specific cases selected on that day. The data was analyzed using the Statistical Package for the Social Sciences (SPSS) version 17. Logistic regression analysis was done to check for and adjust for any confounding and interactions between the predictor variables.

This study found out that alcohol consumption and being over-weight or obese had strong dose-response relationships with having type 2 diabetes. Physical activity had dose-response relationship with having type 2 diabetes that was of borderline significance. Smoking and amount of fiber in diet were found not to have any significant relationships with having type 2 diabetes.

The recommendations from the study included strict enforcement of the regulations set out in the Alcoholic Drinks Control Act, 2010 and the development and conduction of continuous public awareness campaigns on the health hazards of alcohol consumption. Other recommendations include formulation of policies that encourage use of public and non-motorized transport, promote physical activity among members of the public and promote consumption of wholesome indigenous foods while discouraging the consumption of fast foods and limiting the amount of unhealthy ingredients in the foods. The study also recommended that in view of the contradicting findings of this study vis-à-vis previous studies, more studies be done on the relationship between type 2 diabetes and smoking with larger sample size so as to increase the power to detect any relationship.

CHAPTER ONE

INTRODUCTION

1.1 Background of the study

The American Diabetes Association (ADA) defines diabetes mellitus as a group of diseases characterized by high blood glucose levels that result from defects in the body's ability to produce and/or use insulin (ADA, 2010). Diabetes occurs in three forms; in type 1 diabetes, the body does not produce insulin while in type 2 diabetes, either the body does not produce enough insulin or the cells do not respond to the insulin. Gestational diabetes occurs during pregnancy when the body is not able to make and use all the insulin it needs for pregnancy (ADA, 2010).

Diabetes is recognized as one of the non communicable diseases (NCDs) that are increasingly becoming a major cause of morbidity and mortality in the world (WHO, 2008). Diabetes, heart disease, stroke, cancer and chronic respiratory diseases account for almost 47% of the global burden of disease and 60% of deaths with close to 80% of these deaths occurring in the developing countries (WHO, 2004). It is estimated that type 2 diabetes accounts for over 85% of all diabetes in high-income countries and probably an even higher proportion in the low and middle-income countries (IDF, 2008).

The global diabetes prevalence rose from 151 million cases in 2000 to 285 million in 2010, corresponding to 6.4% of the world's adult population and the number is expected to grow to 438 million by 2030, which will correspond to about 7.8% of the projected adult population then (IDF, 2010). As at 2008, about 70% of diabetics lived in low and middle income countries. This prevalence has been termed an epidemic and the developing world is expected to be the hardest hit by it (WDF, 2010).

The number of cases of diabetes in the low and middle income countries is expected to rise from 84 million in 2010 to 228 million by the year 2030 with about 24 million of these being in sub-Saharan Africa (WHO, 2008). In Kenya the estimated prevalence of

diabetes mellitus was at 3% in 2003, and above 6% in 2007 with some rural parts of the country such as Nyeri in central Kenya and Kilifi in the coast province having a prevalence as high as 11.6% and above 20% respectively (Chege, 2010).

The economic burden of type 2 diabetes both at individual and national levels is enormous. Healthcare expenditure on diabetes is expected to account for 11.6% of the total healthcare expenditure in the world in 2010 but only a paltry 20% of this expenditure will be incurred in the low and middle-income countries where over 70% of people with diabetes live (IDF, 2010). Diabetics in resource-limited countries will bear the greatest financial burden associated with type 2 diabetes due to the lack of or limited access to affordable and high quality health care in these countries. At the national level, the economic impact associated with lost man-hours, lower productivity at work, permanent disability and loss of life as a result of the disease itself and its related complications will be huge (WDF, 2010).

Type 2 diabetes is one of the major causes of premature illness and death worldwide with serious complications that include stroke, blindness, kidney failure and limb amputations. An estimated 50% of people with diabetes die of cardiovascular complications while the overall risk of dying among people with diabetes is at least double the risk of their peers without diabetes (WHO, 2010). Close to four million deaths in the 20-79 age group may be attributable to diabetes in 2010, accounting for 6.8% of global all-cause mortality in this age group (IDF, 2010).

Diagnosis of type 2 diabetes is often made late, when the complications have already set in due to its long asymptomatic phase. A recent study in several African countries revealed that undiagnosed diabetes accounted for between 75% and 85% of all diabetes cases (WDF, 2010). If the diagnosis and treatment are not timely then an exponential rise in the severity of complications and the rate of mortality becomes unavoidable (WHO, 2008). However, type II diabetes is largely preventable through lifestyle modification. Recent scientific evidence has shown that most of the cases of type 2 diabetes can be

prevented by changing diet, increasing physical activity and avoiding tobacco-containing products (WHO, 2005).

Medical research has compelling evidence linking obesity, alcohol intake, cigarette smoking, physical inactivity and dietary habits to type 2 diabetes as modifiable risk factors (Buttar et al., 2005). Maintaining modest weight through balanced diet and physical activity for over 3 to 4 years reduces the incidence of type II diabetes in high-risk persons by about 40% to 60% (Williamson et al., 2004). Several epidemiological studies have found high intake of cereal fiber to be associated with a lower risk of diabetes and a high glycemic index of the overall diet to be associated with a greater risk of type II diabetes (Willett et al., 2002).

Physical activity has been shown by several studies to decrease the risk of development of impaired glucose tolerance and type 2 diabetes mellitus while low-to-moderate amount of alcohol intake has been shown to decrease the risk of development of diabetes by increasing insulin sensitivity and slowing glucose uptake from a meal (Schulze et al., 2005; Bazzano et al., 2005). There is increasing scientific evidence linking tobacco smoking as a major risk factor for type II diabetes. In the Nurses Health Study, women who smoked more than 25 cigarettes per day had a 42% greater risk of developing diabetes than those who had never smoked, after adjustment for obesity and other risk factors (Rimm et al., 1993) while in the Physicians' Health Study, in a cohort of 21,068 men, the risk was 70% among smokers of at least 20 cigarettes daily compared to non-smokers (Manson et al., 2000).

Despite the compelling scientific evidence establishing relationships between obesity, alcohol intake, cigarette smoking, physical inactivity and type of diet to type 2 diabetes as modifiable risk factors, not much research has been done to establish how strong these relationships are. As noted earlier, majority of type 2 diabetes cases are found in the developing countries which face major challenges in providing even the most basic health

services to their populations due to lack of resources. It is therefore imperative to get value for every dollar spent on health care, hence the need for targeting and prioritizing the meager resources to areas that will yield maximum impact.

Prevention programs that involve lifestyle changes in terms of diet, smoking, alcohol consumption and weight would require large amounts of resources. Therefore countries would need to prioritize their efforts and resources to prevention programs targeting those risk factors that have the strongest relationships with type 2 diabetes and whose prevention would therefore have the greatest impact in the prevention of this disease. This study therefore seeks to determine the respective relationships between the selected lifestyle factors and type 2 diabetes. This knowledge would potentially help in prioritizing efforts and resources and therefore maximize the efficiency and effectiveness of preventive programs against this deadly disease.

1.2 Statement of the Problem

Diabetes mellitus is a group of diseases characterized by high blood glucose levels that result from defects in the body's ability to produce or to use insulin (IDF, 2010). Type 2 diabetes is characterized by a relative resistance to insulin by the body's cells and it accounts for about 95% of all diabetes cases globally. This disease is associated with high morbidity, mortality and economic burdens (WDF, 2010).

The current prevalence levels of type 2 diabetes have reached epidemic levels (WDF, 2010). Due to the enormous morbidity, mortality and financial burdens associated with type 2 diabetes, many studies to determine the factors associated with the exponential rise in its prevalence have been done. These studies have revealed causative relationships between several lifestyle factors and type II diabetes. These factors are obesity, alcohol intake, cigarette smoking, physical inactivity and type of diet (Bazzano et al., 2005). Since these are largely modifiable lifestyle factors, type 2 diabetes is therefore largely preventable through lifestyle modification.

Prevention of type 2 diabetes would require the affected countries to institute nationwide prevention programs targeting lifestyle modifications with respect to the already identified modifiable lifestyle risk factors. Since such programs would require substantial resources, prioritization would therefore be imperative especially in resource-poor countries, so that resources are allocated to these programs proportionate to their expected impact in terms of prevention of type 2 diabetes in the general population. This would require scientific studies to establish how each of the modifiable lifestyle factors is related to type 2 diabetes as a risk factor. This study therefore sought to determine the relationship between each of the five modifiable lifestyle factors and type 2 diabetes.

1.3 General Objective of the Study

To determine the relationships between the having type 2 diabetes and selected modifiable lifestyle factors among the out-Patients at the St Mary's Mission Hospital, Langata in Nairobi.

1.4 Specific Objectives of the study

1. To determine the demographic and the socio-economic characteristics of the study participants.
2. To establish the prevalence of modifiable lifestyle factors among type 2 diabetic patients and controls patients.
3. To determine the relationship between each of the selected lifestyle factors and having type 2 diabetes.

1.5 Research Questions

1. What are the demographic and the socio-economic characteristics of the study participants?
2. How prevalent are the modifiable lifestyle factors among type 2 diabetic patients and control patients?
3. What is the relationship between each of the selected lifestyle and having type 2 diabetes.

1.6 Hypothesis

There is no relationship between having type 2 diabetes and each of the selected modifiable lifestyle factors.

1.7 Justification of the Study

Type 2 diabetes is a chronic disease responsible for high morbidity and mortality globally (WHO, 2009). It has a long asymptomatic phase during which serious complications arise that could lead to permanent disability. The economic burden associated with this disease is huge not just to the affected individuals but also to the entire health system and the national economy. This due to not only the costs of diagnosis, treatment and rehabilitation but also the lost productivity of those affected (IDF, 2009).

In Kenya the Ministry of Health (MOH) estimates the current prevalence of diabetes to be above 10% in 2010 while a survey by the Diabetic Management Institute (DMI) in 2003 indicated that diabetes was responsible for about 27% of hospital admissions then (Chege, 2010). With 50% of the Kenyan population estimated to be living below the poverty line, the vast majority of diabetic patients will not be able to afford the high costs associated with treatment and management of diabetes and its complications. This heavy burden underscores the prime importance of primary prevention of this disease.

Several studies that have been done on the etiology of type 2 diabetes have established strong etiological relationships between certain lifestyle factors and the causation of type 2 diabetes. Obesity, alcohol intake, cigarette smoking, physical inactivity and type of diet have been linked by many studies as its main lifestyle risk factors (Bazzano et al., 2005). This makes type 2 diabetes largely preventable through lifestyle modification. To help curb the continued increase in the prevalence of this disease, there is need to establish prevention programs targeting the modification of the main lifestyle risk factors within the general population.

Prevention programs especially those aiming at lifestyle modification would however require substantial amounts of resources. In Kenya the biggest share of the health budget goes to curative services and therefore getting resources for preventive programs targeting the modification of all these lifestyle risk factors within the general population would be a big challenge. It therefore becomes important to prioritize the limited

resources to the factor(s) which offer the greatest potential for prevention of type 2 diabetes. To achieve this there is a need to have the knowledge of the magnitude of the relationship between type 2 diabetes and each of these risk factors. The factors(s) with the strongest relationship(s) and therefore the greatest potential in terms of prevention of type 2 diabetes will then be given priority in terms of the resource allocation for the prevention programs. This study therefore sought to determine the relationship between each of the five modifiable lifestyle factors and type 2 diabetes.

1.8 Assumptions of the Study

1. The study population was representative of the general population in Kenya in terms of demographic characteristics and lifestyle habits.

2. Patients seen at the diabetic clinic did not get any information on the importance of lifestyle modification elsewhere before diagnosis with type 2 diabetes and therefore only started to modify their lifestyle once they got diagnosed.

3. Patients seen at the diabetic clinic who got any information on the importance of lifestyle modification elsewhere before diagnosis with type 2 diabetes did not modify their lifestyle and if they did the response to the modification was suboptimal.

4. The newly diagnosed diabetic patients who participated in this study did not suffer from any other diseases that would demand lifestyle modification on the factors that are the subjects of this study.

1.9 Limitations of the Study

1. The clientele at the hospitals where the study was done were mainly of low and lower middle in terms of affluence and therefore the study results could not be generalized to the affluent members of the Kenyan population.

2. The study population represented a small part of the Kenyan population geographically and therefore the results from this study might have been biased towards lifestyle habits that are unique to the communities that live in the environs of Nairobi and Naivasha.

3. The composition of the study population was limited by the proximity to the hospital, affordability of the health services and individual preferences.

CHAPTER TWO

LITERATURE REVIEW

2.1 Definition

The American Diabetic Association (ADA) defines diabetes as a group of diseases characterized by high blood glucose levels that result from defects in the body's ability to produce and/or use insulin (ADA, 2010), while the WHO defines it as a chronic disease that occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces resulting in raised blood sugar and serious damage over time to many of the body's systems if not well controlled (WHO, 2010).

IDF classifies diabetes into 3 main types of diabetes; Type 1, type 2 and gestational diabetes. Type 1 diabetes is also known as insulin-dependent, immune-mediated or juvenile-onset diabetes. It is caused by an auto-immune reaction where the body's defense system attacks the insulin-producing cells through mechanisms that are poorly understood. This leads to minimal or no insulin production by the beta-cells of the pancreas meaning that those affected require daily injections of insulin to survive. It usually occurs in children or young adults though people of other ages can also be affected (IDF, 2010).

Type II diabetes is also known as non-insulin dependent diabetes or adult-onset diabetes and results from relative insulin resistance whereby body cells fail to or poorly respond to the body's own insulin sometimes combined with sub-optimal insulin production by the pancreas. Genetics have been linked to its onset though obesity, physical inactivity, unhealthy diet, smoking and alcohol use have been found to increase the risk of it (Ligaray et al., 2010).

This form of diabetes is most common in people older than 45 years who are overweight though it is increasingly becoming common in children and young adults due to the rise in the prevalence of obesity within this group. Control of type II diabetes usually involves careful watch of diet, regular exercise, weight loss and oral medication. Insulin injections are only used in severe cases where the other forms of control have failed. Type II diabetes is the most common form of diabetes accounting for about 90% of all cases of diabetes (WHO, 2009).

The third form of diabetes is known as gestational diabetes which affects pregnant women. It is a temporary condition that affects 3-10% of pregnancies and usually disappears after delivery or termination of the pregnancy. No specific cause has been identified, but pregnancy hormones are thought to increase the body's resistance to insulin, resulting in impaired glucose tolerance. Its treatment is similar to that of type II diabetes (Moore, 2010). Having gestational diabetes increases the pregnant woman's risk of later development of type II diabetes (ADA, 2010).

If poorly controlled over time, diabetes affects many major body organs and organ-systems including the heart, blood vessels, nerves, eyes and kidneys and although these complications develop gradually over many years, once they set in they can be disabling and even fatal. In the cardiovascular system, type II diabetes dramatically increases the risk of angina, hypertension, arthrosclerosis, and heart attack and more than doubles the risk of stroke within the first five years of its diagnosis. About 50% of people with diabetes die of cardiovascular causes (WHO, 2009).

Nerve damage by diabetes can lead to tingling, numbness, burning or pain feet sensation, vomiting, diarrhea or constipation and erectile dysfunction while kidney damage can lead to irreversible end-stage kidney disease requiring dialysis or kidney transplant. Eye involvement increases the risk of cataracts and glaucoma and can lead to blindness while foot damage can lead to serious infections and impaired blood circulation which if very severe leads to toe, foot or even leg amputation. Other long term complications associated with type II diabetes include chronic or repeated urinary, skin and mouth infections, osteoporosis, Alzheimer's' disease and hearing loss (MayoClinic, 2010).

The current prevalence of diabetes is estimated to be about 285 million people, corresponding to 6.4% of the world's adult population in 2010. The number is expected to grow to 438 million by 2030, corresponding to 7.8% of the adult population then and it is the African region that is expected to experience the largest share of this increase. More than 70% of the current cases of diabetes are in low and middle income countries (WDF, 2010). The world's highest diabetes prevalence is found in the Micronesian population of Nauru with 31% of the adult population affected while India has the world's largest diabetes population with an estimated 50.8 million people affected (IDF, 2010). The most affected age group currently is the 40-59 years age group but WDF projects that this will shift to the 60-79 age groups by 2030 (WDF, 2010).

Prevalence and incidence data for sub-Saharan Africa is very limited and the data that is currently available has largely been extrapolated from distant and probably dissimilar countries and populations making it of limited accuracy. The high burden of infectious disease in Africa has tended to overshadow the increasing impact of diabetes and other chronic non-communicable diseases in the region. The prevalence of diabetes in the region in 2010 is estimated to be at 3.2% of the adult population representing an estimated 12.1 million people (IDF, 2008).

The number of people with diabetes in Africa is expected to double in the next 20 years to 23.9 million by 2030. With the rapid urbanization being experienced in the region, in the next decade, diabetes is poised to become one of the major health problems of the region. Current estimates indicate that at least 1 in 20 deaths of those aged 20 to 79 years is due to diabetes.

2.2 Economic Impact of Diabetes

Diabetes care is associated with substantial costs to the individuals affected, their families, entire health systems and national economies. The costs are both the direct costs of medical care and the indirect costs arising from lost productivity due to diabetes-

related morbidity and premature mortality. Diabetics have on average two to five times higher per capita total medical expenditures and per capita out-of-pocket expenses than people without diabetes because they visit their physician's offices, hospital outpatient departments, and emergency rooms more frequently than their non-diabetic counterparts and are more likely to be admitted to the hospital than their non-diabetic counter-parts (Javitt et al., 1992).

Diabetes will account for about 11.6% of the total global healthcare expenditure in 2010 and about 80% of the countries will spend between 5% and 13% of their total healthcare expenditure on diabetes. The global expenditure on diabetes is projected to be at least USD 376 million in 2010 and is projected to rise to about USD 490 million by the year 2030 and substantial proportions of these expenditures will be associated with diabetic complications (IDF, 2008).

There is a large disparity in healthcare spending on diabetes between regions and countries. Less than 20% of the global expenditure on diabetes is incurred in the low and middle-income countries where over 70% of diabetics live while over 80% of this expenditure is incurred in a small number of developed countries. The North American and Caribbean Regions alone are projected to spend about 57% of the global total on diabetes in 2010 in contrast to the entire African Region which will spend a meager 0.4% (IDF, 2008). As opposed to the western economies where large proportions of the expenditures on diabetes are done within the health care systems, in most developing economies most of the expenditure is out-of-pocket due to the absence of well developed health care and health insurance systems. This leaves many households with little or no finances to spend on other basic items like food and clothing which worsens their state of poverty. There is no specific data available on the economic impact of diabetes in Kenya.

2.3 Etiology of Diabetes

Due to the enormous morbidity, mortality and financial burdens associated with type II diabetes, many studies to determine the factors associated with the exponential rise in its

prevalence have been done. These studies have revealed etiological relationships between several lifestyle factors and type II diabetes. These factors are obesity, alcohol intake, cigarette smoking, physical inactivity and type of diet. Since these are largely modifiable lifestyle factors, type II diabetes is therefore largely preventable through lifestyle modification (Knowler et al., 2002).

Because of the high morbidity, mortality and economic burdens that is associated with it, type II diabetes is a disease of huge public health importance and prevention of even a small part of the growing number of cases would save thousands of lives and billions of health care dollars. To reduce the burden of this devastating disease, prevention programs must target not only the affected individuals but also families, workplaces, schools, and communities (Bazzano et al., 2005).

2.4 Obesity

BMI is defined by WHO as a simple index of weight-for-height that is commonly used in classifying overweight and obesity in adult populations and individuals and is calculated as the weight in kilograms divided by the square of the height in meters (kg/m2). A BMI of less than 18.5 is termed as underweight while normal weight is defined as a BMI of between 18.5 and 24.99. A BMI between 25.0 and 29.99 is termed overweight while obesity is any BMI of 30 and above (WHO, 2010). In 2005 approximately 1.6 billion people aged over 14 years were overweight and 400 million of them were obese. It is further projected that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese. Overweight and obesity, once considered problems of the western countries, are now on the rise in the low and middle-income countries and even among the poorer sections of the society especially in urban settings (WHO, 2006).

Diabetes and hypertension are major predisposing factors for cardiovascular diseases which are responsible for about 18 million deaths annually. Propelling the upsurge in cases of diabetes and hypertension is the growing prevalence of overweight and obesity (Haslam et al., 2005). In the developing world, the situation is increasingly becoming

worse as rates of obesity are estimated to have tripled in the last 20 years due to the increasing adoption of western lifestyles that are characterized by low physical activity and high consumption of cheap energy-dense food (Hossain et al., 2007).

Obesity has been recognized by many studies to be one of the strongest risk factors for the development of type II diabetes and has been estimated to account for between 60% - 90% of the risk variance (Bazzano et al., 2005). Coldtz et al. (1990) quote findings of a 1976 cohort study of American women aged 30–55 years followed up for 8 years. For women of BMI 23–23.9 kg/m^2 the relative risk of development of type II diabetes was 3.6 times that of those with a BMI less than 22 kg/m^2 and the risk continued to increase above this level of body mass index. For an increase of 20–35 kg, the relative risk was 11.3, and for an increase of more than 35 kg, the relative risk was 17.3. These results were independent of family history of diabetes.

Colditz et al. (1995) found that the risk of type II diabetes increased by nearly 90-fold among female nurses who were morbidly obese (BMI 35) at ages 30 to 55 years and had normal weight at age 18 (BMI <22). Studies examining the potential benefits of sustained weight loss on the risk of development of type II diabetes suggest that even modest weight loss is associated with significantly reduced risk of diabetes (Resnick et al., 2000).This suggests that obesity and excess energy consumption are perhaps the most important factors contributing to risk of type II diabetes and therefore even minor weight reductions may have major beneficial effects on subsequent risk of development of type II diabetes in overweight persons (Bazzano et al., 2005).

Christensen et al. (2008) in a study that sought to assess the impact of ethnicity and urbanization on obesity and regional fat distribution in Kenyan populations found that the prevalence of overweight was 39.8% in urban areas compared to 15.8% in the rural areas while the prevalence of obesity was 15.5% in urban areas compared to 5.1% in the rural areas. A BBC report titled *Obesity epidemic out of control on* 31st October 2004 which was based on proceeds from the first meeting of the International Association for the Study of Obesity in Africa in 2004, warned that unless something is done, health care

services in the developing world will not be able to cope with treating people with diseases linked to obesity.

2.5 Smoking

Wikipedia defines smoking as a practice in which a substance, most commonly tobacco or cannabis, is burned and the smoke tasted or inhaled. Smoking is primarily practiced as a route of administration for recreational drug use, as combustion releases the active substances in drugs such as nicotine and makes them available for absorption through the lungs. The most common method of smoking today is through cigarettes manufactured or hand-rolled but there other smoking tools that include pipes, cigars, bidis, hookahs and bongs.

The WHO in its *Tobacco Atlas, 2002* estimated that globally about one billion men smoked which represented 35 percent of men in developed countries and 50 percent of men in developing countries then. But it went further to observe that smoking rates had then peaked and were slowly on the decline in both the developed and developing countries. The more educated males were giving up smoking more than their uneducated counter-parts, progressively making smoking more of a habit of the poor and the less educated. About 250 million women in the world were daily smokers representing about 22 percent of women in developed countries and 9 percent of women in developing countries then. In Kenya, the prevalence of adult male smokers is estimated to be about 19% with only 2% of the women being smokers (KDHS, 2008/09).

Tobacco use has been implicated as one of the main risk factors for a number of chronic diseases, including cancer, lung diseases and cardiovascular diseases. In type II diabetes smoking may increase the risk by causing elevations in blood glucose concentration and increasing insulin resistance. A 1997 study to evaluate the effects of chronic cigarette smoking on insulin sensitivity in patients with non-insulin-dependent diabetes mellitus (NIDDM) examined 28 smokers and 12 nonsmokers with NIDDM of similar sex, age, body mass index, waist/hip ratio, alcohol consumption, physical activity level, glycol-

metabolic control, diabetes duration, and treatment. The results indicated that smoking markedly aggravates insulin resistance in patients with NIDDM (Giovanni et al., 1997).

Nilsson et al. (1997) conducted a study comparing serum lipoprotein lipids, glucose, insulin secretion, and insulin sensitivity among 41 smokers and 150 nonsmokers recruited from a health survey. The subjects were examined in the morning during a fasting state and after abstinence from smoking for 10 to 12 hours. Smokers examined in the abstinence phase showed no signs of impaired insulin action. The effect on insulin sensitivity appeared to be reversible over 10 to 12 hours.

A Japanese study conducted between May 1994 and May 1999 among male office workers, 35 to 59 years of age, concluded that the number of cigarettes smoked daily and the number of pack-years of exposure seemed to be associated with development of impaired fasting glucose and type II diabetes. After controlling for potential predictors of diabetes, the relative risk for impaired fasting glucose compared with never-smokers was 1.62 for ever-smokers, 1.14 for persons who smoked 1 to 20 cigarettes/d, 1.33 for those who smoked 21 to 30 cigarettes/d, and 2.56 for those who smoked 31 or more cigarettes/d. The respective multivariate-adjusted relative risks for type II diabetes compared with never-smokers were 1.08, 1.88, 3.02 and 4.09 (Nakanishi et al., 2000).

Rimm et al. (1993) in a study among female smokers found that current smokers had an increased risk of diabetes with a significant dose-response trend for higher risk among heavier smokers. The relative risk of diabetes, adjusted for obesity and other risk factors, was 1.42 among women who smoked 25 or more cigarettes per day compared with nonsmokers suggesting that cigarette smoking may be an independent modifiable risk factor for type II diabetes.

Other studies that have shown a relationship between smoking and type II diabetes include a prospective study of 7,124 British men where men who smoked cigarettes had a 74% higher risk of developing diabetes than those who had never-smoked, after

adjustment for age and BMI (Wannamethee et al., 2001). In the Physicians' Health Study, involving a cohort of 21,068 men, smokers of at least 20 cigarettes daily had a 70% greater risk of developing diabetes than participants who never smoked, after adjustment for multiple risk factors (Manson et al., 2000).

2.6 Alcohol Consumption

Wikipedia defines an alcoholic beverage as a drink containing ethanol commonly known as alcohol and classifies alcoholic beverages into beers, wines, and spirits. A standard drink is a notional drink that contains a specified amount of pure alcohol. The standard drink is used in many countries to quantify alcohol intake. It is usually expressed as a measure of beer, wine, or spirits. One standard drink always contains the same amount of alcohol regardless of the serving size or the type of alcoholic beverage. The WHO defines a standard alcoholic drink as containing 10 grams of ethanol (WHO STEPS, 2010).

There are about two billion people worldwide who consume alcoholic beverages and 76.3 million with diagnosable alcohol use disorders globally. Alcohol is thought to be responsible for about 1.8 million deaths and a loss of 58.3 million of Disability-Adjusted Life Years and to cause about 20–30% of esophageal cancer, liver cancer, cirrhosis of the liver, homicide, epileptic seizures, and motor vehicle accidents worldwide (WHO, 2002). There is not much data available on the prevalence of alcohol consumption in Kenya but a study in 2000 found out that the lifetime prevalence rates of alcohol use for two urban health centers were 54% and 62% compared to 54% for a rural health centre (Othieno et al., 2000).

Bazzano et al. (2005), note that epidemiologic studies of alcohol intake and risk of type II diabetes mellitus have produced conflicting results. Nakanishi et al. (2001) in their 1994 to 2001 study of 2,953 Japanese male office workers, aged 35–59 years, found out that the risk for development of type II diabetes decreased progressively up to levels of moderate drinking (23.0–45.9g ethanol/day) and increased in heavy drinkers (≥69.0 g

ethanol/day). These results indicated that moderate alcohol consumption was associated with a reduced risk for type II diabetes and were consistent with those of Rimm et al. (1995); Perry et al. (1995) ; Wei et al. (2000).

These studies found a U-shaped relationship between alcohol consumption and diabetes incidence where moderate drinkers had the lowest risk for diabetes, while nondrinkers and heavy drinkers had a higher risk. However in other studies, alcohol consumption and diabetes incidence were inversely related but the prevalence of heavy drinking was low (1%–3%), hence these studies had limited power to detect a relationship between heavy alcohol use and diabetes (Bazzano et al., 2005).

Joline et al. (2007) found that moderate to heavy alcohol consumption (>5 g/day for women and >10 g/day for men) was associated with a decreased risk of diabetes among women, with an odds ratio of 0.45, but not men where the odds ratio was 1.08. Kiechl et al. (1996) found out that low to moderate amounts of alcohol, when taken on a regular basis, improve insulin sensitivity. In this study low amount of alcohol intake was defined as an intake of ethanol between 1–50 g/day, moderate intake as 51–99 g/day while heavy drinking was defined as an intake of more than 100 g/day.

2.7 Physical Inactivity

Physical activity has for a long time been recommended to patients with type II diabetes as one way of controlling the disease. Physical activity is thought to increase insulin sensitivity, resulting in a higher rate of insulin-stimulated glucose disposal at a defined insulin dose (Bazzano et al., 2005). Hollenbeck et al. (1985) in a study to evaluate the effect of habitual physical activity on regulation of insulin-stimulated glucose disposal in older males concluded that the extensive variation previously noted in vivo insulin-stimulated glucose disposal of older subjects is related to differences in habitual physical activity.

Rosenthal et al. (1983) in a study of 33 healthy non obese subjects to investigate the relationship between level of physical training and in vivo insulin-stimulated glucose utilization concluded that differences in levels of physical training play a regulatory role in control of in vivo insulin action. King et al. (1987) performed a study to evaluate insulin sensitivity and responsiveness performed on 11 endurance-trained and 11 untrained volunteers. The results demonstrated that improved insulin action in healthy trained subjects was due to increased sensitivity to insulin and trained subjects have a smaller plasma insulin response to an identical glucose stimulus than untrained individuals. These results suggest that exercise training increases tissue sensitivity to insulin.

In a follow up study from 1962 to 1976 to examine patterns of physical activity and other personal characteristics in relation to the subsequent development of type II diabetes, leisure-time physical activity, expressed in kilocalories expended per week was inversely related to the development of type II diabetes. The incidence rates declined as energy expenditure increased from less than 500 kcal to 3500 kcal. For each 500-kcal increment in energy expenditure, the age-adjusted risk was reduced by 6% and this protective effect was strongest in persons at the highest risk for type II diabetes (Helmrich et al., 1991).

Physically active lifestyle is associated with a lower risk of later development of impaired glucose tolerance and type II diabetes mellitus as compared to sedentary lifestyle. Hu and colleagues in a follow up study between 1986 and 2002, where physical activity was assessed according to the intensity and amount of exercise, found that there was a progressive increment in the multivariable-adjusted relative risk of diabetes with decreasing quintiles of total MET hours per week (Hu et al., 1999). The Health Study and the Health Professionals' Follow-up Study had similar findings (Manson et al., 1991 and 1992). Those who performed the most physical activity were 26% less likely to develop diabetes than those who were sedentary, and even among women who did not perform vigorous physical activity, those who walked most also were 26% less likely to develop diabetes than those who walked least.

2.8 Unhealthy diet

Bazzano and colleagues in a 2005 review article noted that decades of research had indicated that diets with high saturated fat content and low fiber content may increase the risk of insulin resistance and lead to development of type II diabetes, but epidemiologic data have been relatively inconsistent (Bazzano et al., 2005). In addition, they observed that many aspects of these studies diminished the strength of their conclusions, including large differences in diets, the non-randomized assignment of diets, lack of standardized methods to measure insulin sensitivity and the relatively short duration of intervention in many of these studies.

The role of specific types of fat in the development of type II diabetes mellitus has been evaluated in several studies both prospective and cross-sectional. Monounsaturated or polyunsaturated fats appear to have beneficial effects on insulin action, whereas saturated fats and diets with high total-fat content appear to decrease insulin sensitivity in animal studies (Storlien et al., 1991). Vessby et al. (2001) found that a diet high in saturated fat decreased insulin sensitivity more than a diet high in monounsaturated fats among 162 healthy men and women in a 3-multicentre follow up study. Other studies that have reported similar findings include Feskens et al. (1994); Marshall et al. (1997).

However, one study by Mayer Davis and colleagues to evaluate the cross-sectional relation of habitual dietary fat intake with insulin sensitivity, found a non-significant inverse relationship between total fat intake and insulin sensitivity which was consistent for monounsaturated, polyunsaturated, and saturated fats (Mayer-Davis et al., 1997). The Nurses Health Study (Salmeron et al., 2001) reported an inverse association between development of diabetes and intake of vegetable fat and polyunsaturated fat, a positive association for *trans*-fatty acids, but no association for total fat in the diet.

The role of dietary fiber in the etiology of impaired glucose tolerance and type II sensitivity has also been a subject of several studies. Several large prospective cohort

studies have shown inverse associations between dietary fiber intake and risk of developing type II diabetes mellitus (Salmeron et al., 2001; Feskens et al., 1995; Marshall et al., 1997; Stevens et al., 2001). The Health Professional's Follow-up Study and the Nurses Health Study found stronger associations for cereal fiber than for fiber from other sources (Meyer et al., 2000).

Another area that has been of interest to researchers is the relationship between the intake of whole-grain foods and risk of type II diabetes mellitus. In the Nurses Health Study, Liu and colleagues reported that when the highest and the lowest quintiles of intake were compared, the age and energy-adjusted relative risks were 0.62 for whole grain, 1.31 for refined grain, and 1.57 for the ratio of refined- to whole-grain intake. These findings remained significant in multivariate analyses. The findings were most evident for women with a body mass index greater than 25 and suggested that intake of whole grain instead of refined-grain products may decrease the risk of diabetes mellitus (Liu et al., 2000).

In the Iowa Women's Health Study (Meyer et al., 2000), the relative risks of developing diabetes were 1.0, 0.99, 0.98, 0.92, and 0.79 across quartiles of whole-grain intake, after multivariate adjustment. Those in the highest quartile consumed more than 33 servings of whole-grain foods per week while those in the lowest quartile consumed less than 13 servings per week. Fung and colleagues reported similar results by using data from the Health Professionals' Follow-up Study (Fung et al., 2002).

Two large cross-sectional studies have supported the hypothesized beneficial effects of a high intake of fruits and vegetables on type II diabetes and glucose metabolism (Williams et al., 1999; Sargeant et al., 2001). However the results of prospective cohort studies are inconsistent (Liu et al., 2000b). In some studies, fruit and vegetable consumption was inversely related to incident type II diabetes (Snowdon et al., 1985; Colditz et al., 1992; Feskens et al., 1995; Ford et al., 2001). On the other hand, Meyer and colleagues (Meyer et al., 2000), in a prospective cohort study of 35988 older Iowa women which sought to examine the relations of baseline intake of carbohydrates, dietary fiber, dietary magnesium, and carbohydrate-rich foods and the glycemic index with incidence of

diabetes, intakes of total carbohydrates, refined grains, fruit and vegetables, and soluble fiber and the glycemic index were unrelated to diabetes risk.

Liu and colleagues in a study to evaluate the hypothesis that a high intake of fruits and vegetables protects against the incidence of type II diabetes and to explore whether specific subgroups of fruits and vegetables differentially affect diabetes risk analyzed prospective data from the Women's Health Study from 1993 to 2003. Whereas, they found no inverse association between total intake of fruits and vegetables and risk of incident type II diabetes after adjustment for known risk factors, they found that high intake of green leafy or dark yellow vegetables was associated with a reduced risk of type II diabetes among overweight women (Liu et al., 2000).

Glycemic index and its relation to the etiology of type II diabetes have aroused much research in the last three decades. Since its introduction in 1981, the role of carbohydrates in the development of type II diabetes has been thought to depend less on the size and structure of the carbohydrate molecule and more on the body's glycemic response to different carbohydrates (Jenkins et al., 1981). Jenkins and colleagues did a study in 1981 to determine the effect of different foods on blood glucose, where 62 commonly eaten foods and sugars were fed individually to groups of 5 to 10 healthy fasting volunteers.

Blood glucose levels were measured over 2 hours and expressed as a percentage of the area under the glucose response curve when the same amount of carbohydrate was taken as glucose. The largest rises were seen with vegetables (70 +/- 5%), followed by breakfast cereals (65 +/- 5%), cereals and biscuits (60 +/- 3%), fruit (50 +/- 5%), dairy products (35 +/- 1%), and dried legumes (31 +/- 3%). A significant negative relationship was seen between postprandial glucose rise and fat ($p<0.01$) and protein ($p<0.001$) but not with fiber or sugar content (Jenkins et al., 1981).

Glycemic load, the product of the glycemic index value of a food and its total carbohydrate content, captures both aspects of the glucogenic potential of a food (Bazzano et al., 2005). Liu and colleagues in a study to prospectively evaluate the

relations of the amount and type of carbohydrates with the risk of Coronary Heart Disease (CHD), found that dietary glycemic load was directly associated with the risk of CHD after adjustment for age, smoking status, total energy intake, and other coronary disease risk factors . They concluded that a high dietary glycemic load from refined carbohydrates increases the risk of CHD, independent of known coronary disease risk factors and that a carbohydrate classified by glycemic index, as opposed to its traditional classification as either simple or complex, was a better predictor of CHD risk (Liu, 2000b).

Several large prospective cohort studies that have examined the relationship between glycemic index or load and the risk of developing type II diabetes mellitus have shown that persons with a diet at the highest level of the glycemic index or glycemic load were significantly more likely to develop type II diabetes mellitus than those at the lowest levels (Bazzano et al., 2005). Salmerón and others conducted a study in 1986 to examine the relationship between diet and risk of type II diabetes in a cohort of 42,759 men, 40-75 years of age, without type II diabetes or cardiovascular disease. They found that the dietary glycemic index was positively associated with the risk of type II diabetes after adjustment for age, BMI, smoking, physical activity, family history of diabetes, alcohol consumption, cereal fiber, and total energy intake (Salmeron et al., 1997a). A similar study in 65,173 women, 40 to 65 years of age, had similar findings (Salmeron et al., 1997b).

Two large prospective studies however, found no relationship between dietary glycemic index or glycemic load and the risk of developing type II diabetes mellitus (Meyer et al., 2000; Stevens et al., 2002). Meyer and colleagues examined the relations of baseline intake of carbohydrates, dietary fiber, dietary magnesium, and carbohydrate-rich foods and the glycemic index with incidence of diabetes. They found that intakes of total carbohydrates, refined grains, fruit and vegetables, and soluble fiber and the glycemic index were unrelated to diabetes risk.

Stevens and colleagues studied 12,251 adults aged 45–64 years and free of diabetes at baseline, to determine the association of dietary fiber and glycemic index with incident type II diabetes in African-Americans and whites. They found that after adjustment for age, BMI, education, smoking status, physical activity, sex, and field center, there were no statistically significant associations of intake of total dietary fiber, fruit fiber, legume fiber, glycemic index, or glycemic load with the incidence diabetes (Stevens et al., 2002). However the lack of association in these studies may have been related to the methods of diet assessment used (Bazzano et al., 2005).

2.9 Summary of evidence

Bazzano and colleagues did a review of the evidence to date regarding prevention of diabetes (Bazzano et al., 2005). They concluded that the strength of evidence regarding overweight, obesity, central adiposity, and physical inactivity as risk factors for diabetes type II was convincing. They further concluded that dietary intake of saturated fat was a probable risk factor, while intake of dietary fiber, whole-grain or non-starch polysaccharides was a probable protective factor. Cigarette smoking and intake of *trans*-fatty acids and total fat were possible risk factors, while consumption of a low glycemic index diet was possibly protective. The data on alcohol consumption in relation to diabetes were considered insufficient to render a judgment. Their findings supported the recommendations for the prevention of diabetes that the WHO published in a 2003 technical report (WHO/FAO, 2003).

2.10 Diabetes prevention trials

Several large studies have been done to test the feasibility of long-term prevention of type II diabetes by life-style modification. Eriksson and Lindgärde selected a series of 41 subjects with early-stage type II diabetes mellitus and 181 subjects with impaired glucose tolerance from a previously reported population-based screening program in Malmo, Sweden. They developed a 5-year protocol consisting of dietary treatment and/or increase

of physical activity or training with annual check-ups. Body weight was reduced by 2.3-3.7% among participants, whereas values increased by 0.5-1.7% in non-intervened subjects with impaired glucose tolerance and in normal controls. Glucose tolerance was normalized in greater than 50% of subjects with impaired glucose tolerance, the accumulated incidence of diabetes was 10.6%, and more than 50% of the diabetic patients were in remission after a mean follow-up of 6 years (Eriksson et al., 1991).

In a 1986 randomized follow up study in China, 557 participants with impaired glucose tolerance were randomly assigned by a clinic to a control group or to one of three lifestyle-intervention groups: diet, exercise, and diet plus exercise. After 6 years, the researchers found that compared to the control group, diet, exercise, and diet-plus-exercise interventions were associated with 31%, 46%, and 42% reductions in risk of type II diabetes respectively (Pan, 1997).

Tuomilehto and colleagues in the Finnish Diabetes Prevention Study to determine whether type II diabetes can be prevented by interventions that target the lifestyles of subjects at high risk for the disease, randomly assigned 522 middle-aged, overweight subjects with impaired glucose tolerance to either the intervention group or the control group. The mean duration of follow-up was 3.2 years. The risk of diabetes was reduced by 58 percent ($p<0.001$) in the intervention group and the reduction in the incidence of diabetes was directly associated with changes in lifestyle (Tuomilehto et al., 2001).

In the Diabetes Prevention Program, Knowler and colleagues randomly assigned 3234 non diabetic persons with elevated fasting and post-load plasma glucose concentrations to placebo, metformin or a lifestyle-modification program with the goals of at least a 7% weight loss and at least 150 minutes of physical activity per week. After an average follow-up of 2.8 years, the lifestyle intervention reduced the incidence by 58% while metformin reduced the incidence by 31% as compared with placebo (Knowler et al., 2002).

From the evidence adduced above, it is apparent that early identification of risk factors and intervention may contribute to the prevention of diabetes. Individualized strategies that focus on losing weight, improving dietary composition, increasing physical activity, and avoiding smoking should be pursued on persons with high risk of development of type II diabetes (Bazzano et al., 2005). Satterfield and colleagues in review of literature on community-based interventions intended to prevent or delay type II diabetes, note that approaches that focus on individuals at risk work well for those who are motivated, but community-based prevention programs can benefit more people by facilitating the spread of culturally-relevant messages and providing access to social support systems (Satterfield et al., 2000).

CHAPTER THREE

STUDY METHODS

3.1 Study Site

The study was conducted at St Mary's Mission Hospital in Langata, Nairobi. The choice of this study site was guided by the desire by the researcher to have a sample that is well representative of the large geographical, ethnic and economic diversity of the general Kenyan population. The hospital was chosen as the study sites mainly because it is a big hospital that serves large numbers of patients daily and has a wide catchment area that has large cosmopolitan populations. Since the composition of these populations is not only large but also cuts widely across geographical, ethnic and economic divides, the sample selected in this study is a good representation of the general Kenyan population. This will ensure that the results obtained from the study, and the subsequent recommendations, can easily be generalized to the general Kenyan population.

St. Mary's Mission Hospital is a non-profit making, faith-based hospital. The hospital is made up of several departments that serve the various specialties in medicine. These include out-patient, antenatal and maternity, obstetrics and gynecology, surgical, ophthalmology and radiology departments. The hospital is well equipped and staffed with medical specialists, medical officers, clinical officers, nurses, nurse aides, cooks, watchmen and grounds men.

St Mary's Mission Hospital in Langata, Nairobi is located at Otiende Estate off Langata Road in Nairobi and serves an average of 1,000 outpatients and 350 hospitalized patients daily mainly from the low income areas of Nairobi and its environs. Its catchment area also includes the southern parts of central Kenya, central and southern Rift Valley areas and the central areas of Eastern Province. About 300 members of staff serve at the hospital.

The Diabetic clinic is part of the out-patient department and monthly average of 400 diabetic patients. Most of the cases are diagnosed in other clinical areas but once a diagnosis of diabetes is made, the patient is then referred to the diabetic clinic for follow-up. A diagnosis of diabetes is made according to the WHO criteria for diagnosis of diabetes.

At diagnosis or at first contact with a diabetic patient, several baseline tests are done that include blood counts, kidney function tests, lipoprotein profile and eye check up which are then repeated every 3-6 months of follow up. At each clinic visit blood pressure, body weight, body temperature and random blood sugar measurements are taken before the patient gets to see the doctor. The treatment regimes at the clinic includes not only diabetic medication, but also advice on modification of known lifestyle factors that include body weight, level of physical activity, type of diet, alcohol use and smoking. The patients are then followed up on a monthly basis or as needed.

3.2 Study Population

The study population was made up of newly diagnosed diabetic patients seen at the diabetic clinics and patients seen at the general out-patient clinics for diseases other than diabetes, hypertension, cancer, chronic respiratory disease or any chronic cardio-vascular or cerebro-vascular disease at St Mary's Mission Hospital Langata, Nairobi.

3.3 Study Design

This was a matched case-control study at the out-patient department of the St Mary's Mission Hospital Langata, Nairobi. A case was defined as any patient who was seen at the diabetic clinic, was a newly diagnosed with type II diabetes as per the WHO criteria and gave a fully informed written consent for inclusion into the study. A control was defined as any adult out-patient who was seen at the general out-patient clinic for any disease other than diabetes, hypertension, cancer, chronic respiratory disease or any

chronic cardio-vascular or cerebro-vascular disease, who matched a particular case for age and gender and who gave a fully informed written consent for inclusion into the study.

3.4 Sampling

3.4.1 Sample size

Dupont (1988) gives the calculation for the estimated sample size *n* for a matched case-control study as follows

$$n = \frac{\left[(1/\sigma_\psi)Z_{\alpha/2} + Z_\beta\right]^2}{d^2}$$

$$\sigma_\psi = \sqrt{\sum_{k=1}^{m} \frac{k\, t_k \psi (m-k+1)}{(k\psi + m - k + 1)^2}}$$

$$t_k = p_1(k-1)p_{0+}^{k-1}(1-p_{0+})^{m-k+1} + (1-p_1)\,k\,p_{o-}^{k} - (1-p_{0-})^{m-k}$$

$$p_{0+} = \frac{p_1 p_0 + r\sqrt{p_1(1-p_1)p_0(1-p_0)}}{p_1}$$

$$p_{0-} = \frac{p_0(1-p_1) - r\sqrt{p_1(1-p_1)p_0(1-p_0)}}{1-p_1}$$

$$d = \frac{\left[\sum_{k=1}^{m} \frac{k t_k \psi}{k\psi + m - k + 1}\right] - 1}{\sigma_\psi}$$

Where;

α = alpha,

β = 1 – power,

ψ = odds ratio of exposure in cases relative to controls.

r = correlation coefficient for exposure between matched cases and controls.

p_0 = probability of exposure in the control group.

m = number of control subjects matched to each case subject.

This was a matched case-control study with one matched control per case. The power of the test will be set at 0.8 therefore β **= 0.2** while **α**, the type I error, will be set at **0.05**. The odds ratio of exposure in cases relative to controls will be estimated from the Relative Risk (RR) of type II diabetes in smokers compared to non-smokers. In a large prospective study of 7,124 British men, smokers had a RR for development of type II diabetes of 1.74 compared to non-smokers (Wannamethee et al., 2001), therefore **ψ = 1.74.**

The probability of exposure in the control group was be estimated from the prevalence of smoking in the general population. The prevalence of smoking in Kenya is estimated to be about 19% (KDHS, 2008), therefore p_0 **=0.19.** No data is available from the literature on the correlation coefficient for smoking between matched cases and controls. In such a scenario, Dupont, (1988) advices that, it is better to use a small arbitrary value for **r**, about 0.2, than it is to assume independence, therefore ***r* = 0.2.**

The sample size calculation was done using an internet-based statistical program, *PS Power and Sample Size Calculator, Version 3.0.* Of the five predictor variables, the values for smoking gave the largest sample size, of 132 cases, and were therefore used to calculate the sample size for this study. Therefore, to be able to reject the null hypothesis

that the odds ratio of 1.74 equals 1.0 with a probability of 0.8, at least 132 cases with one matched control per case were studied.

3.4.2 Selection of cases

Any patient who was seen at the diabetic clinic and met the criteria for a case was included into the study. Cases were selected as they become available and questionnaire administration was done continuously on a daily basis during official working hours until the desired sample size was attained.

3.4.3 Selection of controls

Controls were purposively selected to match specific cases selected on that day for age and gender. This was repeated every working day until the desired sample size was attained. For purposes of matching for age a patient was only be considered a suitable control for a particular case if he/she was of the same gender as the case and his/her age was within a range of ± 5 years the age of the case.

3.5 Variables

Dependent variable

- Presence of type 2 diabetes

Predictor variables

- Body Mass Index (BMI).
- Number of pack-years smoked.
- Type of diet.
- Level of physical activity.
- Level of alcohol consumption.

Possible confounding variables

- Level of education

- Work status
- Genetic risk factors of type 2 diabetes unknown at the time of study

3.6 Data Collection Procedure

3.6.1 Data Collection tool

An adapted questionnaire from the WHO STEPwise approach to chronic disease risk factor surveillance (STEPS) was used to collect the data from both the cases and the controls.

3.6.2 Pre-testing of the questionnaire

To check the practicability, reliability and the validity of the questionnaire, pre-testing of the questionnaire was done. Twenty subjects, who did not qualify for inclusion into the study, were selected haphazardly from among the out-patients at any of the two hospitals and the questionnaire was administered to them. Among the things that were of interest during pre-testing and which were be recorded were; the subjects responses to the questions, their ease of understanding the questions, time taken to fill the questionnaire, their reactions to the individual questions and the questionnaire as a whole that included irritation, boredom, antagonism, impatience and the subjects comments on the whole exercise. From these the necessary changes to the questionnaire were identified and made.

3.6.3 Recruitment and training of the research assistants

Two research assistants were recruited from among students at the Kenya Medical Training College. The research assistants were briefed on what the research was all about. They were also trained on how to handle the subjects with courtesy and patience and to explain the whole purpose, importance and any benefit and/or risks of the research and its findings to the subjects and the society as a whole. They were also trained on how to seek their fully informed consent in writing before commencing the questionnaire

administration and to thank them for their participation and seek their comments on the whole exercise at the end of the questionnaire administration. They were also involved in the pre-testing of the questionnaire in order to familiarize themselves with the questionnaire and the whole process of questionnaire administration. This also helped to standardize the way the research assistants ask the questions, seek clarifications and record the responses.

3.6.4 Data collection

A structured, pilot-tested questionnaire was used to collect data on the demographic, educational and work status characteristics as well as the height, weight, levels of alcohol use, smoking, physical activity and dietary habits of the study participants. The subjects were selected as they become available with those who fitted the inclusion criteria and gave a fully informed and written consent being included in the study. Once the subject was through with the doctor, they were directed to a separate room where the research assistant was and after explaining to the respondent about the research and obtaining an informed consent in writing, the research assistant administered the questionnaire to the subject.

A single height board was used to measure the height of all the subjects. Each subject was asked to remove any footwear or headgear before he/she could stand on the board, facing the investigator. Height measurement was done with the feet together, heels against the board and knees straight and was recorded to the nearest 0.5 cm. Weight was determined using the same electronic scale for all the subjects and was adjusted to read 0.0 kg before every use. Weight was taken without shoes or socks and in light clothing. The subjects was asked to step onto the scale with one foot on each side, to stand still with the face forward and arms on the side. The weight was recorded to the nearest 0.5 kg. BMI (Body Mass Index) was calculated for each study subject using the formula: BMI = weight (in kg)/height (in metres) ^{2}.

Sex was categorized into male and female while age was categorized into six mutually exclusive categories of under 25, 25-34, 35-44, 45-54, 55-64 and over 64 years as per the WHO STEPS questionnaire. BMI was categorized according to the WHO classification where there will be four categories; underweight (under 18.5), normal (18.5 to 24.99), overweight (25.0 to 29.99) and obese (over 30.0). Number of pack-years smoked was categorized into six categories; non smokers, 0-4, 5-9, 10–14, 15–19 and 20 or more pack years. Any subject who had not smoked at all in the last 10 years was categorized as a non-smoker. One pack year was defined as the equivalent of smoking 20 cigarettes per day for one year.

Servings of vegetables and fruits were categorized as per as per the WHO STEPS questionnaire. A single serving of vegetables was defined as half a standard plate of green leafy vegetables like sukumawiki and spinach, ¼ of a plate of other vegetables like tomatoes, carrots, pumpkin, cabbage, fresh beans and onion or ½ cup of vegetable juice. A single serving of fruits was defined as one medium size piece of a fruit or ½ cup of canned fruit or fresh fruit juice. Type of diet was categorized into two categories; low in fiber and high in fiber. Low fiber diet was defined as diet that contains at least one serving of vegetable and/or fruit per meal for three meals in a day for at least four days in a week while any diet that had less than this amount of vegetable and/or fruit was categorized as low fiber diet.

Level of alcohol intake was categorized into three categories; no drinking, moderate drinking and heavy drinking as per as per the WHO STEPS questionnaire. A standard alcoholic drink was defined as one standard bottle of regular beer of 500ml, one single measure of spirits of 30ml, one medium size glass of wine of 120ml or a single measure of a local brew that contains about 10 grams of ethanol. A no drinker was defined as any subject who had not taken any alcohol within the last 12 months while a heavy drinker was any subject who took an average of six or more standard alcoholic drinks daily for men and four or more standard alcoholic drinks daily for women for at least five days per week. Any subject who did not fit into any of the above two categories was categorized as a moderate drinker.

Physical activity was categorized into vigorous, moderate and low activity as per as per the WHO STEPS questionnaire. Work related activities that were considered to be of vigorous intensity included, but not limited to digging, cutting and chopping wood, sawing, crop harvesting, grinding, loading, fitness instruction, driving heavy equipment like trucks and cranes. Leisure related activities that were considered to be of vigorous intensity included, but not limited to playing soccer, rugby and tennis, running, aerobics, dancing and swimming. Work related activities that were considered to be of moderate intensity included, but not limited to cleaning, washing, gardening, milking, planting crops, weaving, walking with load on head, drawing water and tending of animals. Leisure related activities that were considered to be of moderate intensity included, but not limited to cycling, jogging, dancing, horse-riding, yoga and playing cricket. Any activity that was of much lower intensity than the two categories above was considered to be of low intensity.

3.7 Ethical considerations

In this study the researcher was guided by the following ethical principles:

3.7.1 Ethical Approval

The study proposal was approved by the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee and the St Mary's Mission Hospitals Ethics and Research Committees.

3.7.2 Confidentiality

Voluntary and fully informed written consent was obtained from all the respondents before their inclusion into this study. All the information given by the respondents was treated with utmost confidentiality. The information was used only for purposes of the study and not for any other purpose.

3.7.3 Plagiarism

All persons whose works were quoted or in any way contributed towards the successful completion of this study were duly acknowledged and credited. The research findings will be fully disseminated to all the stakeholders in this study without any bias.

3.7.4 Consent

Voluntary and fully informed consent was obtained from each subject before his/her inclusion into this study. The research assistants explained to each subject what the study was all about, what was required of them and their rights and obligations as participants in the study. Explanatory forms and consent forms were then provided to each respondent. Each respondent was requested to read through the explanatory statement and the consent form and was then given the opportunity to consider the information, ask any questions or seek any clarifications. Once satisfied by the information and guarantees provided and all his/her queries have been fully addressed by the researcher, he/she signed the consent form. Its then and only then, that he/she was included in the study.

3.8 Data entry, collation and cleaning

Once the target number of both controls and cases was achieved, data entry screens were developed using the SPSS software and verification was done by having the data entered by two different people to check against omissions and double entry. Frequencies were be done for all the variables in the data set to look out for out of range data and summarized in form of frequency tables and graphs.

3.9 Data analysis

The data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 17. The results were presented in form of frequency tables, graphs and contingency tables. To check for any dose-effect relationship and sex differences between each of the lifestyle factors and the presence of type II diabetes, an odds ratio with a 95%

confidence interval was calculated for each age stratum separately within each of the two sex categories for each of the five lifestyle factors.

CHAPTER FOUR

FINDINGS

Introduction

Questionnaires were administered to 132 patients known to have type 2 diabetes to 132 non-diabetics matched for age and sex.

4.1 Socio-demographic Characteristics

Table 1: Age and Sex Distribution among the Cases and the Controls

	CASES				CONTROLS			
AGE	**MALE**	**FEMALE**	**TOTAL**	**%**	**MALE**	**FEMALE**	**TOTAL**	**%**
UNDER 25	3	4	7	5.3	3	4	7	5.3
25-34	9	11	20	15.2	9	11	20	15.2
35-44	19	5	24	18.2	19	5	24	18.2
45-54	16	11	27	20.5	16	11	27	20.5
55-64	17	12	29	22.0	17	12	29	22.0
65-74	15	6	21	15.9	15	6	21	15.9
0VER 74	3	1	4	3.0	3	1	4	3.0
TOTAL	**82**	**50**	**132**	**100**	**82**	**50**	**132**	**100**

The age and sex distribution was the same for both the cases and the controls (Table 1) because the each case was matched to a control for each of these two variables. There were more male patients (164) than female patients (100) seen at the diabetic clinic and interviewed for this study. The extreme age categories of under-25 and over-74 years had the least representation (5.3%, n=7 and 3.0%, n=4 respectively) while the middle-age categories of 45-54 and 55-64 years had the highest representation (20.5%, n=27 and 22.0%, n= 29 respectively).

Table 2: Education level among the Cases and the Controls

	CASES		CONTROLS		TOTAL	
EDUCATION LEVEL	**NUMBER**	**%**	**NUMBER**	**%**	**NUMBER**	**%**
NO FORMAL SCHOOLING	9	6.8	6	4.5	15	6.8
PRIMARY SCHOOL	29	22.0	21	15.9	50	22.0
SECONDARY SCHOOL	65	49.2	69	52.3	134	49.2
COLLEGE/UNIVERSITY	29	22.0	36	27.3	65	22.0
TOTAL	**132**	**100.0**	**132**	**100.0**	**264**	**100.0**

Majority of the study participants (71.2%, n=103) had completed secondary school level of education (Table 2). There was not much difference between the cases and the controls in terms of the distribution of education levels.

Table 3: Marital Status among the Cases and the Controls

	CASES		CONTROLS		TOTAL	
MARITAL STATUS	**NUMBER**	**%**	**NUMBER**	**%**	**NUMBER**	**%**
NEVER MARRIED	15	11.3	16	12.1	15	11.7
MARRIED	92	69.7	88	66.7	50	68.2
SEPARATED	17	12.9	17	12.9	134	12.9
WIDOWED	8	6.1	11	8.3	65	7.2
TOTAL	**132**	**100.0**	**132**	**100.0**	**264**	**100.0**

About two-thirds (68.2%, n=50) of the study participants were married and the distribution of the study participants according to marital status among the cases was similar to the one among the controls (Table 3).

Table 4: Work status among the Cases and the Controls

	CASES		CONTROLS		TOTAL	
WORK STATUS	**NUMBER**	**%**	**NUMBER**	**%**	**NUMBER**	**%**
EMPLOYED	57	43.2	61	46.2	118	44.7
SELF-EMPLOYED	49	37.1	55	41.7	104	39.4
UNEMPLOYED	21	15.9	12	9.1	33	12.5
STUDENT	5	3.8	4	3.0	9	3.4
TOTAL	**132**	**100.0**	**132**	**100.0**	**264**	**100.0**

Overall, 44.7% (n=118) and 39.4% (n=104) of the study participants were either employed or self-employed, respectively and the distribution of the study participants according to work status among the cases and the controls was similar (Table 4).

4.2 Smoking

Majority of the study participants (79.2%, n=209) were non-smokers among both the cases and the controls (Table 5). Among the smokers, the over-19 pack-years categories had the most (7.2%, n=19) study participants among both the cases and the controls while the 5-9 pack-years category had the least representation (1.5%, n=4). In all the categories of smoking, cases were significantly more than controls except in the 10-14 pack-years category where cases were equal to the controls at 3.0% (n=8) .

Table 5: Smoking status among the Cases and the Controls

SMOKING STATUS (Pack-years)	CASES		CONTROLS		TOTAL		ODDS RATIO	95% C.I.	p-VALUE
	Number	%	Number	%	Number	%			
Non-Smoker	93	70.5	116	87.9	**209**	**79.2**	1.0	**Ref**	**Ref**
1 to 4	8	6.1	7	5.3	**15**	**5.7**	1.43	0.43 - 4.79	0.5951
5 to 9	3	2.3	1	0.8	**4**	**1.5**	3.74	0.29 – 198.01	0.3293
10 to 14	4	3	4	3	**8**	**3**	1.25	0.23 – 6.87	>0.9999
15 to 19	7	5.3	2	1.5	**9**	**3.4**	4.37	0.8 – 43.77	0.0835
>19	17	12.9	2	1.5	**19**	**7.2**	10.61	2.4 – 96.14	0.0001
TOTAL	**132**	**100**	**132**	**100**	**264**	**100**			
All Smokers							3.04	1.6 – 5.78	0.0003
MANTEL-HAENSZEL							3.02	1.66 – 5.48	0.0003

The results (Table 5) show that smokers with 1-4 pack-years of smoking were 1.43 times more likely than non-smokers to have type 2 diabetes (OR =1.43, 95% CI = 0.43 – 4.79, p=0.5951) while those with 5-9 pack-years had a likelihood of 3.74 (OR =3.74, 95% CI = 0.29 – 198.01, p=0.3293) compared to non-smokers. This likelihood drops to 1.25 at 10-14 pack-years (OR =1.25, 95% CI =- 0.23 – 6.87, p=>0.9999), rises to 4.37 at 15-19 pack-years (OR = 4.37, 95% CI = 0.8 – 43.77, p=0.0835) up to 10.61 (OR = 10.61, 95% CI = 2.4 – 96.14, p=0.0001) for those with over-19 pack-years of smoking. The general trend is therefore of an increase in the likelihood of having type 2 diabetes, with an increase in the number of pack-years smoked.

With the exception of the over-19 pack-years category the relationships between all categories of smoking and having type 2 diabetes were not significant. It was therefore concluded that there was no significant relationship between having type 2 diabetes and being a smoker with less than 20 pack-years of smoking (p =0.6, 0.33, 0.99 and 0.08 for the 1-4, 5-9, 10-14 and 15-19 pack-years respectively). At 20 pack-years and above, this relationship becomes significant (p=0.0001).

The Mantel-Haenszel statistic showed that smokers in general were 3.02 times more likely than non-smokers to have type 2 diabetes (OR = 3.02, 95% CI = 1.66 – 5.48, p=0.0003). This compares well with common odds ratio for all smokers which was 3.04 (95% CI = 1.6 – 5.78, p=0.0003). It was concluded with 95% confidence that the odds of having type 2 diabetes while a smoker for the population from which the sample for this study was drawn, were between 1.66 and 5.48 as compared to non-smokers in this population. The null hypothesis that there was no relationship between having type 2 diabetes and smoking was rejected. A significant relationship existed between having type 2 diabetes and smoking in the population from which the sample for this study was drawn. The strength of this relationship increased with increase in the number of pack-years smoked but only became significant at 20 pack years of smoking.

4.3 Alcohol

For both cases and controls (Table 6), the modal category was the non-drinker (62.5%, n=165) while heavy drinker had the least representation (1.5%, n=4). Moderate drinkers accounted for about 36% (n = 95) of all patients interviewed for this study. Drinkers, that is both moderate and heavy drinkers combined, accounted for about 56.1% (n = 74) among the cases and 19.2 % (n = 25) among the controls. Therefore majority of the cases were alcohol drinkers while the majority of controls were non-drinkers and for all those interviewed that were alcohol drinkers only a small proportion were heavy drinkers, the rest of them being moderate drinkers.

Table 6: Alcohol-Intake status among the Cases and the Controls

	CASES		CONTROLS		TOTAL		ODDS RATIO	95% C.I.	P-VALUE
LEVEL OF ALCOHOL INTAKE	**Number**	**%**	**Number**	**%**	**Number**	**%**			
NON DRINKER	58	43.9	107	81.1	165	62.5	1.0	**Ref**	**Ref**
MODERATE DRINKER	71	53.8	24	18.2	95	36	5.46	3.01 – 10.02	<0.0001
HEAVY DRINKER	3	2.3	1	1	4	1.5	5.53	0.43 – 293.19	0.1344
ALL DRINKERS	74	56.1	25	19.2	99	37.5	5.46	3.14 – 9.51	<0.0001
TOTAL	**132**	**100**	**132**	**100**	**264**	**100**			
MANTEL-HAENSZEL							5.46	3.16 – 9.43	<0.0001

Moderate alcohol drinkers (Table 6) were 5.46 times more likely to have type 2 diabetes than non-drinkers (OR = 5.46, 95% CI =3.01 – 10.02, p=<0.0001) with only a very marginal increase of this likelihood to 5.53 for the heavy alcohol drinkers (OR = 5.53, 95% CI = 0.43 – 243.2, p=0.1344). The relationship between having type 2 diabetes and moderate alcohol drinking was therefore significant (p=<0.0001). The relationship between having type 2 diabetes alcohol and heavy drinking was not statistically significant (p=0.1344).

The Mantel-Haenszel statistic (Table 6) showed that alcohol drinkers, in general, were 5.46 times more likely to have type 2 diabetes than those who did not take alcohol (OR = 5.46, 95% CI = 3.14 -9.51, p<0.0001). This compares well with common odds ratio for all alcohol drinkers (OR = 5.46, 95% CI = 3.16 -9.43, p<0.0001). It was concluded with 95% confidence that the odds of having type 2 diabetes for all those who took alcohol was between 3.16 and 9.43. A significant relationship existed between having type 2 diabetes and alcohol intake (p = <0.0001). The strength of this relationship increased from 5.46 times to 5.53 times with increase in the level of alcohol intake from moderate to heavy drinking. The null hypothesis that there was no relationship between having type 2 diabetes and alcohol intake was rejected

4.4 Diet

Table 7: Relationship between Diabetic status and High-fiber diet

	CASES		CONTROLS		TOTAL		ODDS RATIO	95% C.I.	P-VALUE
TYPE OF DIET	**Number**	**%**	**Number**	**%**	**Number**	**%**			
LOW FIBRE	83	62.9	81	61.4	164	62.1	1.00	**Ref**	**Ref**
HIGH FIBRE	49	37.1	51	38.6	100	37.9	0.94	0.55 -1.59	0.8991
TOTAL	**132**	**100**	**132**	**100**	**264**	**100**			

The two categories of dietary intake had a similar distribution, 62.9% (n=83) and 37.1% (n=49) among the cases and 61.4% (n=81) and 38.6% (n=51) among the controls, for the low and high fiber categories respectively (Table 7). In both cases and controls, those on low fiber diet were the majority (62.1%, n=164). Therefore, there wasn't much difference between cases and controls in terms of the distribution of the two categories of dietary intake.

Patients on high fiber diet were 0.94 (OR =0.94, 95% CI = 0.55 – 1.59) times more likely to have type 2 diabetes than those on low-fiber diet (Table7). The relationship between having type 2 diabetes and intake of high fiber diet was not significant (p=0.8991). A conclusion was made that there was no significant relationship between having type 2 diabetes being diabetic and the amount of fiber taken in diet by the subjects in this study. The null hypothesis that there was no relationship between having type 2 diabetes and amount of fibre in diet was not rejected.

4.5 Weight

Table 8: Odds Ratio of being diabetic for the different weight categories

	CASES		CONTROLS		TOTAL		ODDS RATIO	95% C.I.	pp-VALUE
WEIGHT STATUS	**Number**	**%**	**Number**	**%**	**Number**	**%**			
NORMAL	49	37.1	74	56.1	123	46.6	**1.0**	**Ref**	**Ref**
UNDER-WEIGHT	1	0.8	20	15.2	21	8	0.08	0.002 – 0.51	0.001
OVER-WEIGHT	44	33.3	32	24.2	76	28.8	2.08	1.12 – 3.87	0.019
OBESE	38	28.8	6	4.5	44	16.6	9.56	3.6 – 29.41	<0.0001
TOTAL	**132**	**100**	**132**	**100**	**264**	**100**			
OVER-WEIGHT + OBESE	82	62.1	38	28.7	120	45.4	3.26	1.92 – 5.52	<0.0001
MANTEL-HAENSZEL (OVER-WEGHT +OBESE)							3.44	2.15 – 5.52	<0.0001

Normal weight was the modal category (46.6%, n = 123) in both cases and controls and under-weight had the least proportion among cases (0.8%, n=1) while the obese category had the least proportion (4.5%, n=6) among the controls (Table 8). There were more overweight and obese patients among the cases (62.1%, n=82) as compared to the controls where the majority of patients were in the under-weight and normal weight categories (71.3%, n=94). The general trend was therefore of an increase in the proportion of patients with increase in weight among the cases as opposed to the controls where the proportion of patients increased as weight decreased.

Under-weight patients (Table 8) were 0.08 times more likely to be have type 2 diabetes than normal-weight patients (OR =0.08, 95% CI= 0.002 – 0.51, p=0.001) and this likelihood rose to 2.08 (OR = 2.08, 95% CI = 1.12 – 3.87, p=0.019) times for the over-weight and peaked at 9.56 times (OR = 9.56, 95% CI = 3.6 – 25.41, p<0.0001) for the obese patients. The trend therefore was of increasing odds of having type 2 diabetes with an increase in body weight.

Mantel-Haenszel statistic was calculated for the over-weight and obese categories. From this statistic over-weight or obese patients were 3.44 times (OR = 3.44, 95% CI = 2.15 –

5.52, p<0.0001) more likely to have type 2 diabetes than normal-weight patients. This compares well with common odds ratio for all over-weight and obese participants (Table 8) where the odds ratio was found to be 3.26 (95% CI = 1.92 – 5.52, p<0.0001). A significant relationship (p=<0.0001) existed between having type 2 diabetes and being over-weight or obese. The strength of this relationship increased with increase in weight from 0.08 times for the underweight participants to 2.08 and 9.56 times for the overweight and the obese participants respectively. The null hypothesis that there was no relationship between having type 2 diabetes and body weight was rejected.

4.6 Physical Activity

Table 9: Relationship between Diabetic status and Physical Activity

	CASES		CONTROLS		TOTAL		ODDS RATIO	95% C.I.	pP-VALUE
LEVEL OF PHYSICAL ACTIVITY	**COUNT**	**%**	**COUNT**	**%**	**COUNT**	**%**			
LOW	29	22	19	14.4	48	18.2	**1.0**	**Ref**	**Ref**
MODERATE	54	40.9	49	37.1	103	39.0	0.72	0.34 – 1.53	0.3846
VIGOROUS	49	37.1	64	48.5	113	42.8	0.5	0.24 – 1.05	0.0583
MODERATE + VIGOROUS	103	78	103	85.6	226	81.8	0.6	0.32 – 1.13	0.0539
TOTAL	**132**	**100**	**132**	**100**	**264**	**100**			
MANTEL-HAENSZEL							0.6	0.37 – 0.98	0.0539

There were more study participants in the moderate activity category among the cases (40.9%, n=54) while there were more study participants in the vigorous activity category (48.5%, n=64) among the controls (Table 9). The low activity category had the least proportion in both the cases and the controls (22%, n=29 and 14.4%, n=19 respectively). The combined proportion of the vigorous and the moderate activity categories was almost the same in the cases (78%, n = 103) as in the controls (85.6%, n = 113).

Study participants who undertook low intensity activities were 0.5 times more likely to have type 2 diabetes (OR = 0.5, 95% CI = 0.24 – 1.0, p=0.0583) than those who

undertook vigorous intensity activities and 0.72 times more likely to have type 2 diabetes (OR = 0.72, 95% CI = 0.34 – 1.53, p=0.3846) as compared to those who undertook moderate intensity activities (Table 9). The likelihood of having type 2 diabetes seemed therefore, to increase with decrease in the in the intensity of physical activity. There was a statistical relationship of borderline significance between being having type 2 diabetes and physical activity of moderate to vigorous intensity. (p= 0.0539).

The Mantel-Haenszel statistic revealed that it could be concluded with 95% confidence that, the odds of being having type 2 diabetes were between 0.37 and 0.98 among those engaged in moderate to vigorous intensity physical activities as compared to those engaged in low intensity physical activities. There was a significant statistical relationship (p=0.0539) between having type 2 diabetes and intensity of physical activity. The null hypothesis that there was no relationship between having type 2 diabetes and intensity of physical activity was rejected.

4.7 Results of Multivariate Analysis

Multivariate Regression analysis was done to assess the relationships between having type 2 diabetes and the five predictor variables while adjusting for any interactions between the variables. The independent variables included in the regression model were: level of alcohol consumption, body weight, pack-years of smoking, level of fiber in diet and level of physical activity.

Table 10: Results of Logistic Regression Model Analysis

	B	Z	p-value	ODDS RATIO	95% CI
INTERCEPT	0.43	1.10	0.2706		
ALCOHOL	1.59	4.94	< 0.0001	4.92	2.61 - 9.27
WEIGHT	1.45	4.97	< 0.0001	4.27	2.41 - 7.56
SMOKING	0.40	0.99	0.3245	1.46	0.68 - 3.20
DIET	0.28	0.94	0.3465	0.75	0.42 - 1.36
PHYSICAL ACTIVITY	0.96	2.52	0.0117	0.38	0.18 - 0.81
MODEL	**BEING DIABETIC = -0.43 + 1.59 ALCOHOL + 1.45 WEIGHT + 0.4 SMOKING -0.28 DIET -0.96 PHYSICAL ACTIVITY**				

The logistic regression analysis model (Table 10) revealed that alcohol consumption and body weight had strong positive relationships with having type 2 diabetes. Alcohol consumers were 4.92 times more likely to be diabetic (OR = 4.92, 95% CI = 2.61 – 9.27, p<0.0001) than those who did not take alcohol while over-weight or obese people were 4.27 times more likely to be diabetics (OR = 4.27, 95% CI = 2.41 – 7.56, p<0.0001) than normal-weight people. Smoking also had a positive relationship with having type 2 diabetes. Smokers were 1.46 times more likely to have type 2 diabetes (OR = 1.46, 95% CI = 0.68 – 3.2, p=0.3245) than non-smokers.

Those on low fiber diet were 1.33 times more likely to have type 2 diabetes (OR = 0.75, 95% CI = 0.42 – 1.36, p=0.3265) than those on high fiber diet. Those who were involved in low intensity physical activities were 2.63 times more likely to have type 2 diabetes (OR = 0.38, 95% CI = 0.18 – 0.81, p=0.0117) as compared to those who were involved in moderate to vigorous intensity physical activities. The odds ratios for smoking and amount of fibre in diet were not statistically significantly different from the null value of 1 (p values = .0.32 and 0.35 respectively) in both controls and cases.

CHAPTER FIVE

DISCUSSION

5.1 Socio-demographic characteristics

There were no significant differences between cases and controls in terms of the distribution of educational levels, marital status and work status.

5.2 Smoking

The study concluded that studied on its own, smoking had a significant dose-response relationship with having type 2 diabetes. Smokers were 1.46 (OR = 1.46, 95% CI = 0.68 – 3.20, p=0.3245) times more likely to have type 2 diabetes than non-smokers. However, after multivariate adjustment for interactions between smoking and the other variables under study, this relationship was not found to be significant.

Prospective studies by Nakanishi (2005) found the respective multivariate-adjusted relative risks for type 2 diabetes compared with never-smokers were 1.08 (95% CI = 0.34 - 3.42), 1.88 (95% CI = 0.71 - 5.00), 3.02 (95 % CI =1.15 - 7.94), and 4.09 (95 % CI = 1.62 - 10.29) (p for trend for current smokers only < 0.001) for never-smokers, ever-smokers, persons who smoked 1 to 20, 21 to 30 and 31 or more cigarettes/day respectively. Wannamethee et al. (2001) showed that male smokers had about 70% higher risk of developing type 2 diabetes than non-smokers. A prospective study among female smokers by Rimm et al. (1995) found a significant dose-response relationship between smoking and development of type 2 diabetes.

The possible explanation for the differences between this study's findings and the findings of the other studies could be the low number of participants at the higher levels of pack-years of smoking. This would have made the power to detect any relationship between type 2 diabetes and smoking to be low.

5.3 Alcohol Intake

The study found out that there existed a significant relationship between having type 2 diabetes and alcohol intake with the strength of this relationship increasing with rise in the level of alcohol intake. The odds of having type 2 diabetes were almost the same for those who took alcohol in moderate and heavy amounts at 5.43 and 5.53 respectively. The relationship between heavy alcohol intake and having type 2 diabetes was however not significant probably due to the low number of study participants that took alcohol in heavy quantities and therefore the power to detect any relationship was low. After multivariate adjustment for interactions between alcohol intake and the other variables under study, those who took alcohol were found to be 4.92 times more likely to have type 2 diabetes than those who did not.

Other studies done on the relationship between alcohol intake and the incidence of type 2 diabetes have had variable results. Nakanishi et al. (2001); Rimm et al. (1995); Perry et al. (1995) and Wei et al. (2000), found that the risk of developing type 2 diabetes decreased progressively up to levels of moderate drinking (23.0–45.9g ethanol/day) and increased in heavy drinkers (≥69.0 g ethanol/day). Rimm et al. (1995) showed that compared with abstainers, men who drank 30.0-49.9 g of alcohol daily had a relative risk of diabetes of 0.61 Bazzano et al., (2005) in a meta-analysis of several prospective studies, on the other hand noted an inverse relationship between alcohol consumption and the incidence of type 2 diabetes but the prevalence of heavy drinking was low (1%–3%), hence these studies had limited power to detect a relationship between heavy alcohol use and type 2 diabetes.

i5.4 Dietary Fiber

This study found out that there was no significant relationship between having type 2 diabetes and the amount of fiber taken in diet. Snowdon et al., 1985, showed that compared with vegetarians, the relative risk of diabetes, was 2.2 for male non-vegetarians and 1.4 for female non-vegetarians. Feskens et al., (1995) showed that increase in the consumption of vegetables and legumes, potatoes, and fish during a 20-year follow-up study was inversely related with 2-hour glucose level ($p < 0.05$).

Meyer et al., (2000) showed that total grain, whole-grain, total dietary fiber, cereal fiber, and dietary magnesium intakes showed strong inverse associations with incidence of diabetes after adjustment for potential non-dietary confounding variables. Multivariate-adjusted relative risks of diabetes were 1.0, 0.99, 0.98, 0.92, and 0.79 (p for trend = 0.0089) across quintiles of whole-grain intake; 1.0, 1.09, 1.00, 0.94, and 0.78 (p for trend = 0.005) across quintiles of total dietary fiber intake. However, the relationships between intakes of total carbohydrates, refined grains, fruit and vegetables, and soluble fiber and the glycemic index and type 2 diabetes were insignificant.

5.5 Weight

This study found that a significant relationship existed between being having type 2 diabetes and being over-weight or obese and that the strength of this relationship increased with increase in weight. After multivariate adjustment for interactions between weight and the other variables under study, overweight and obese people were found to be significantly 4.27 times more likely to have type 2 diabetes than normal-weight people . The finding in this study of a strong dose-response relationship between having type 2 diabetes and body weight corroborates the findings of Coldtz et al. (1990) who found the relative risk for type 2 diabetes among women who had a weight gain of 5.0 to 7.9 kg to be 1.9 times while the corresponding relative risk for women who gained 8.0 to 10.9 kg was 2.7.

Resnick et al., (2000) noted that obesity and excess energy consumption are perhaps the most important factors contributing to risk of type 2 diabetes and therefore even minor weight reductions may have major beneficial effects on subsequent risk of development of type II diabetes in overweight persons.

5.6 Physical Activity

Physical activity was found to have an inverse dose-response relationship with having type 2 diabetes for vigorous activity and for moderate activity. After multivariate adjustment for its interactions with the other variables under study, this relationship was found to be of borderline significance (p=0.0539). Other studies that have been done elsewhere have shown a progressive decrease in the risk of development of type 2 diabetes with increasing physical activity even at much lower levels of physical activity.

Hu et al., 1999 in a 8-year follow-up study found the relative risks of developing type 2 diabetes across quintiles of physical activity, least to most, were 1.0, 0.84, 0.87, 0.77, 0.74 (*p* for trend = 0.002) after adjusting for age, smoking, alcohol use, history of hypertension, history of increased cholesterol levels and BMI. When Helmrich et al., 1991 examined a continuum from no sports to moderate sports only, to vigorous sports only, and finally to a combination of moderate and vigorous sports, in a group of men, the associated rates of type II diabetes decreased significantly, with relative risks of 1.00, 0.90, 0.69, and 0.65, respectively.

Manson et al., 1991 and 1992 found the age-adjusted relative risk of type 2 diabetes decreased with increasing frequency of exercise as follows from 0.77 for once weekly, to 0.62 for two to four times per week, and 0.58 for five or more times per week (*p* trend =.0002). A statistically significant reduction in risk of type 2 diabetes persisted after adjustment for both age and body-mass index with a relative risk of 0.71 for at least once per week compared with less than once weekly.

CHAPTER SIX

CONCLUSIONS

6.1 Alcohol consumption and being over-weight or obese had strong dose-response relationships with having type 2 diabetes.

6.2 Physical activity had a dose-response relationship with having type 2 diabetes that was of borderline significance.

6.3 Smoking and amount of fiber in diet did not have any significant relationships with having type 2 diabetes.

CHAPTER SEVEN

RECOMMENDATIONS

7.1 Alcohol Intake

a. The County Alcoholic Drinks Regulation Committees, Ministry of Health and Kenya Bureau of Standards should strictly enforce the regulations set out in the Alcoholic Drinks Control Act, 2010.
b. All stakeholders in the health sector should develop and conduct continuous public awareness campaigns on the health hazards of alcohol consumption.

7.2 Body Weight

a. Urban physical planning and transportation policies should encourage use of public and non-motorized transport and discourage use of motorized transport.
b. National agricultural and food policies should aim to promote consumption of wholesome indigenous foods while discouraging the consumption of fast foods and limiting the amount of unhealthy ingredients in the foods.

7.3 Physical Activity

a. Urban physical planning and transportation policies should encourage use of public and non-motorized transport and discourage use of motorized transport.
b. Provision of recreation facilities in schools and residential areas to promote physical activity among members of the public.

7.4 Research Recommendations

In view of the contradicting findings of this study vis-à-vis previous studies, more studies on the relationship between type 2 diabetes and smoking should be done with larger sample size so as to increase the power to detect any relationship

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Appendices

Appendix I: Questionnaire

Demographic Information

1. Sex

Male [ ] Female [ ]

2. How old are you (years)?

Under 25 [ ]
25-34 [ ]
35-44 [ ]
45-54 [ ]
55-64 [ ]
65-74 [ ]
Over 75 [ ]

What is the highest level of education that you have completed?

No formal schooling [ ]
Primary school [ ]
Secondary school [ ]
College/university [ ]

What is your marital status?

Never married [ ]

Married [ ]

Separated [ ]

Widowed [ ]

What is your work status?

Employed [ ]

Self employed [ ]

Unemployed [ ]

Student [ ]

Physical Measurements

Height (cm)……

Weight (kg)……

Blood pressure (mm Hg)……

Body Mass Index …….

Behavioral Measurements

Tobacco Use

6. Do you currently smoke any tobacco products, such as cigarettes, cigars or pipes?

Yes [ ] No [ ] *If No, go to 16*

7. Do you currently smoke tobacco products daily?

Yes [ ] No [ ] *If No, go to 12*

8. How old were you when you first started smoking daily?

Age (years)…….. Don't know [ ]

If known, how long ago was it?

Years……

Months……

Weeks……

9. On average, how many of the following do you smoke each day?

Manufactured cigarettes……

Hand-rolled cigarettes……

Pipes of tobacco……

10. Before you started smoking daily, were you smoking but less frequently?

Yes [ ] No [ ] *If No, Go to 16*

11. On average, how many of the following were you smoking each week?

Manufactured cigarettes……

Hand-rolled cigarettes……

Pipes of tobacco……

Go To 16

12. On average, how many of the following do you smoke each week?

Manufactured cigarettes……

Hand-rolled cigarettes……

Pipes of tobacco……

13. In the past, did you ever smoke daily?

Yes [ ] No [ ] *If No, go to 16*

14. How old are you when you started smoking daily?

Age (years)…….. Don't know [ ]

If known, how long ago was it?

Years……

Months……

Weeks……

15. How old were you when you stopped smoking daily?

Age (years)…….. Don't know [ ]

If known, how long ago was it?

Years……

Months……

Weeks……

16. Do you currently use any smokeless tobacco such as snuff?

Yes [ ] No [ ]

If yes, for how long have you used it?

Years……

Months……

Weeks……

Alcohol Consumption

17. Have you ever taken alcohol?

Yes [ ] No [ ] *If No, go to 26*

18. How old were you when you first took alcohol?

Age (years)…….. Don't know [ ]

If known, how long ago was it?

Years……

Months……

Weeks……

19. Since you started taking alcohol, on average how frequently have you had at least one alcoholic drink?

Daily [ ]

5-6 days per week [ ]

3-4 days per week [ ]

1-2 days per week [ ]

Less than once a month [ ]

20. Have you consumed an alcoholic drink within the past 12 months?

Yes [ ] No [ ] *If No, go to 26*

21. During the past one year, how frequently have you had at least one alcoholic drink?

Daily [ ]

5-6 days per week [ ]

3-4 days per week [ ]

1-2 days per week [ ]

Less than once a month [ ]

22. Have you consumed an alcoholic drink within the past 30 days?

Yes [ ] No [ ] *If No, go to 26*

23. During the past 30 days, when you drank alcohol, on average, how many standard alcoholic drinks did you have on one single occasion?

1-2 [ ]
3-5 [ ]
5-10 [ ]
More than 10 [ ]

24. During the past 30 days, what was the largest number of standard alcoholic drinks you had on a single occasion?

1-2 [ ]
3-5 [ ]
5-10 [ ]
More than 10 [ ]

25. During the past 30 days, how many times did you have (for men: five or more for women: four or more) alcoholic drinks on a single day?

None [ ]
2 - 5 [ ]
5-10 [ ]
More than 10 [ ]

26. During each of the past 7 days, how many standard drinks of any alcoholic drink did you have each day?

1-2 [ ]
3-5 [ ]
5-10 [ ]
More than 10 [ ]

Diet

In a typical week, on how many days do you eat fruit?

One [ ]

Two [ ]

Three [ ]

Four [ ]

Five [ ]

Six [ ]

Seven [ ]

How many servings of fruit do you eat on one of those days?

One [ ]

Two [ ]

Three [ ]

More than 3 [ ]

In a typical week, on how many days do you eat vegetables?

One [ ]

Two [ ]

Three [ ]

Four [ ]

Five [ ]

Six [ ]

Seven [ ]

How many servings of vegetables do you eat on one of those days?

One [ ]

Two [ ]

Three [ ]

More than 3 [ ]

Physical Activity

Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like *[carrying or lifting heavy loads, digging or construction work]* for at least 10 minutes continuously?

Yes [ ] No [ ] *If No, go to 28*

In a typical week, on how many days do you do vigorous-intensity activities as part of your work?

One [ ]
Two [ ]
Three [ ]
Four [ ]
Five [ ]
Six [ ]
Seven [ ]

How much time do you spend doing vigorous-intensity activities at work on a typical day?

Less than 30 minutes [ ]
30 minutes to one hour [ ]
1 -2 hours [ ]
2 – 4 hours [ ]
Over 4 hours [ ]

Do you do any vigorous-intensity sports, fitness or recreational (*leisure*) activities that cause large increases in breathing or heart rate like [*running or football,]* for at least 10 minutes continuously?

Yes [ ] No [ ] *If No, go to 28*

In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (*leisure*) activities?

One [ ]

Two [ ]

Three [ ]

Four [ ]

Five [ ]

Six [ ]

Seven [ ]

How much time do you spend doing moderate-intensity sports, fitness or recreational (*leisure*) activities on a typical day?

Less than 30 minutes [ ]

30 minutes to one hour [ ]

1 -2 hours [ ]

2 – 4 hours [ ]

Over 4 hours [ ]

Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking *[or carrying light loads*] for at least 10 minutes continuously?

Yes [ ] No [ ]

In a typical week, on how many days do you do moderate-intensity activities as part of your work?

One [ ]

Two [ ]

Three [ ]

Four [ ]

Five [ ]

Six [ ]

Seven [ ]

How much time do you spend doing moderate-intensity activities at work on a typical day?

Less than 30 minutes [ ]

30 minutes to one hour [ ]

1 -2 hours [ ]

2 – 4 hours [ ]

Over 4 hours [ ]

How much time do you spend walking or bicycling for travel on a typical day?

Less than 30 minutes [ ]

30 minutes to one hour [ ]

1 -2 hours [ ]

2 – 4 hours [ ]

Over 4 hours [ ]

History of Blood Pressure

Have you ever been told by a doctor or other health worker that you have raised blood pressure or hypertension?

Yes [ ] No [ ]

Appendix II: Explanation/consent form.

EXPLANATION FORM

Title of Project: The Relationship between the Presence of Type II Diabetes and Selected Modifiable Lifestyle Factors**: A Case-Control Study at the Out-Patient Departments of the St. Mary's Mission Hospital, Langata, Nairobi and the St. Mary's Mission Hospital, Elementaita, Naivasha.**

Researcher: Dr Isaac Wangai, St Mary's Mission Hospital, Box 3409 Nairobi 00506.

Ethical Approval: This study has received ethical approval from the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee, Located at Kenyatta National Hospital, Hospital Rd. along Ngong Rd, Box 20723 Nairobi.
Tel: 726300-9 Fax: 725272 Email: KNHplan@Ken.Healthnet.org.

Dr Isaac Wangai is a Masters in Public Health (MPH) student at the University of Nairobi. He is doing a study on Lifestyle Factors in Relation to Type II Diabetes: A Case-Control Study at the Out-Patient Department of the St. Mary's Mission Hospital**,** Langata, Nairobi. The results of this study will be used to assist the stake-holders in health-care provision in developing public health programs aimed at lowering the prevalence of the risk factors of type II diabetes in the general population.

This study will determine the type and extent of the relationships between several modifiable lifestyle factors and type II diabetes. These factors include tobacco use, □alcohol consumption, □low intake of fruit and vegetable, physical inactivity and obesity. We will do this by comparing the proportions of these factors in diabetic patients with those in non-diabetic patients. Information will be gathered through questionnaire administration and measurements of height, weight, blood pressure. The questionnaire will have questions concerning your age, sex, level of education, marital status and work

status, level of education, level of tobacco and alcohol use, extent of fruit and vegetable intake, level of physical activity and raised blood pressure.

In the study you will be given a short questionnaire to fill and this will take at most 20 minutes. Only those who consent by signing this consent form will be given the questionnaire. You will not be required to provide your name or any other information that might identify you. By signing the consent form you will be indicating that you fully understand what is expected of you and that you are willing to participate in this study. It is within your right to decline not to take part in the study, □withdraw your consent at any time or □decline to answer any questions in the interview that you do not wish to answer. Your participation and data provided will be completely confidential and your name will not be used in any report of the study. The results will be published in a research report and can be made available to you through the researcher or the School of Public Health at the University of Nairobi Box 19676-00202, Nairobi. Tel +254 (020) 2726300
Email: dept-chealth@uonbi.ac.ke.

There are no major potential harm or risks that you will be exposing yourself to by participating in this study except that you may find some of the questions especially those concerning past lifestyle history of smoking, alcohol intake and diet to be a little personal and intrusive. You are free to decline to answer any of the questions, whether in part or fully, at any stage of the interview. You may be inconvenienced by having to remove your shoes, head gear and any heavy clothing during the height and weight measurements and by spending extra time in the hospital as a result of the interview with research assistant. This study does not involve any invasive medical tests and therefore by participating in this study you will not be subjected to any physical or psychological harm or risk. There are no monetary or any other material benefits that you will gain by participating in this study. However, you may consider it a gain that you will be helping the society at large to acquire knowledge that will help in the prevention of a major killer disease.

Consent

I agree to take part in the study specified above. I have had the project explained to me, I have read and understood the Explanatory Statement and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. I understand that agreeing to take part means that I am willing to answer all the questions in the questionnaire as truthfully as possible and to the best of my knowledge.

I understand that my participation is voluntary, that I can choose not to participate in part or all of the study, and that I can withdraw at any stage of the project without being penalised or disadvantaged in any way.

I understand that any data that the research assistant from the questionnaire for use in reports will not, under any circumstances, contain names or identifying characteristics, any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party.

I understand that I will receive no direct benefit in terms of monetary reward for participation. I understand that the results of this study will be given to me if I ask for them and that if I have any questions about study or about my rights as a study participant I can contact: Dr Isaac Wangai, St Mary's Mission Hospital, Box 3409 Nairobi 00506 Tel 0722678261 or the KNH/UoN Ethics and Research Committee Box 20723 Nairobi. Tel: 726300-9, Fax: 725272 Email: KNHplan@Ken.Healthnet.org.

Participants Name:……..

Signature:…….. Date:……

Interviewers name:…….

Signature:……Date:……