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Prevalence, Risk factors and Predictors of Diabetes-related Complications: Foot ulcers, Lower extremity amputations and Sexual dysfunction in three selected hospitals in Ghana

by

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DECLARATION

I hereby declare that this submission is my own work towards the award of MPhil degree and that, to the best of my knowledge, it contains no material previously published by another person nor material which has been accepted for the award of any other degree of this university or elsewhere, except where due acknowledgement has been made in the text.

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ABSTRACT

The prevalence and complications of diabetes is currently on the rise, thus this study investigated the prevalence, risk factors and predictors of diabetic foot ulcers, lower extremity amputations and sexual dysfunction to improve preventive strategies and care for diabetics. The study was a cross-sectional multicenter study conducted over a period of two months from June to July, 2015. It was carried out at the Korle Bu Teaching Hospital, Komfo Anokye Teaching Hospital and Tamale Teaching Hospital and involved 100 diabetics randomly selected from the diabetes clinics of the study facilities. The socio-demographic characteristics, medical history, lifestyle variables, physical characteristics and sexual dysfunction of the participants were investigated using a structured questionnaire. Blood samples were also taken from subjects and analyzed for triglycerides, total cholesterol, high density lipoprotein cholesterol, low density lipoprotein cholesterol, serum creatinine and serum urea. Estimated glomerular filtration rate was also determined using the serum creatinine. The sex distribution of the study participants was 31% males and 69% females with a mean age of 53.82±13.754 years. Among the patients, 11% had diabetic foot ulcers, 3% had lower extremity amputation and 54.8% and 68.1% of males and females had sexual dysfunction respectively. The prevalence of sexual dysfunction severity was 6.5% and 4.3% in males and females respectively. In univariate analysis the significant factors associated with diabetic foot ulcers were previous history of foot ulcers (p=0.000), foot deformities (p=0.002), impaired vision (p=0.042), serum creatinine (p=0.023) and estimated glomerular filtration rate (p=0.029). In the multivariate binary logistic regression analysis, only previous history of foot ulcers (OR= 40.441, 95% CI=5.453-299.93) and foot deformities (OR= 14.388, 95% CI=1.284-161.24) were identified as independent predictors of diabetic foot ulcers. Foot deformities (P=0.043) and serum urea (P=0.002) were significantly associated with diabetic lower extremity amputations in the univariate analysis. In the multivariate binary logistic regression analysis, only high serum urea (OR= 45, 95% CI=2.0015-1004.773) was identified as an independent predictor of diabetic lower extremity amputations. However, none of the independent variables were associated with sexual dysfunction in both men and women in the univariate analysis. This study has shown that the prevalence of diabetic foot ulcers, lower extremity amputations and sexual dysfunction are high among diabetics. Foot deformities and previous history of foot ulcers were predictive of diabetic foot ulcers while renal failure (high serum urea) was predictive of diabetic lower extremity amputations. Based on the findings of the present study, it is recommended that, interventions geared towards the prevention of foot ulcers, lower extremity amputations and sexual dysfunction in diabetics should be implemented.

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ABBREVIATIONS

aOR:	Adjusted odd ratio
BMI:	Body Mass Index
CI:	Confidence interval
eGFR:	Estimated glomerular filtration rate
GRISS:	Golombok Rust Inventory of Sexual Satisfaction
HDL-C:	High density lipoprotein cholesterol
IBM:	International Business Machines
JHS:	Junior High School
LDL-C:	Low density lipoprotein cholesterol
MDRD:	Modification of diet in renal disease
OHAs:	Oral hyperglycemic agents
PPG:	Postprandial plasma glucose
SD:	Standard Deviation
SHS:	Senior High School
SPSS:	Statistical Package for Social Sciences
TC:	Total cholesterol
TG:	Triglycerides
USA:	United States of America
VCD:	Vacuum Constriction Device
WHO:	World Health Organization

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background to the study

Diabetes mellitus, also known as diabetes, is a chronic disease characterized by high blood glucose concentrations as a result of defects in the release of insulin, action of insulin, or both (Mahan and Escott-Stump, 2008). In short term, high blood glucose can result in excessive thirst, frequent urination, excessive hunger and weight loss, whereas in long-term, it can result in blindness, renal failure, impotence, foot disorders and amputations (World Health Organization, 2015). The prevalence of diabetes in the world and Africa stands at 8.3% and 5.1% respectively; the prevalence of diabetes in adults in Ghana is 3.3% (International Diabetes Federation, 2014b).

Diabetic ulcers occur most often on the bottom of the big toe or on the pad (ball) of the foot (American Diabetes Association, 2015). Diabetic foot ulcers are characterized by a full-thickness perforation of the dermis of the foot in diabetics (Hunt, 2009). It is one of the most common and dreadest complications of diabetes mellitus; the prevalence of diabetic foot ulcers stands at 4.54% in newly diagnosed diabetics (Sinhara *et al*., 2012). People with diabetes develop foot ulcers because of neuropathy, ischemia, or both (Cavanagh *et al*., 2005). Duration of diabetes, age, smoking and insulin/oral hypoglycemic treatment are important factors associated with foot ulcers (Shahi *et al*., 2012).

Regarding diabetic amputations, prevalences of lower extremity amputations in type 1 and type 2 diabetes patients are 1.7% and 0.8%, respectively (National Institutes of Health, 2006). History of previous foot ulcers or amputations (Burns and Jan, 2012), foot

ulceration and evidence of microvascular diseases (Davi *et al*., 2006) are significant factors associated with diabetic lower extremity amputations.

Sexual dysfunction is any difficulty an individual is encountering with the various aspects of sexuality such as arousal, attraction, orgasm and pleasure (Ananya, 2014). Hyperglycemia can cause damage to blood vessels and nerves which can affect sexual performance and enjoyment and can result in diabetic sexual dysfunction in men and women (Josylin Diabetes Center, 2015). Impotence is the commonest sexual problem that occurs in diabetic men whilst painful sexual intercourse, decreased libido, decreased vaginal lubrication and decreased sexual response are also common in diabetic women (National Institute of Diabetes and Digestive and Kidney Diseases, 2012). Body Mass Index (BMI), diabetes duration and diabetes complications are important factors associated with sexual dysfunction in men. Depression and quality of the partner relationship are also associated with sexual dysfunction in women (Enzlin *et al*., 2003). Diabetic sexual dysfunction among men in Ghana stands at 69.3% (Owiredu *et al*., 2011).

These diabetes related complications lead to human suffering, economic burden and mortality. Foot ulcers can be prevented, and interventions can reduce lower extremity amputations by 80% (Shahi *et al*., 2012). Keeping blood glucose levels, cholesterol and blood pressure close to normal can delay or prevent complications of diabetes; diabetics need regular monitoring for complications (International Diabetes Federation, 2013).

The aim of this study was to assess the prevalence, risk factors and predictors of foot ulcers, lower extremity amputations and sexual dysfunction in patients with diabetes to improve preventive strategies and care for diabetics.

1.2 Problem statement

The prevalence of diabetes is increasing in every country; by 2035 the global prevalence which stands at 8.3% will rise to 10.1% and that of Africa which stands at 5.1% will rise to 5.3% (International Diabetes Federation, 2014a) whilst the prevalence in Ghana which is 3.3% (International Diabetes Federation, 2014b) is also bound to rise.

As the prevalence of diabetes increases, so does the prevalence of diabetic foot ulcers, lower extremity amputations and sexual dysfunction, in that, the lifetime risk of a person with diabetes developing a foot ulcer is 25% (Richard and Schuldiner, 2008). The risk for lower extremity amputation is 15 to 40 times higher in people with diabetes than people without diabetes (Centers for Disease Control and Prevention, 2003). More than a third of women with diabetes experience sexual dysfunction (Josylin Diabetes Center, 2015) and men with diabetes are more likely to have erectile dysfunction than men without diabetes (National Institute of Diabetes and Digestive and Kidney Diseases, 2012).

Diabetes complications lead to reduced quality of life, disability and death. As the prevalence of diabetes grows in low- and middle-income countries, so too does the impact on both human and economic terms (International Diabetes Federation, 2013). With regards to diabetic foot ulcers, 12% of all hospitalized diabetic patients in Africa have foot ulceration (Mbanya and Sobngwi, 2003). Research indicates that diabetics with foot ulcers encounter stigma, loss of social role, social isolation and unemployment (Harrington *et al*., 2000). Diabetic foot ulcer is a costly and debilitative disease with severe consequences in diabetic patients (Bijan-Iraj *et al*., 2013). Also, mortality after lower extremity amputations in diabetics varies from 39% to 80% at 5 years (Moulik *et al*., 2003). More than half of all amputations per year are due to diabetes and diabetesrelated complications (Woolley, 2014). Limb amputation causes distortion of body image, increase dependency,

loss of productivity and increase costs of treating diabetic foot ulcers (Shobhana *et al*., 2000). However, no prospective study has been conducted on the prevalence, risk factors and predictors of foot ulcers and lower extremity amputations in people with type 1 or type 2 diabetes in Ghana despite the burden of these complications.

Sexual dysfunction is associated with poorer quality of life (Berardis *et al*., 2002). Sexual dysfunction also results in loss of physical and emotional intimacy and sometimes results in divorce; the prevalence of diabetic sexual dysfunction in men stands at 69.3% in Ghana (Owiredu *et al*., 2010), but this study was limited to only men and was conducted only in Tema General Hospital in the Greater Accra region. Thus there is the need for a multicenter study on the prevalence, risk factors and predictors of diabetic sexual dysfunction in Ghana.

Furthermore, prevalence of diabetic ulcers, amputations and sexual dysfunction vary among countries, in that, diabetic neuropathy, the main cause of these complications varies widely from country to country depending on the methodology used (Mbanya and Sobngwi, 2003). For instance, lower extremity amputation varies from 1.5 to 7% (Mbanya and Sobngwi, 2003) and foot ulcers vary from 4-19% (Abbas and Archibald, 2005). For comparative reasons, it is critical to conduct similar studies in Ghana. Hence studies aimed at defining the extent, the associated risk factors and predictors of diabetes related complications such ulcers, amputations and sexual dysfunctions in diabetic patients would help to improve preventive strategies to lessen the burden of these diabetes related complications.

1.3 Conceptual framework

The conceptual framework presented below was developed from the literature. The dependent variables are foot ulcer, lower-extremity amputation and sexual dysfunction. The independent variables are history of previous ulcer or amputation, impaired vision, foot deformity, diabetic diet, oral hyperglycemic agents and/or insulin use, nephropathy, age, body composition, smoking, alcoholism, hypertension, diabetes duration and dyslipidemia.

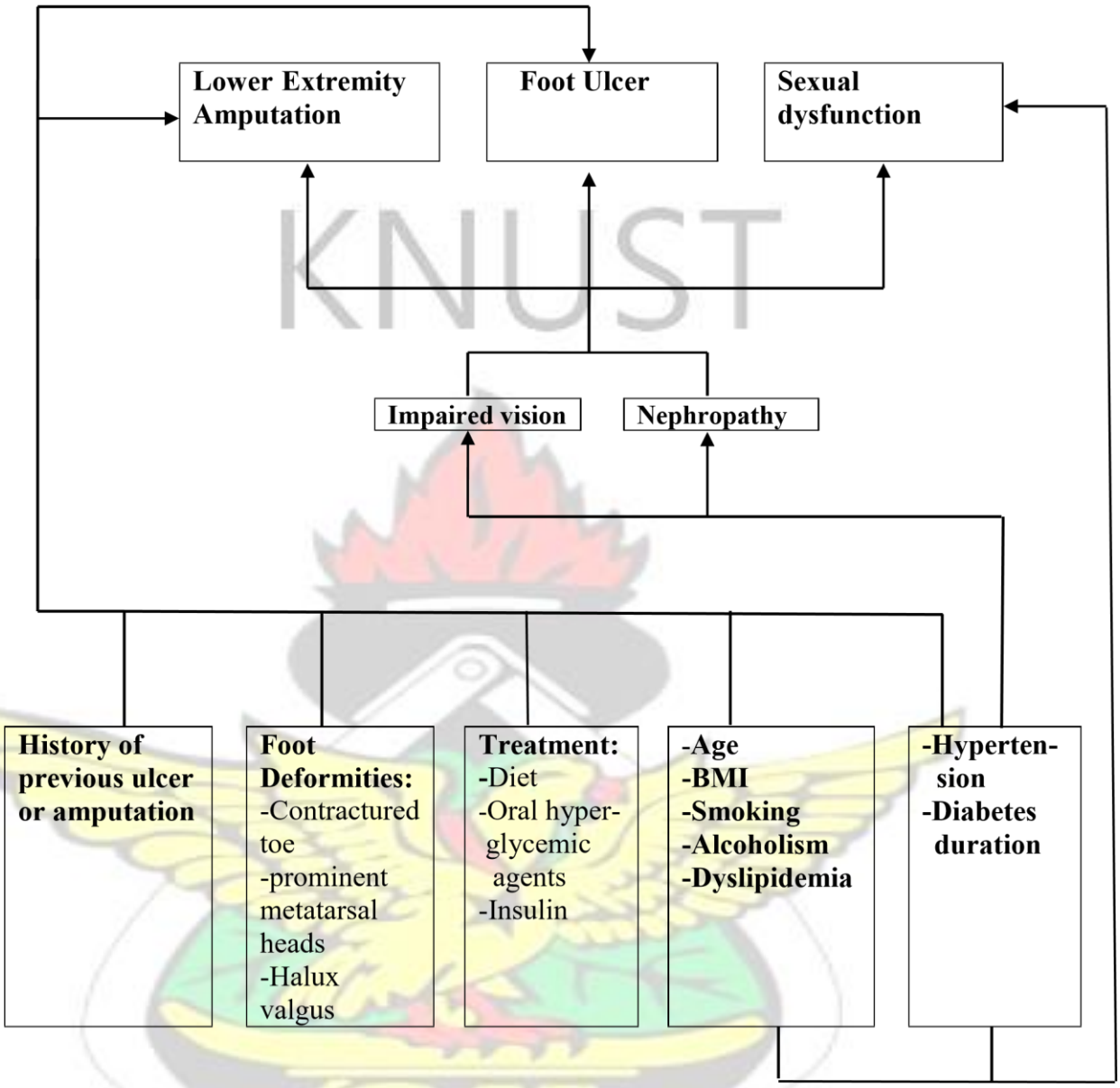


Figure 1.1 Conceptual framework of risk factors and predictors of diabetic foot ulcers, lower extremity amputations and sexual dysfunction

1.4 General and specific objectives of the study

1.4.1 General objective

To assess the prevalence, risk factors and predictors of diabetes related complications: foot ulcers, lower extremity amputations and sexual dysfunction in Ghana.

1.4.2 Specific objectives

- To determine the prevalence, risk factors and predictors of foot ulcers among diabetes patients attending hospitals in Ghana
- To determine the prevalence, risk factors and predictors of lower extremity amputations among diabetes patients attending hospitals in Ghana
- To determine the prevalence, risk factors, predictors and severity of sexual dysfunction among diabetes patients attending hospitals in Ghana

1.5 Justification

This study will provide information on the prevalence, risk factors and predictors of diabetic foot ulcers, lower extremity amputations and sexual dysfunction to improve preventive strategies and care for diabetics. The results of this study will also be useful to care providers and the general public in the management of diabetic foot ulcers, lower extremity amputations and sexual dysfunction to enhance their quality of life. Finally it is hoped that this work will contribute to further research and to policy formulation and implementation.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Diabetes mellitus

Diabetes is a chronic disease that occurs when the body cannot produce enough of the hormone insulin or cannot use insulin effectively; insulin acts as a key that lets the body's cells take in glucose and use it as energy (International Diabetes Federation, 2013). Diabetes Mellitus is diagnosed when fasting plasma glucose is ≥ 7.0mmol/l (126mg/dl) or 2–hour plasma glucose ≥ 11.1mmol/l (200mg/dl) (World Health Organization, 2006).

2.2 Types of diabetes

There are three main types of diabetes namely type 1 diabetes, type 2 diabetes and gestational diabetes (Mahan and Escott-Stump, 2008). Type 1 diabetes results from a cellular-mediated autoimmune destruction of the beta cells of the pancreas leading the body's inability to produce enough insulin (American Diabetes Association, 2008). The cause of type 1 diabetes is not known and it is not preventable with current knowledge; symptoms include excessive excretion of urine, thirst, constant hunger, weight loss, vision changes and fatigue. These symptoms may occur suddenly (World Health Organization, 2015).

In type 2 diabetes, the body is able to produce insulin but either this is not enough or the body is unable to respond to its effects, resulting in the build-up of glucose in the blood (International Diabetes Federation, 2013). Type 2 diabetes is the result of excess body weight and physical inactivity. Symptoms may be similar to those of Type 1 diabetes, but are often less marked, due to this, the disease may be diagnosed many years after onset,

once complications have already set in. Until now, type 2 diabetes was common among adults but it is now also prevalent in children (World Health Organization, 2015).

Gestational diabetes is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (American Diabetes Association, 2008). Women who develop insulin resistance and subsequent high blood glucose during pregnancy are considered to have gestational diabetes (International Diabetes Federation, 2013). Women with gestational diabetes are at high risk of complications during pregnancy and at delivery; they are also at increased risk of type 2 diabetes in the future (World Health Organization, 2015).

2.3 Incidence and prevalence of diabetes

Global incidence and prevalence of diabetes is on the rise. A total of 387 million people have diabetes in the world and by 2035 this will rise to 592 million; 77% of people with diabetes live in low- and middle-income countries; the greatest number of people with diabetes is between 40 and 59 years of age (International Diabetes Federation, 2014a). Prevalence of diabetes in Africa stands at 5.1% and is projected to rise to 5.3% by 2035; in 2014, there were 450,000 (3.3%) cases of diabetes in adults in Ghana (International Diabetes Federation, 2014b). The number of people with diabetes is increasing due to population growth, aging, urbanization, and increasing prevalence of obesity and physical inactivity (Wild *et al*., 2014).

2.4 Mortality of diabetes

Diabetes caused 4.9 million deaths in 2014; every seven seconds a person dies from diabetes (International Diabetes Federation, 2014a). In 2012, about 1.5 million deaths were caused by diabetes; more than 80% of diabetes deaths occur in low- and middle-income countries. World Health Organization projects that diabetes will be the 7th leading cause of death in 2030 (World Health Organization, 2015). In Africa, 8.6% of all deaths can be attributed to diabetes. In 2013 a staggering 76.4% of those deaths occurred in people under the age of 60; there were more than 50% more deaths from diabetes in women compared to men (International Diabetes Federation, 2013). In Ghana, number of deaths due to diabetes is 8,528 (International Diabetes Federation, 2014b).

2.5 Complications of diabetes

Without effective insulin, hyperglycemia (elevated blood glucose) occurs, which can lead to serious complications and premature death (Mahan and Escott-Stump, 2008). Diabetes complications are divided into microvascular and macrovascular complications. Microvascular complications are due to damage to small blood vessels and include damage to eyes leading to blindness, to kidneys leading to renal failure and to nerves leading to impotence and diabetic foot disorders (which include severe infections leading to amputation) (World Health Organization, 2015). Diabetes macrovascular complications are due to damage to larger blood vessels and include cardiovascular diseases such as heart attacks, strokes and insufficiency in blood flow to legs (World Health Organization, 2015).

2.5.1 Diabetic foot ulcer

Diabetic foot is one of the most significant and devastating complications of diabetes, and is defined as a foot affected by ulceration that is associated with neuropathy and/or peripheral arterial disease of the lower limb in a patient with diabetes (Alexiadou and John, 2012). Diabetic foot ulceration is full-thickness penetration of the dermis of the foot in a person with diabetes (Hunt, 2009).

2.5.1.1 Pathogenesis of diabetic foot Ulcer

The major causes of foot ulcers in diabetic patients are peripheral neuropathy and ischemia from peripheral vascular disease (Bowering, 2001). Diabetic peripheral neuropathy is as a result of damage to peripheral nerves, most commonly the nerves of the feet and legs (Stöppler, 2014). In patients with peripheral diabetic neuropathy, loss of sensation in the feet leads to repetitive minor injuries from internal (calluses, nails, foot deformities) or external causes (shoes, burns, foreign bodies) that are unnoticed at the time and may finally lead to foot ulceration. More than 60% of diabetic foot ulcers are the result of underlying neuropathy (Bowering, 2001). One of the most common mechanisms is the polyol pathway. In the etiology of neuropathy, the hyperglycemic state leads to an increase in action of the enzymes aldose reductase and sorbitol dehydrogenase which results in the conversion of intracellular glucose to sorbitol and fructose. The buildup of these sugar products results in a decrease in the synthesis of nerve cell myoinositol needed for normal neuron conduction (Clayton and Elasy, 2009).

Additionally, the chemical conversion of glucose results in a depletion of nicotinamide adenine dinucleotide phosphate (NADP) stores, which are needed for the detoxification of reactive oxygen species and for the synthesis of the vasodilator nitric

oxide. This results in increase in oxidative stress on the nerve cell and an increase in vasoconstriction leading to ischemia, which will promote nerve cell injury and death. Hyperglycemia and oxidative stress also contribute to the abnormal glycation of nerve cell proteins and the inappropriate activation of protein kinase C, leading to further nerve damage and ischemia (Clayton and Elasy, 2009).

Ischemia is a condition in which the blood flow (and thus oxygen) is restricted or reduced in a part of the body (American Heart Association, 2012). Peripheral vascular disease is a chronic limb ischemia caused by atherosclerosis of the peripheral arteries (Ikem *et al.,* 2010). Atherosclerosis is a condition in which plaque builds up inside the arteries. Plaque is made of cholesterol, fatty substances, cellular waste products and fibrin (American Heart Association, 2012). Atherosclerosis is accelerated in diabetic patients compared to non-diabetics and may result in foot ischemia characterized by intermittent claudication, pain with rest and elevation, ulceration and gangrene (Birke *et al*., 1991). Peripheral arterial disease is 2–8 times more prevalent in patients with diabetes and usually more severe than in the general population (Alexiadou and John,
2012).

2.5.1.2 Prevalence of Diabetic Foot Ulcers

In the western world, the prevalence of diabetic foot ulcers has been investigated in several studies. A cross sectional study involving 1260 participants carried out in India revealed that the prevalence of diabetic foot ulcers is 14% (Reddy *et al*., 2015). In a similar study in Jordan involving 1000 subjects, the prevalence of diabetic foot ulcers was reported to be 4.6% (Bakri *et al.*, 2012). Al-Rubeaan *et al*. (2015) also evaluated the prevalence of foot complications associated with diabetes in a survey of 62681 diabetics

attending a hospital in Saudi Arabia. The overall prevalence of diabetic foot complications was 3.3%, whilst the prevalence of foot ulcer was 2.05%.

Several studies have also been done in Africa regarding the prevalence of diabetic foot ulcers. These studies revealed that the prevalence of diabetic foot ulcers vary among Africa countries (Mbanya and Sobngwi, 2003). For instance, in Ethiopia, a cross sectional study was conducted on 216 diabetic clients attending a hospital to investigate the prevalence and factors influencing diabetic foot ulcers. Out of the total 216 study subjects, 32 (14.8%) had diabetic foot ulcers (Deribe *et al*., 2013). In a similar study in Egypt involving 1220 diabetic patients (36.8% males and 63.2% females), the prevalence of foot ulceration was 1.2% (El-Nahas *et al.,* 2008). In Tanzania, the prevalence of foot ulcers was found to be 15% among 404 diabetic patients (Achiwanga and Njelekela, 2015). Also, out of a total of 1788 diabetics screened for diabetic foot ulcers in Kenya, 82 (4.6%) had foot ulcers (Nyamu *et al.,* 2003). Regarding Ghana, a cross sectional retrospective study involving 548 type 2 diabetes patients reported a prevalence of 3.8% (Amissah and Amoako-Boateng, 2014).

2.5.1.3 Factors associated with Diabetic Foot Ulcers

2.5.1.3.1 Body Mass Index (BMI)

Obesity is known to increase plantar peak pressure under the lateral forefoot (Tang *et al*., 2015). An increase in plantar peak pressure may cause tissue breakdown and the development of foot ulcers in diabetics especially those with sensory neuropathy (Rich and Veves, 2000). This correlation between obesity and diabetic foot ulcers has been confirmed in several studies (Pinzur *et al*., 2005; Min-Woong *et al*., 2011; Zaine *et al*., 2014). In contrast, a study by Kafrawya *et al*. (2014) showed no correlation between

obesity and diabetic foot ulcers. Similarly, Altenburg *et al*. (2011) also revealed no link between obesity and diabetic foot ulcers.

2.5.1.3.2 Hypertension

High blood pressure often results in atherosclerosis or hardening of the arteries, which may lead to poor circulation and peripheral arterial disease. Decreased circulation in the feet makes the feet less able to heal and thus results in ulcers (American Podiatric Medical Association). Several studies also identified hypertension as a risk factor for diabetic foot ulcers (Khan *et al*., 2011; Rizka and Ameen, 2013; Kibachio *et al.*, 2011). On the other hand, a study by Nyamu *et al*. (2003) failed to show this relationship. Similarly, Hellar and Mbembati (2011) reported no relationship between hypertension and diabetic foot ulcers.

2.5.1.3.3 Duration of diabetes

Neuropathy and peripheral vascular disease, the main cause of foot ulcers in diabetics develop slowly over time (World Health Organization, 2015). Thus the longer the duration of diabetes, the higher the foot ulcer risk. This link has been proven by Tseng (2003) who identified duration of diabetes as a risk factor for diabetic foot ulcers. Similarly, Al-Rubeaan *et al.* (2015) and Shahi *et al*. (2012) also showed an association between duration of diabetes and foot ulcers.

2.5.1.3.4 Impaired Vision

Foot care is one of the key preventive strategies for reducing foot ulcer risk in diabetics. However, impaired vision often affects the ability of patients with diabetes to

successfully prevent or treat lesions on their foot which leads to foot ulceration (Gils and Stark, 2006). The Seattle Diabetic Foot Study in the United States of American confirmed this relationship (Boyko *et al*., 1999). Leymarie *et al*. (2005), Aziz (2010), Rizka and Ameen (2013) and Kafrawya *et al*. (2014) also revealed a strong correlation between poor vision and diabetic foot ulcer risk.

2.5.1.3.5 Nephropathy

The correlation between foot ulcers and renal dysfunction in diabetics may be due to long duration of diabetes, which predisposes to both renal dysfunction and foot ulcers and the high risk of patients with renal dysfunction to develop ischemia or neuropathy (Michael *et al.*, 2000). Studies done by Apelqvist and Agardh (1992), Fernando *et al*. (2009) and Al-Rubeaan *et al*. (2015) also showed a link between dysfunction and diabetic foot ulcers risk. In contrast, Shahi *et al*. (2012) reported no association between renal dysfunction and diabetic foot ulcer risk.

2.5.1.3.6 Smoking

Smoking has been identified in previous studies (Musa and Ahmed, 2012; Kafrawya *et al*., 2014) as a risk factor for diabetic foot ulcers. This may be due to the fact that smoking leads to the development of peripheral vascular diseases, one of the main causes of foot ulceration in diabetics (American Diabetes Association, 2014). On the other hand, Altenburg *et al*. (2011) did not identify smoking as a risk factor for diabetic foot ulcers. Similarly, Sriyani *et al*. (2013) and Boyko *et al*. (1999) found no relationship between smoking and diabetic foot ulcer risk.

2.5.1.3.7 Foot deformity

Foot deformities are known to predispose diabetes patients with peripheral neuropathy to abnormal weight bearing areas of concentrated pressure in the feet which results in the development of foot ulceration (Lavery *et al*., 1995). Abbott *et al*. (2002) in a study to determine the risk factors of diabetic foot ulcers revealed a strong correlation between foot deformities and diabetic foot ulcer risk. This finding is also in consonance with that of El-Nahas *et al*. (2008), Khan *et al*. (2011) and Kafrawya *et al*. (2014).

2.5.1.3.8 Dyslipidemia

Dyslipidemia has been confirmed as a risk factor for diabetic foot ulcers in some studies (Tseng, 2003; Nyamu *et al*., 2003). This may be linked to the role of dyslipidemia in the etiology of peripheral vascular diseases, one of the causes of foot ulceration in diabetics (American Diabetes Association, 2014). In contrast, Hellar and Mbembati (2011) failed to show an association between dyslipidemia and foot ulcer risk in diabetics.

2.5.1.3.9 Diabetes treatment

According to Musa and Ahmed (2012), treatment of diabetes with either diet or medication (insulin/or OHAs) does not increase foot ulcer risk in diabetics. Contrarily, Shahi *et al*. (2012), in a study to evaluate the predictors of lower extremity amputations indicated that insulin/or oral hypoglycemic treatment is predictive of lower extremity amputations in diabetics. Insulin/or oral hypoglycemic agents use has been noted to cause

peripheral nerve degeneration which can result in diabetic foot ulcers (Gibbons and Freeman, 2010).

2.5.1.3.10 Alcoholism

The use of alcohol can cause permanent nerve damage, in that ethanol, the main component of alcohol, is toxic to nerve tissue (American Health Network, 2015). Nerve damage in the feet results in loss of sensation which may increase foot ulcer risk in diabetics. A study by Altenburg *et al*. (2011) confirmed this correlation. In contrast, Sriyani *et al*. (2013) and Achiwanga and Njelekela, (2015) showed no correlation between alcoholism and diabetic foot ulcers.

2.5.1.3.11 Previous history of foot ulcer/Amputation

After wound healing following ulceration or amputation, the skin plantar to that area may become less resilient to accept repetitive stress and often results in subsequent breakdown leading to foot ulceration (Helm *et al*., 1991). Abbott *et al*. (2002) in a study to evaluate the risk factors for new foot ulceration in diabetic patients indicated a link between previous history of foot ulcer or amputation and diabetic foot ulcer risk. Similarly, Kafrawya *et al*. (2014), Achiwanga and Njelekela (2015) and Boyko *et al*. (1999) also found a strong correlation between history of foot ulcer or amputation and foot ulcer risk in patients with diabetes.

2.5.1.3.12 Age

Increasing age causes changes in inflammatory response including a delay in Tcell infiltration into wound sites with changes in chemokine production and a reduction in

macrophage phagocytic capacity resulting in a delay in wound healing (Guo, 2010). This may account for the link between age and diabetic foot ulcers identified by Leung *et al.* (2001), Iversen (2009) and Wang *et al*. (2014). On the other hand, a study carried out to assess the risk factors for diabetic foot ulcers revealed that age was not associated with diabetic foot ulcer risk (Kafrawya *et al.*, 2014).

2.5.1.4 Treatment of Diabetic foot ulcer

Successful treatment of diabetic foot ulcers consist of addressing these three basic issues: debridement, offloading, and infection control (Kruse and Edelman, 2006).

2.5.1.4.1 Debridement

Debridement consists of removal of all necrotic tissue, peri-wound callus, and foreign bodies down to viable tissue. Proper debridement is necessary to decrease the risk of infection and reduce peri-wound pressure, which can impede normal wound contraction and healing. After debridement, the wound should be irrigated with saline or cleanser, and a dressing should be applied (Kruse and Edelman, 2006).

2.5.1.4.2 Offloading

In the treatment of diabetic foot ulcers, pressure modulation, commonly referred to as "offloading," is most successful when pressure is mitigated at an area of high vertical or shear stress (Armstrong *et al*., 1998). Having patients use a wheelchair or crutches to completely halt weight bearing on the affected foot is the most effective method of offloading to heal a foot ulceration (Kruse and Edelman, 2006).

2.5.1.4.3 Infection control

Infection should be controlled using antibiotics. Antibiotics selected to treat severe or limb-threatening infections should include coverage of gram-positive and gram-negative organisms and provide both aerobic and anaerobic coverage. Patients with such wounds should be hospitalized and treated with intravenous antibiotics (Kruse and Edelman, 2006). Mild to moderate infections with localized cellulitis can be treated on an outpatient basis with oral antibiotics such as cephalexin, amoxicillin with clavulanate potassium, moxifloxacin, or Clindamycin; the antibiotics should be started after initial cultures are taken and changed as necessary (Kruse and Edelman, 2006).

2.5.2 Diabetes-related lower extremity amputation

2.5.2.1 Definition and etiology

Diabetic Lower Extremity Amputation refers to the loss of a lower limb caused by diabetes. The loss of a limb is a frequent complication of diabetes mellitus, most commonly the result of diabetic foot problems such as ulcers and infection (Payne, 2000). Infection is the major cause of amputations among patients with diabetes (Viswanathan and Kumpatla, 2011). People with diabetes often have nerve damage that reduces the ability to feel. This inability to feel makes it hard to notice that a wound has occurred so the wound goes untreated; left untreated infections can enter these wounds and spread causing irreversible damage that may result in amputation (Maine Medical Center, 2015).

2.5.2.2 Prevalence of Diabetes-related Lower Extremity Amputation

The prevalence of lower extremity amputations in diabetics was found to be 4% in United State of America by Freeman and Hosey (1993). In Jordan, a cross sectional study revealed that the prevalence of lower extremity amputations is 1.7% among diabetes patients (Bakri *et al*., 2012). Similarly, in Taiwan, the prevalence of lowerextremity amputation among patients with diabetes mellitus was also found to be 1.7% and 1.5% in Thailand (Krittiyawong *et al*., 2006). Regarding Ghana, a retrospective study involving Type 2 Diabetes Mellitus patients aimed at determining the prevalence of lower extremity amputations reported a prevalence of 1.1% (Amissah and Amoako-Boateng, 2014).

2.5.2.3 Factors associated with Diabetic Lower Extremity Amputation

2.5.2.3.1 Body mass index (BMI)

Overweight increases plantar peak pressure under the feet and thus causes tissue breakdown resulting in wounds or ulcers especially in diabetics with neuropathy (Rich and Veves, 2000). These wounds can get infected and result in amputation (Maine Medical Center, 2015). Contrary to this relationship, a study by Sohn *et al*. (2012) found no correlation between obesity and lower extremity amputations in diabetics. Similarly, according to Jung *et al*. (2007), obesity is not related to lower extremity amputation risk in diabetics.

2.5.2.3.2 Hypertension

Hypertension increases the risk of amputations through its role in the etiology of atherosclerosis. Atherosclerosis causes peripheral arterial disease, a condition characterized by a decreased blood flow to the feet. Reduced blood flow makes the feet less able to fight infection and to heal and thus results in ulcers and infections that may lead to amputation (American Diabetes Association, 2015). Studies by Lee *et al*. (1993) and Moss *et al*. (1992) demonstrated a strong relationship between hypertension and lower extremity amputations in diabetics. Gürlek *et al*. (1998) and Jung *et al*. (2007) did not identify hypertension as a risk factor for lower extremity amputations in diabetics.

2.5.2.3.3 Duration of diabetes

The longer the duration of diabetes, the higher the amputation risk. This is attributed to the fact that nerve damage and decreased blood flow, the main causes of lower extremity amputations in diabetics develop over time (World Health Organization, 2015).

A study by Jbour *et al*. (2003) concluded that long duration of diabetes is associated with increased risk of lower extremity amputation. Similarly, Gallagher *et al*. (2014) found a strong correlation between duration of diabetes and lower extremity amputation.

2.5.2.3.4 Impaired vision

Poor diabetic foot care can result in infections leading to amputations. Impaired vision in diabetics impairs their ability to care for their feet properly which can result in amputations. It is no wonder that Jbour *et al*. (2003) and Laclé and Valero-Juan (2012) found a similar relationship. In contrast, Gürlek *et al*. (1998) in a study to determine the risk factors for lower extremity amputations in diabetics found no link between poor vision and diabetic lower extremity amputations. Similarly, Jung *et al*. (2007) revealed no link between poor vision and diabetic lower extremity amputations.

2.5.2.3.5 Nephropathy

Nephropathy can lead to the development of neuropathy. Kidney disorders can result in abnormally high amounts of toxic substances in the blood that can damage nerve tissues (National Institute of Neurological Disorders and Stroke, 2015) leading to loss of sensation in the feet making diabetics more prone to foot ulcers which can result in amputations. Similarly, nephropathy was identified as significant predictor of diabetic lower extremity amputations in a study by Jiang, et al., 2015. In line with this finding, Young *et al*. (2003) reported that the presence of diabetic nephropathy increases the risk of diabetic amputations.

2.5.2.3.6 Smoking

Nicotine in cigarette smoke increases blood vessel density and inhibits blood flow. Furthermore, other by-product of cigarette smoke especially hydrogen cyanide and carbon monoxide reduce tissue perfusion and oxygenation leading to ischemia (Zheng and Cheung, 2008). Ischemia inhibits the normal metabolism of healing and also causes tissue death which can result in amputation in diabetics. Gürlek *et al*. (1998) and Alder *et al.* (1999) on the other hand showed no connection between smoking and lower extremity amputations in diabetics.

2.5.2.3.7 Foot Deformity

Foot deformities are associated with increased plantar peak pressure which can cause the skin to breakdown leading to ulcers and infections. These deformities are also portals for bacterial entry, resulting in the development of serious limb infections and possibly amputations in diabetics (Varma, 2011). A study by Srinivas *et al.* (2012) also showed that foot deformities can result in lower limb amputations in diabetics, although multivariate analysis was not performed in the study. In contrast, Assumpção *et al*. (2009) in a study aimed at assessing the risk factors for amputations, failed to show that foot deformities are independent predictors of lower extremity amputations in diabetics.

2.5.2.3.8 Dyslipidemia

Dyslipidemia worsens diabetic atherosclerosis, the buildup of fats, cholesterol and other substances in the artery (Cassoobhoy, 2014). Atherosclerosis of peripheral arteries results in peripheral vascular disease, a chronic limb ischemia (Ikem *et al*.,

2010). Ischemia reduces blood flow to the feet leading to foot ulcers and infections which can result in amputation. On the contrary, findings of Selby and Zhang (1995) and Rajamani *et al.* (2009) did not support this correlation.

2.5.2.3.9 Diabetes Treatment

Insulin or oral hyperglycemic agents treatment in diabetics causes the peripheral nerve to degenerate (Gibbons and Freeman, 2010) resulting in loss of sensation in the feet leading to injuries going unnoticed, increasing the risk for ulcer development, infections and hence amputations. Krittiyawong *et al*. (2006), in a study to evaluate the risk factors associated with lower extremity amputations, confirmed that insulin use is predictor of lower extremity amputations in diabetics. On the other hand, oral hyperglycemic agents use was not identified as a risk factor for lower extremity amputations by Yekta *et al*. (2011). Regarding diabetic diet, Yekta *et al*. (2011) also identified it as an insignificant risk factor for lower extremity amputation in diabetics.

2.5.2.3.10 Alcoholism

Alcohol abuse causes nerve damage (alcoholic neuropathy). This may be due to the fact that the ethanol, present in alcohol is toxic to nerve tissues (American Health Network, 2015). Nerve damage in the feet results in loss of sensation, thus increases the risk of ulcer which when infected can result in amputation. In contrast, Adam *et al*. (2009) and Jung *et al*. (2007) did not confirm this correlation.

2.5.2.3.11 Previous history of foot ulcers/amputations

The skin on scars, formed following the healing of ulcers or wounds easily breakdown when there is an increase in foot pressure, hence increases ulceration and reamputation risk (Helm, 1991). A study by Siddiqui *et al.* (2004) showed that previous history of foot ulcer increases the risk of lower extremity amputation in diabetics. In contrast, Monteiro *et al*. (2014) in a study to determine risk factors for diabetic foot's amputation showed previous history of amputation not to be a risk factor for lower extremity amputation in diabetics.

2.5.2.3.13 Age

Increasing age has been linked to increase risk of lower extremity amputations in diabetics in several studies (Jung *et al.*, 2007; Rajamani *et al*., 2009; Wang *et al*., 2014) as increasing age causes changes in inflammatory response including a delay in T-cell infiltration into wound sites resulting in a delay in wound healing (Guo, 2010). A delay in wound healing may lead to infections which can progress to amputations. Contrarily, Sekamatte (2014), Monteiro *et al*. (2014) and Gürlek *et al*. (1998) found no correlation between age and lower extremity amputations.

2.5.3 Diabetic sexual dysfunction

2.5.3.1 Definition and Etiology

Sexual dysfunction refers to any difficulty a person or couple are experiencing with the various aspects of sexual activity such as attraction, arousal, pleasure and orgasm (Ananya, 2014). Hyperglycemia can result in blood vessel and nerve damage that hamper sexual performance and enjoyment in both men and women (Josylin Diabetes Center, 2015).

2.5.3.2 Diabetic Sexual Dysfunction in Men

Male sexual dysfunctions among diabetic patients include erectile dysfunction, disorders of libido and ejaculatory problems, with erectile dysfunction being the commonest (Penson and Wessells, 2004). The causes of impotence (erectile dysfunction) in men with diabetes are complex and involve impairments in nerve, blood vessel, and muscle function (Smith, 2013). Nitric oxide is a chemical released into the bloodstream by the lining of blood vessels and acts as a chemical messenger that tells the smooth muscles and arteries in the penis to relax and let in blood. High blood sugar causes blood vessel and nerve damage which blocks the release of nitric oxide resulting in constricted blood vessels and reduces blood flow to the penis (Derrer, 2014) and thus leads to erectile dysfunction.

2.5.3.3 Diabetic Sexual Dysfunction in Women

The commonest sexual problems in women with diabetes include: decreased vaginal lubrication, decreased or no desire for sexual activity and decreased or absent sexual response. The causes of these sexual problems include nerve damage, reduced blood flow to genital and vaginal tissues, and hormonal changes (National Institute of Diabetes and Digestive and Kidney Diseases, 2012). Diabetes-related blood vessels damage leads to reduced blood supply to the clitoris and thus causes vaginal dryness and affects arousal. Diabetes also reduces the secretion of estrogen in the body thereby reducing lubrication in the vagina (Galaly, 2012). Diabetes-related nerve damage causes vaginal dryness and loss of sensation in the genital area making intercourse uncomfortable and orgasm difficult or impossible to achieve (Josylin Diabetes Center, 2015).

2.5.3.4 Prevalence of sexual dysfunction in diabetics

2.5.3.4.1 Prevalence of Diabetic Sexual Dysfunction in Men

The prevalence of sexual dysfunction in diabetic men varies among studies. A cross-sectional, descriptive study done in Nigeria reported a sexual dysfunction prevalence of 58% in diabetic men (Unadike *et al*., 2008). Similar studies in Ghana by Amidu *et al*. (2010) and Owiredu *et al.* (2011) reported prevalences of 70% and 69.3% respectively. Regarding the study by Owiredu *et al*. (2011), sexual dysfunction was related to infrequency (79.2%), non-sensuality (74.5%), dissatisfaction with sexual acts (71.9%), non-communication (70.8%) and impotence (15.8%).

2.5.3.4.2 Prevalence of Diabetic Sexual Dysfunction in Women

The prevalence of female sexual dysfunction has been observed to vary among studies. Singh *et al.* (2009) in a study to investigate the prevalence of sexual dysfunction in female diabetics reported a prevalence of 73.2%. A prevalence of 59.6% was also reported among Jordanian diabetic women by Ali *et al.* (2008). A similar study conducted among diabetic women in Italy reported a prevalence of 53.4% (Esposito *et al*., 2010). Owiti *et al*. (2012) in Kenya reported a prevalence of 36.6%.

2.5.3.5 Factors associated with Diabetic Sexual Dysfunction

2.5.3.5.1 Body mass index (BMI)

Obesity is known to be associated with sexual dysfunction. Mechanisms through which obese diabetics develop sexual dysfunction include hormonal imbalance, dyslipidemia and psychological factors (poor sexual self-esteem) (Mozafari *et al.*, 2015). Owiredu *et al.* (2011) in a study to evaluate the determinants of sexual dysfunction in diabetic men in Ghana confirmed the relationship between obesity and sexual dysfunction risk. In contrast, Hosseinzadeh *et al.* (2014) and Vafaeimanesh *et al.* (2014) showed no link between obesity and sexual dysfunction in women and men respectively.

2.5.3.5.2 Hypertension

High blood pressure worsens atherosclerosis or hardening of the arteries in diabetics which can lead to a decrease in blood flow. Decreased blood flow through the arteries and veins result in erectile dysfunction in men and in women, leading to lower libido and less interest in sex (American Heart Association, 2015). Contrarily, Ziaei-Rad *et al.* (2010) revealed no link between high blood pressure and sexual dysfunction in both

genders. Similarly, Esposito *et al*. (2010) and Vafaeimanesh *et al.* (2014) found no association between high blood pressure and sexual dysfunction in diabetic women. On the contrary, Sharifi *et al*. (2012) and Peter *et al*. 2012) showed an association between hypertension and sexual dysfunction in diabetics.

2.5.3.5.3 Diabetes duration

Long duration of diabetes leads to blood vessel and nerve damage as these complications develop slowly over time in diabetics. Diabetic nerve and artery damage in the genital area can disrupt blood flow necessary for erection in men. Nerve damage can also lead to dryness of the vagina and loss of sensation in the genital area in women (Josylin Diabetes Center, 2015). On the other hand, Ziaei-Rad *et al*. (2010) failed to show this connection in both genders. Similarly, Esposito *et al*. (2010) and Omidvar *et al*. (2013) found no association between duration of diabetes and sexual dysfunction in diabetic women.

2.5.3.5.4 Impaired vision

The link between impaired vision and sexual dysfunction could be due to the role of endothelial dysfunction in the pathogenesis of sexual dysfunction which is also implicated in the etiology of impaired vision. Furthermore, pro-inflammatory cytokines which are high in people with impaired vision also lead to atherosclerosis resulting in reduced blood flow causing sexual dysfunction (Chew *et al.,* 2013). Impaired vision has been identified as a risk factor for sexual dysfunction in men (Henis *et al.,* 2011). Ali *et al*. (2008) and Vafaeimanesh *et al.* (2014) have also proven this relationship in diabetic women.

2.5.3.5.5 Nephropathy

Kidney dysfunction can result in the accumulation of high amounts of toxic substances in the blood that can damage nerve tissue (National Institute of Neurological Disorders and Stroke, 2015). Neuropathy (nerve damage) in the genital area can lead to loss of sensation which can cause sexual dysfunction in both men and women. Chernyshova *et al*. (1991) confirmed in a study that renal dysfunction is a significant risk factor for sexual dysfunction in male diabetics. Similarly, Copeland *et al*. (2012) also demonstrated that renal dysfunction is linked to sexual dysfunction in women.

2.5.3.5.6 Smoking

Tobacco smoking can reduce arterial flow to the penis or acute vasospasm of the penile arteries, in that it causes damage to the vascular endothelium, peripheral nerves and the corporal tissue (Tostes *et al*., 2008). Peripheral nerve damage caused by smoking leads to sexual dysfunction in women as it results in loss of sensation in the genital area and vagina dryness (Josylin Diabetes Center, 2015). Despite the theoretical basis of this relationship, Mutagaywa *et al*. (2014) showed no correlation between smoking and sexual dysfunction in diabetic men. Similarly, Ali *et al*. (2008) and Esposito *et al*. (2010) found no association between smoking and sexual dysfunction in diabetic women.

2.5.3.5.7 Dyslipidemia

Dyslipidemia often result in atherosclerosis, the buildup of fats, cholesterol and other substances in the arteries (Cassoobhoy, 2014). Atherosclerosis leads to decreased blood flow in arteries and veins which can result in erectile dysfunction in men and a lower

libido in women (American Heart Association, 2015). A study by Esposito *et al.* (2010) showed that prevalence of female sexual dysfunction is correlated to dyslipidemia. In contrast, Ali *et al*. (2008) showed no correlation between dyslipidemia and sexual dysfunction in diabetic women. Similarly, Sharifi *et al*. (2012) and Mutagaywa *et al.* (2014) did not identify dyslipidemia as a risk factor for sexual dysfunction in men.

2.5.3.5.8 Alcoholism

Alcohol intake worsens diabetes-related complications such as nerve damage (neuropathy), because the ethanol in alcohol has been known to be toxic to nerve tissue (American Health Network, 2015). Nerve damage results in loss of sensation in the genitals which affects sexual function in both genders. Contrarily, alcohol intake has been shown to be an insignificant risk factor for sexual dysfunction in men (Peter *et al*., 2012). Mutagaywa *et al.* (2014) did not also confirm the relationship between alcohol intake and sexual dysfunction in men.

2.5.3.5.9 Age

Testosterone level declines with age (Camacho *et al*., 2005). Low testosterone levels leads to sexual dysfunction as a result of decreased libido and sexual drive. Similarly, Esposito *et al*. (2010) also identified increasing age as a risk factor for sexual dysfunction in diabetics. Contrarily, Ziaei-Rad *et al*. (2010) revealed no significant association between age and sexual dysfunction in both genders. Omidvar *et al.* (2013) also failed to show any connection between age and sexual dysfunction in female diabetics.

2.5.3.6 Treatment of sexual dysfunction in diabetics

Treatments available for impotence in diabetic men include oral medications, intraurethral therapy, penile implants and vacuum constriction devices. Oral medications such as cialis, levitra, staxyn, stendra, and viagra are often used. Intracavernous injection therapy with alprostadil or papaverine hydrochloride or phentolaminemesylate can help facilitate intercourse if the oral drugs are ineffective. The Vacuum Constriction Device (VCD) has an acrylic cylinder that is often placed over the penis before intercourse. The intraurethral therapy involves using an applicator to place a pellet containing medicine into the urethra (Derrer, 2014).

In women with diabetes, vaginal lubricants may be useful for women experiencing vaginal dryness. Techniques to treat decreased sexual response include changes in position and stimulation during sexual relations. Kegel exercises that strengthen the pelvic muscles may also improve sexual response (National Institute of Diabetes and Digestive and Kidney Diseases, 2012).

CHAPTER THREE

3.0 SUBJECTS AND METHODS

3.1 Study design

The study was a cross- sectional multicenter study conducted from 15th June to 30th July, 2015.

3.2 Study sites

To ensure that the findings of the study were representative enough for Ghana in terms of geographical distribution and population size, the study was carried out in the outpatient diabetes clinics of the Korle Bu Teaching Hospital (Accra), Komfo Anokye Teaching Hospital (Kumasi) and Tamale Teaching Hospital (Tamale) representing the southern, middle and northern part of Ghana respectively. These hospitals were selected for the study because large diabetic patient care is provided at these hospitals as they are the hospitals with the largest referrals and reliable supply of the necessary equipment and drugs for diagnosis and management of diabetes mellitus in Ghana.

The Korle Bu Teaching Hospital is located in the Accra Metropolis, the capital of the Greater Accra region with a population of 1,848,614 (Ghana Statistical Service, 2012). The 2000 bed hospital is the third largest hospital in Africa and the leading national referral center in Ghana; it has an average daily attendance of 1,500 patients and about 250 patient admissions (Korle Bu Teaching Hospital, 2015).

The Komfo Anokye Teaching Hospital is located in Kumasi Metropolis, the capital of the Ashanti Region with a total population of 2,035,064 (Ghana Statistical Service, 2012). The strategic location of this 1200-bed hospital, the road network of the country and commercial nature of Kumasi make the hospital accessible to all the areas that share boundaries with Ashanti Region and others that are further away. As such, referrals are received from eight out of the 10 regions of Ghana namely Northern, Upper East, Upper West, Brong Ahafo, Central, Western, Eastern and parts of the Volta Regions (Komfo Anokye Teaching Hospital, 2015).

The Tamale Teaching Hospital is located in the Tamale Metropolis, the capital of Northern region with a population of 371,351 (Ghana Statistical Service, 2012). It serves as the main referral hospital in the three regions of the north namely Northern Region, Upper East Region and Upper West Region, and some parts of the Brong-Ahafo Region of Ghana.

3.3 Study subjects

Diabetics who were booked and attended the diabetes clinics on each clinic day were eligible for the study. The eligible subjects who fulfilled the inclusion criteria were randomly selected to participate in the study.

3.4 Inclusion criteria

- Diabetes diagnosed in accordance with international standards (WHO): fasting plasma glucose (FPG) ≥ 7.0 mmol/L and/or 2 hours postprandial plasma glucose (PPG) or casual plasma glucose ≥ 11.1 mmol/L

- On a diabetic diet or anti-diabetic drug treatment for at least 1 year
- ≥ 18 years old
- In a heterosexual relationship
- Consent to participate in the study

3.5 Exclusion criteria

- Patients who were very ill (unstable vital signs/mental status)
- Pregnant women

3.6 Sampling procedure

Subjects were selected through simple random sampling. The subjects were first screened and those who met the inclusion criteria were given random numbers written on pieces of paper, put in a bowl, mixed and handpicked one at a time with replacement until the required sample was reached. Each hospital was visited twice and selection was done once a week on clinic days. None of those selected declined to participate in the study.

3.7 Sample size

The sample size for the study was calculated using Cochrane formula:

$$n = \frac{Z^2 p(1-p)}{e^2}$$

where n is the sample size, z is the value for the selected confidence level (usually 1.96 for 95% confidence level), e is the desired level of precision, p is the estimated proportion

of an attribute present in the population (prevalence). Prevalence of diabetes in adults in Ghana stands at 3.3% (International Diabetes Federation, 2014b). With a desired confidence level of 95% and $\pm 5\%$ precision, the sample size

$$n = \frac{1.96^2 X 0.033(1-0.033)}{05^2} = \frac{0.1267 X 0.967}{0.0025} = 49$$

Because large sample size provides a better estimate of the population and reduces the effect of outliers or extreme observations, the sample size was increased to 100. This sample size was divided by the number of hospitals; thus 33 diabetics were selected from Komfo Anokye Teaching Hospital, 33 from Tamale Teaching Hospital and 34 from Korle Bu Teaching Hospital since it is the leading national referral hospital in Ghana.

3.8 Data collection

The principal source of data was primary. Secondary data that was relevant to the study was also collected from service providers. Data was collected from diabetics with the aid of a pre-tested structured questionnaire to document information on sociodemographic characteristics, medical history, lifestyle variables, physical characteristics and sexual dysfunction. Biochemical indices of subjects were also assessed.

3.8.1 Socio-demographic characteristics

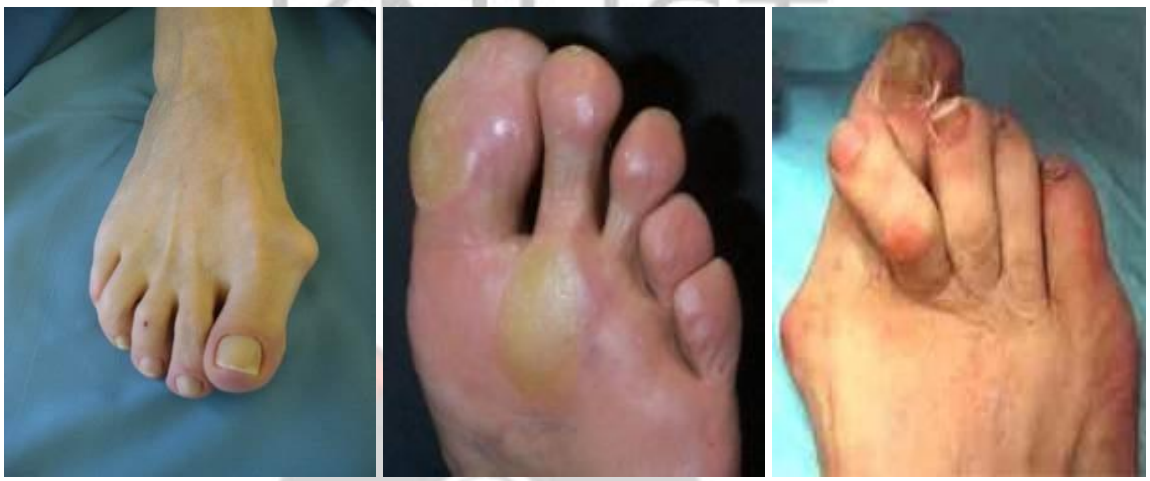
Socio-demographic data regarding sex, age, ethnicity, marital status, religion, level of education and occupation was documented.

3.8.2 Medical history

Medical history regarding duration of diabetes, diabetic diet, diabetes medications (insulin/or oral hyperglycemic agents), self-reported history of poor vision, and previous history of foot ulcers or lower extremity amputations were obtained. Whenever useful, information given by diabetics was confirmed with their medical records.

3.8.3 Physical examination

Participants were physically examined for foot ulcers, lower extremity amputations and foot deformities. Body mass index and blood pressure of the subjects were also assessed. Diabetic foot ulcer was operationally defined as full thickness skin defect that has been present for at least 14 days (Boyko *et al*., 1999). The operational definition of lower extremity amputation used in this study included both major amputations, (above the level of the ankle) and minor amputations (disarticulation of the ankle or below) (Santos *et al*., 2015). In this study, foot deformities were defined as the presence of any of the following structural abnormalities in one or both feet: halux valgus (Figure 3.1a), prominent metatarsal heads (Figure 3.1b) and contractured toe (Figure 3.1c) (Formosaa *et al*., 2013). During the physical examination, findings were confirmed with the medical records of the patients or the consultant physician on duty and were reported as present or absent without further description or grading.



a: Halux valgus (Nandlal, 2014) b: Prominent metartasal heads (Nandlal, 2014) c: Contracture toes (DeVito, 2015)

Figure 3.1 Foot deformities

The body mass index (BMI) was used to assess the nutritional status of the patients. Height (m) was measured without shoes using a microtoise (Seca, Germany) and weight (kg) was measured in light clothing using a uniscale (Seca, Germany). The body mass index (BMI) was determined by dividing the weight (kg) by the square of the height (m^2) and was classified as underweight, normal, overweight and obese according to the World Health Organization (2007) criteria as shown in Table 3.1.

Table 3.1 WHO criteria for classification of obesity

Classification	BMI (kg/m^2) cut-off point
Underweight	<18.5
Normal	18.5-24.99

Overweight	25-29.99
Obese	≥30

BMI=Body Mass Index

Regarding hypertension, blood pressure was measured using a digital sphygmomanometer (Omron, Japan). Before blood pressure measurements, every patient rested for at least 10 minutes. High blood pressure was defined as systolic blood pressure (mmHg) ≥ 140mmHg and/or diastolic blood pressure ≥ 90mmHg or known hypertensive on treatment.

3.8.4 Assessment of sexual dysfunction

Sexual dysfunction was measured using the Golombok Rust Inventory of Sexual Satisfaction (GRISS) questionnaire. The GRISS questionnaire is for the assessment of the existence and severity of sexual problems. The GRISS was used in that it is a standardized questionnaire and also easy to administer. The reliability of the scales is 0.94 for males and 0.87 for females (Rust and Golombok, 1986). Its validity has also been proven (Rust and Golombok, 1986). All the questions are answered on a five-point scale (always, usually, occasionally, hardly ever and never).

The male version of the questionnaire gives a total male score as well as subscales of impotence, non-communication, premature ejaculation, avoidance, infrequency, non-sensuality, and dissatisfaction. The female version also gives a total female score as well as subscales of anorgasmia, vaginismus, non-communication, infrequency, female non-sensuality, female avoidance, and female dissatisfaction. Responses were added up to give a total score. The total scores were transformed using a standard nine point scale. Scores of five or more are considered to indicate sexual dysfunction and scores of eight or more

are considered to indicate severe sexual dysfunction (Rust and Golombok, 1986). Findings were reported as present or absent.

3.8.5 Biochemical Assessment

Three milliliters of venous blood sample was taken from each subject into gel separator tubes in the morning after an overnight fast of 8-10 hours. The gel separator tubes were centrifuged at 3000 rpm for 10 minutes and the serum separated and stored in plain separator tubes at a temperature of -20°C until it was time for analysis. The samples were transported from the hospitals of study to the testing laboratory on frozen ice packs in an ice chest. The samples were analyzed using the Automated Flexor Junior Chemistry Analyzer at Tamale Central Hospital's laboratory. Analysis was done according to manufacturer's procedure.

The biochemical measurements assessed were triglycerides (TG), total cholesterol (TC), high density lipoprotein cholesterol (HDL-C) and low density lipoprotein cholesterol (LDL-C) to diagnose dyslipidemia, characterized by the abnormal concentration of lipids in the blood (Li *et al.,* 2004). Markers of renal function which include serum creatinine and serum urea (Gowda *et al*., 2010) were also assessed and estimated glomerular filtration rate (eGFR) calculated to determine their association with the diabetes complications. The estimated glomerular filtration rate was determined using the serum creatinine in Modification of Diet in Renal Disease (MDRD) equation as recommended by the National Kidney Disease Education Program (2015). This equation has been proven to be valid and superior to other equations (Levey *et al*., 1999) and has also been used in a study in Ghana (Korsah, 2010). Estimated glomerular filtration rate

can detect mild and moderate renal dysfunction which is often poorly deduced from only serum creatinine (National Kidney Disease Education Program, 2015). MDRD equation: eGFR (mL/min/1.73 m^2) = 175 × $(S_{cr})^{-1.154}$ × $(Age)^{-0.203}$ × (0.742 if female) × (1.212 if African American), where S_{cr} is serum creatinine. eGFR < 60 mL/min/1.73 m^2 indicates renal dysfunction (Chronic Kidney Disease) (National Kidney Disease Education Program, 2015).

3.9 Data Analysis

Data entry and analysis were done using SPSS 22 software (IBM, USA). For the univariate analysis, the Pearson correlation (chi-square) or fisher's exact test was used for categorical variables while the student t-test was used for continuous variables. The independent variables that were significant in the univariate analysis were considered for multivariate binary logistic regression analysis so as to control for confounder risk factors. P< 0.05 was considered significant at two tailed tests. Percentages and cross tabulations were used to show respondents' responses. Responses were presented in tables and bar charts.

3.10 Ethical Considerations

Permission to conduct the study was obtained from the Committee on Human Research, Publications and Ethics of the School of Medical Sciences of Kwame Nkrumah University of Science and Technology (CHRPE/AP/228/15). The consent of respondents was equally sought and they were assured of the confidentiality of the information

provided. Permission to conduct the study was also obtained from the management of the hospitals of study.

CHAPTER FOUR

4.0 RESULTS

4.1 Characteristics of study subjects

A total of 100 diabetics attending the three hospitals in Ghana were enrolled into the study. The mean age was 53.82±13.754 years with the minimum and maximum ages of 18 and 85 years respectively. More than half (67%) of the patients were 48 years or above whilst only 5% were aged 18-27 years. Majority of the patients (69%) were females. Akans formed the majority (50%) of the respondents. Most of the subjects (83%) were married. Christians dominated the study subjects forming 64% whilst 36% were Muslims. Regarding level of education, most (41%) of the patients were illiterates or did not have any formal or informal education. Only 3% of the respondents were educated to the primary level. It was also observed that most (62%) of the subjects were self-employed. Table 4.1 shows the socio-demographic characteristics of the study subjects.

Table 4.1: Socio-demographic characteristics of study subjects

Characteristic	Frequency (%)
Age (years):	
Mean	53.82±13.754
Age groups:	
18-27	5 (5)
28-37	9 (9)
38-47	19 (19)
≥48	67 (67)
Sex:	
Male	31 (31)
Female	69 (69)
Ethnicity:	
Northerner	36 (36)
Ga/Adangbe	9 (5)
Ewe	5 (5)
Akan	50 (50)
Marital status:	
Single	9 (9)
Married	83 (83)
Divorced	6 (6)
Widowed	2 (2)
Religion:	
Muslim	36 (36)
Christian	64 (64)
Level of education:	
Primary	3 (3)
JHS	26 (26)
SHS	14 (14)
Tertiary	14 (14)
Informal	2 (2)
None	41 (41)
Employment status:	

Employed	20 (20)
Self-employed	62 (62)
Not employed	18 (18)

As indicated in Table 4.2, patients with diabetes duration <5 years formed the majority (36%) of the population. Among patients on diabetes treatment, most (54%) of them were on oral hypoglycemic agents. Of the total study subjects, 17 (17%) reported history of previous foot ulcers. Regarding previous history of amputation, 5 (5%) of the diabetics reported a previous history of amputation. Only one diabetic was a smoker whilst 9 (9%) were alcohol drinkers. It was also observed that majority (63%) of the subjects were overweight and obese. The prevalences of foot deformities, impaired vision and hypertension among the subjects were 6%, 44% and 60% respectively.

As indicated in Table 4.3, the minimum serum creatinine level was 35.1 µmol/l whilst the maximum value was 304.8 µmol/l, with a mean value of 91.72±44.01 µmol/l. Abnormal levels of serum creatinine were recorded in 14% of the subjects. Estimated glomerular filtration rate (eGFR) values ranged from 13 to 60 mL/min/1.73 m^2 with a mean value of 55.07±10.24 mL/min/1.73 m^2. It was observed that 27% of the subjects had abnormal eGFR. Regarding serum urea levels, the mean level was 53.82±13.75 mmol/l with the minimum and maximum levels of 1.08 and 8.78 mmol/l respectively. A few (3%) of the subjects had abnormal serum urea levels. The minimum total cholesterol level was 1.57 mmol/l whilst the maximum value was 7.79 mmol/l, with a mean value of 4.61±1.17 mmol/l. Abnormal total cholesterol levels were observed in 7% of the subjects.

Triglycerides values ranged from 0.54 to 4.14 mmol/l, with a mean value of 1.52±0.64 mmol/l. It was also seen that 32% of the subjects had abnormal levels of triglycerides. With respect to the high density lipoprotein cholesterol, the mean level was 1.36±0.90 mmol/l, with the minimum and maximum levels of 0.63 and 9.70 mmol/l respectively. It was noted that 22% of the subjects recorded an abnormal high density lipoprotein cholesterol levels. The range of low density lipoprotein cholesterol levels ranged from 0.62 to 5.54 mmol/l, with a mean value of 2.69±1.00 mmol/l. A few (3%) of the subjects had abnormal levels of low density lipoprotein cholesterol.

Table 4.2: Medical history, lifestyle and physical characteristics of the study subjects

Characteristic	Frequency (%)
Duration of diabetes (years):	
<5	36 (36)
5-10	32 (32)
11-15	16 (16)
16-20	11 (11)
>20	5 (5)
Diabetes Treatment:	
Diabetic diet	14(14)
OHAs	54 (54)
Insulin	18 (18)
OHAs and Insulin	14 (14)
Previous foot ulcer:	
Yes	17 (17)
No	83 (83)
Previous amputation:	
Yes	5 (5)
No	95 (95)
Smoking:	
Yes	1 (1)
No	99 (99)
Alcohol intake:	
Yes	9 (9)
No	91 (91)

BMI:	
Underweight	9 (9)
Normal	28 (28)
Overweight	40 (40)
Obese	23 (23)
Foot deformity:	
Present	6 (6)
Absent	95 (95)
Impaired vision:	
Present	44 (44)
Absent	56 (65)
Hypertension:	
Present	60 (60)
Absent	40 (40)

Table 4.3: Biochemical characteristics of study subjects

Characteristic	Frequency (%)
Serum Creatinine (µmol/l):	
Mean	91.72±44.01
Abnormal (>120)	14 (14)
Normal (≤120)	86 (86)
eGFR (mL/min/1.73 m^2):	
Mean	55.07±10.24
Abnormal (<60)	27 (27)
Normal (≥60)	73 (73)
Serum Urea (mmol/l):	
Mean	4.15±1.68
Abnormal (>8.3)	3 (3)
Normal (≤8.3)	97 (97)
Total Cholesterol (mmol/l):	
Mean	4.61±1.17
Abnormal (>6.5)	7 (7)
Normal (≤6.5)	93 (93)
Triglycerides (mmol/l):	
Mean	1.52±0.64
Abnormal (> 1.7)	32 (32)
Normal (≤1.7)	68 (68)
HDL Cholesterol (mmol/l):	
Mean	1.36±0.90
Abnormal (<1.03)	22 (22)
Normal (≥1.03)	78 (78)

LDL Cholesterol (mmol/l):	
Mean	2.69±1.00
Abnormal (>4.9)	3 (3)
Normal (≤ 4.9)	97 (97)

4.2 Diabetic foot ulcers

4.2.1 Prevalence of diabetic foot ulcers

Of the 100 diabetics included in the study, 11 (11%) had foot ulcers. The prevalences of foot ulcers recorded in Korle Bu Teaching Hospital, Komfo Anokye Teaching Hospital and Tamale Teaching Hospital were 3%, 3% and 5% respectively. As shown in the Table 4.4, the prevalence of foot ulcers was higher in males (12.9%) than females (10.1%) but the difference in prevalence was not significant (p=0.683). Difference in mean age between diabetics with foot ulcers and diabetics without foot ulcers was not also statistically significant (p=0.874). Ethnicity was not significantly associated with prevalence of foot ulcers (p=0.044); the Ga/Adangbe group recorded the highest prevalence of foot ulcers (22.2%). Regarding marital status, it was observed that majority (12%) of the married subjects had foot ulcers but the prevalence did not differ significantly (p=0.781). There was no correlation between religion and foot ulcer prevalence (p=0.174) although Muslims recorded a higher (16.7%) prevalence rate of foot ulcers than Christians

(7.8%). Subjects who were educated to the primary level had a higher prevalence rate (33.3%) of foot ulcers than the other levels of education

(p=0.214).

Table 4.4: Univariate analysis of socio-demographic characteristics associated with foot ulcers among study subjects

Characteristic N=100(%)	Total Population	Foot ulcer present	Foot ulcer absent	P-value
		N=11(%)	N=89(%)	
Age (mean±S.D):	53.82±13.754	54.27±9.231	53.76±14.252	0.874
Sex:				
Male	31 (100)	4 (12.9)	27 (87.1)	0.683
Female	69 (100)	7 (10.1)	62 (89.9)	
Ethnicity:				
Northerner	36 (100)	5 (13.9)	31 (86.1)	0.468
Ga/Adangbe	9 (100)	2 (22.2)	7 (77.8)	
Ewe	5 (100)	0 (0.0)	5 (100)	
Akan	50 (100)	4 (8)	46 (92)	
Marital status:				
Single	9 (100)	1 (11.1)	8 (88.9)	0.781
Married	83 (100)	10 (12)	73 (88)	
Divorced	6 (100)	0 (0.0)	6 (100)	
Widowed	2 (100)	0 (0.0)	2 (100)	
Religion:				

Muslim	36 (100)	6 (16.7)	30 (83.3)	0.174
Christian	64 (100)	5 (7.8)	59 (92.2)	
Level of education:				
Primary	3 (100)	1 (33.3)	2 (66.7)	0.214
JHS	26 (100)	5 (19.2)	21 (80.8)	
SHS	14 (100)	0 (0.0)	14 (100)	
Tertiary	14 (100)	0 (0.0)	14 (100)	
Informal	2 (100)	0 (0.0)	2 (100)	
None	41 (100)	5 (12.2)	36 (87.8)	

Figure 4.1 also revealed that 9 (14.5%) of the patients who were self-employed had foot ulcers. Among those who were not employed, 2 (11%) had foot ulcers. None of the employed subjects had foot ulcers; the difference in prevalence was not statistically significant (p = 0.196).

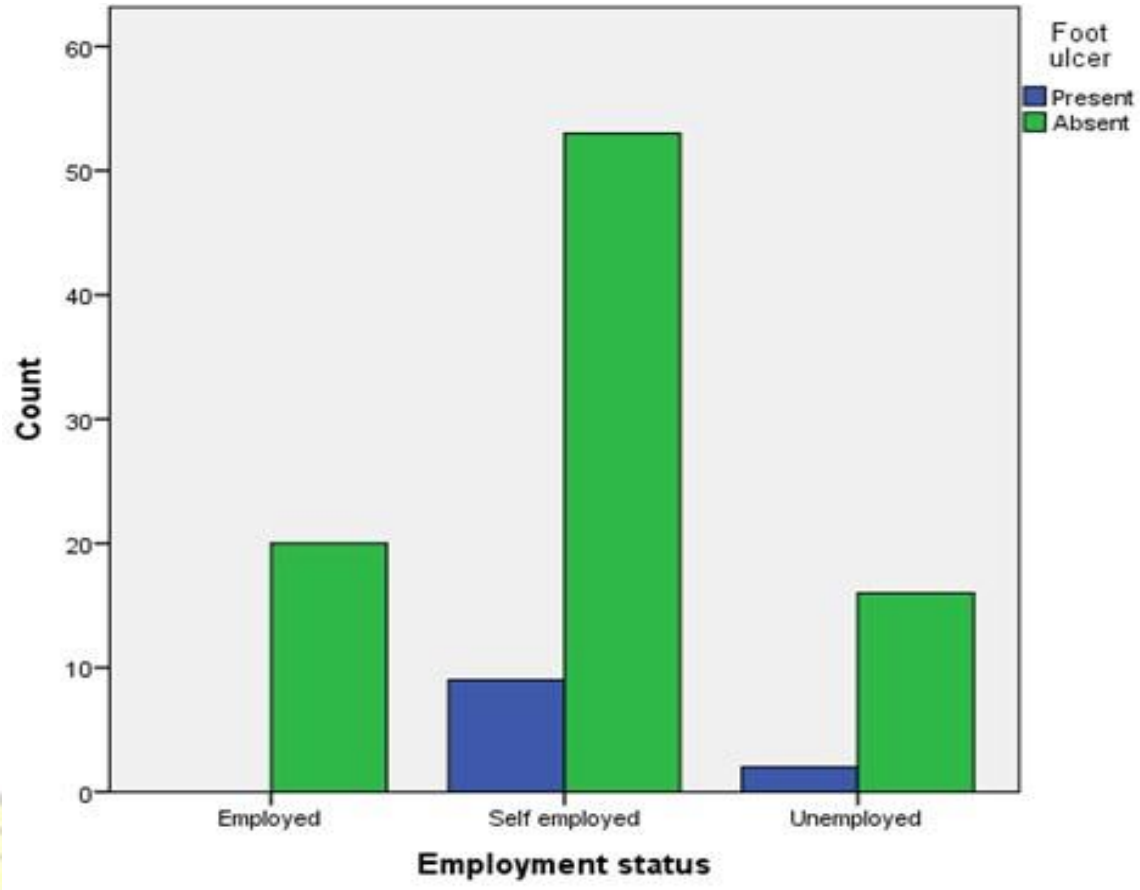


Figure 4.1: Employment status categories by the presence or absence of foot ulcers in study subjects

As indicated in Table 4.5, prevalence of foot ulcers did not differ significantly with duration of diabetes (p= 0.261); it was observed that patients with diabetes duration <5 formed the majority (36%) of the population, however those with diabetes duration ranging from 11-15 years (16%) had the highest foot ulcer prevalence rate (25%). Among patients on diabetes medication, it was seen that those on both oral hypoglycemic agents and insulin recorded the highest prevalence of foot ulcers (15.5%) (p= 0.457). Of the total study subjects with previous foot ulcers, 8 (47.1%) had foot ulcers, the difference was significant (p=0.000). Regarding subjects with previous history of amputation, 20% had foot ulcers (p=0.509). The association between smoking and foot ulcers was not

significant (p=0.724); the only diabetic who was a smoker had no foot ulcer. The association between alcohol intake and prevalence of foot ulcers was not also significant (p=0.724); none of those who were alcohol drinkers had foot ulcers. Subjects with normal BMI recorded the highest prevalence of foot ulcers whilst none of those who were underweight had foot ulcers (p=0.180). Foot deformity and prevalence of foot ulcers were related (p=0.002); out of those who had foot deformity (6%), 50% of them had foot ulcers, 8.5% of the remaining diabetics without foot deformity (94%) had foot ulcers. Prevalence of foot ulcers was higher (18.2%) in patients with impaired vision than those with normal vision (5.4%); the difference was significant (p=0.042). Hypertension was not related to foot ulcer prevalence (p=0.695). With regards to the biochemical parameters (Table 4.6), none were significantly related to foot ulcers except serum creatinine (p=0.023) and estimated glomerular filtration rate (p=0.029).

Table 4.5: Univariate analysis of medical history, lifestyle and physical

characteristics associated with foot ulcers among study subjects

Characteristic Population N=11(%)	Total present N=89(%)	Foot ulcer absent	Foot ulcer N=100	P-value
Duration of diabetes (years):				
<5	36 (100)	4 (11.1)	32 (88.9)	0.261
5-10	32 (100)	3 (9.4)	29 (90)	
11-15	16 (100)	4 (25)	12 (75)	
16-20	11 (100)	0 (0.0)	11(100)	
>20	5 (100)	0 (0.0)	5 (100)	
Diabetes treatment:				
Diabetic diet	14 (100)	2 (14.3)	12 (85.7)	0.120
OHAs	54 (100)	4 (7.4)	50 (92.6)	
Insulin	18 (100)	1 (5.6)	17 (94.4)	
OHAs and Insulin	14 (100)	4 (28.6)	14 (71.4)	
Previous foot ulcer:				
Yes	17 (100)	8 (47.1)	9 (52.9)	0.000
No	83 (100)	3 (3.6)	80 (96.4)	
Previous amputation:				
Yes	5 (100)	1 (20)	4 (80)	0.509
No	95 (100)	10 (10.5)	85 (89.5)	
Smoking:				
Yes	1(100)	0 (0.0)	1(100)	0.732
No	99 (100)	11 (11.1)	88 (89.9)	
Alcohol intake:				
Yes	9 (100)	0 (0.0)	9 (100)	0.269
No	91 (100)	11 (12.1)	80 (87.9)	
BMI:				
Underweight	9 (100)	0 (0.0)	9 (100)	0.180
Normal	28 (100)	5 (17.9)	23 (82.1)	
Overweight	40 (100)	2 (5)	38 (95)	
Obese	23 (100)	4 (17.4)	19 (82.6)	
Foot deformity:				
Present	6 (100)	3 (50)	3 (50)	0.002
Absent	94 (100)	8 (8.5)	86 (91.5)	

Impaired vision:				
Present	44 (100)	8 (18.2)	36 (81.8)	0.042
Absent	56 (100)	3 (5.4)	53 (94.6)	
Hypertension:				
Present	60 (100)	6 (10)	54 (90)	0.695
Absent	40 (100)	5 (12.5)	35 (87.5)	

Table 4.6: Univariate analysis of biochemical characteristics associated with foot ulcers among study subjects

Characteristic	**Population N=100**	**present N=11(%)**	**Foot ulcer absent N=89(%)**	**P-value**
Serum Creatinine (µmol/l):				
Abnormal (>120)	14(100)	4 (28.6)	10 (71.4)	0.023
Normal (≤120)	86 (100)	7 (8.1)	79 (91.9)	
eGFR (mL/min/1.73 m^2):				
Abnormal (<60)	27 (100)	6 (22.2)	21(77.8)	0.029
Normal (≥60)	73 (100)	5 (6.8)	68 (93.2)	
Serum Urea (mmol/l):				
Abnormal (>8.3)	3 (100)	1 (33.3)	2 (66.7)	0.209
Normal (≤8.3)	97 (100)	10 (10.3)	87 (89.7)	
Total Cholesterol (mmol/l):				
Abnormal (>6.5)	7 (100)	1 (14.3)	6(85.7)	0.773
Normal (≤6.5)	93 (100)	10 (10.8)	83 (89.2)	
Triglycerides (mmol/l):				
Abnormal (> 1.7)	32 (100)	4 (12.5)	28 (87.5)	0.742
Normal (≤1.7)	68 (100)	7 (10.3)	61 (89.7)	
HDL Cholesterol (mmol/l):				
Abnormal (<1.03)	22 (100)	1 (4.5)	22 (95.5)	0.273
Normal (≥1.03)	78 (100)	10 (12.8)	68 (87.2)	
LDL Cholesterol (mmol/l):				
Abnormal (>4.9)	3 (100)	0 (0.0)	3 (100)	0.536
Normal (≤ 4.9)	97 (100)	11(11.3)	86 (97)	

4.2.2 Risk factors and predictors of diabetic foot ulcers

The independent variables with p<0.05 on the univariate analysis were considered for multivariate analysis so as to control for confounder risk factors. Table 4.7 shows respondents characteristics associated with foot ulcers on multivariate logistic regression analysis. The logistic regression model was statistically significant, X^2= 33.656, p < 0.000. The model explained 57.2% (Nagelkerke R^2) of the variance in foot ulcers and correctly classified 91% of cases. Diabetics with history of previous foot ulcer were 40.441 times more likely to develop foot ulcers than diabetics without history of previous foot ulcer. Diabetics with foot deformity were 14.388 times more likely to develop foot ulcers than diabetics without foot deformity. Impaired vision (p= 0.063), serum creatinine (p=0.087) and eGFR (p=0.937) could not maintain statistical

significance in the multivariate logistic regression analysis.

Table 4.7: Multivariate analysis of factors associated with foot ulcers among study subjects

Characteristic	aOR	95% CI	p-value
Previous foot ulcer:			
No	1		
Yes	40.441	5.453-299.932	0.000
Foot deformity:			
Absent	1		
Present	14.388	1.284-161.241	0.031
Impaired vision:			
Absent	1		
Present	7.066	0.897-55.649	0.063
Serum Creatinine (µmol/l):			
Normal (≥60)	1		
Abnormal (<60)	10.140	0.711-144.542	0.087
eGFR (mL/min/1.73 m^2):			
Normal (≥60)	1		
Abnormal (<60)	1.092	0.124-9.622	0.937

The reference group is the first group in each category

4.3 Diabetic lower extremity amputations

4.4.1 Prevalence of diabetic lower extremity amputations

Of the total 100 study subjects, 3(3%) had lower extremity amputations. The prevalences of lower extremity amputations recorded in Korle Bu Teaching Hospital, Komfo Anokye Teaching Hospital and Tamale Teaching Hospital were 0%, 1% and 2% respectively. As shown in Table 4.8, lower extremity amputations prevalence was 6.5% in males and 1.4% in females but did not differ significantly (p= 0.175). The mean age in diabetics with lower extremity amputations was higher than the mean age in diabetics without lower extremity amputations but it was not significant (p=0.643). The study revealed that none of the ethnic groups recorded an incident of lower extremity amputation except Northerners (5.6%) and Akans (2.1%) (p= 0.920). It was also observed that lower extremity amputations were not correlated to marital status (p=
0.889); only those who were married (3.6%) had lower extremity amputations. Christians recorded a higher (3.1%) prevalence of lower extremity amputations than Muslims (2.8%) but the difference was insignificant (p= 0.922). Diabetics educated to the JHS level had the highest prevalence of lower extremity amputations; 2.4% of those without any form of

education presented with lower extremity amputations whilst none of the patients in the other levels of education recorded an incident of lower extremity amputations (p= 0.695). The study also revealed that only the self-employed diabetics presented with lower extremity amputations (p= 0.388).

Table 4.8: Univariate analysis of socio-demographic variables of diabetics associated with lower extremity amputations among study subjects

Characteristic	**Total Population N=100 (%)**	**Lower extremity amputation present N=3 (%)**	**Lower extremity amputation absent N=97(%)**	**p-value**
Age (mean±S.D)	53.82±13.754	56.33±8.145	53.74±13.910	0.643
Sex:				
Male	31(100)	2 (6.5)	29 (93.5)	0.175
Female	69(100)	1 (1.4)	68 (98.6)	
Ethnicity:				
Northerner	36 (100)	2 (5.6)	34 (94.4)	0.703
Ga/Adangbe	9 (100)	0 (0.0)	9 (100)	
Ewe	5 (100)	0 (0.0)	5 (100)	
Akan	50 (100)	1 (2)	49 (98)	
Marital status:				
Single	9 (100)	0 (0.0)	9 (0.0)	0.889
Married	83 (100)	3 (3.6)	80 (96.4)	
Divorced	6 (100)	0 (0.0)	6 (100)	
Widowed	2 (100)	0 (0.0)	2 (100)	
Religion:				
Muslim	36 (100)	1 (2.8)	35 (97.2)	0.922
Christian	64 (100)	2 (3.1)	62 (96.9)	

Level of education:				
Primary	3 (100)	0 (0.0)	3 (100)	0.695
JHS	26 (100)	2 (7.7)	24 (92.3)	
SHS	14 (100)	0 (0.0)	14 (100)	
Tertiary	14 (100)	0 (0.0)	14 (100)	
Informal	2 (100)	0 (0.0)	2 (100)	
None	41 (100)	1 (2.9)	40 (97.1)	
Employment status:				
Employed	20 (100)	0 (0.0)	20 (100)	0.388
Self-employed	62 (100)	3 (4.8)	59 (95.2)	
Not employed	18 (100)	0 (0.0)	18 (100)	

As depicted in Table 4.9, subjects with diabetes duration ranging from 11-15 years presented with the highest prevalence (6.2%) of lower extremity amputations (p= 0.897). Among patients on diabetes treatment, it was seen that diabetics on diet (7.1%) and diabetics on both insulin and oral hyperglycemic agents (7.1%) recorded the highest prevalence of lower extremity amputations, but the difference did not differ significantly (p= 0.161). Among the study subjects who reported history of previous foot ulcers, 5.9% had lower extremity amputations as compared to 2.4% of subjects without history of previous foot ulcers (p=0.444). Most (20%) of the subjects with previous history of amputation presented with lower extremity amputations (p= 0.000). There was no correlation between smoking and lower extremity amputations (p=0.860); the only diabetic who was a smoker had no lower extremity amputations. It was seen that none of those who were alcohol drinkers had lower extremity amputations (p=0.580). Regarding BMI, the subjects who were underweight recorded the highest prevalence of lower extremity amputations (p=0.328). Foot deformity and lower extremity amputations were related (p=0.043); 16.7% of those with foot deformity had lower extremity amputations as compared to 2.1% of subjects without lower extremity amputations. None of the subjects with impaired vision had an incident of lower extremity amputation whilst 5.4% of

subjects with normal vision had lower extremity amputations (p=0.119). It was also revealed that 3.3% of subjects with hypertension presented with lower extremity amputations as compared to 2.5% of subjects without hypertension (p= 0.811). Among the biochemical parameters, only serum urea (p=0.002) was significantly associated with lower extremity amputations (Table 4.10).

Table 4.9: Univariate analysis of medical history, lifestyle and physical characteristics associated with lower extremity amputations among study subjects

Characteristic Population N=100 (%)	Total amputation present N=3 (%)	Lower extremity amputation absent N=97(%)	Lower extremity	p-value
Duration of diabetes:				
<5	36 (100)	1 (2.8)	35(97.2)	0.897
5-10	32 (100)	1 (3.1)	32 (96.9)	
11-15	16 (100)	1 (6.2)	15 (93.8)	
16-20	11 (100)	0 (0.0)	11 (100)	
>20	5 (100)	0 (0.0)	5 (100)	
Diabetes treatment:				
Diabetic diet	14 (100)	1 (7.1)	1 (92.9)	0.293
OHAs	54 (100)	0 (0.0)	54 (100)	
Insulin	18 (100)	1 (5.6)	17 (94.6)	
OHAs and Insulin	14 (100)	1 (7.1)	13 (92.9)	

Previous foot ulcer:				
Yes	17 (100)	1 (5.9)	16 (94.1)	0.444
No	83 (100)	2 (2.4)	81(97.6)	
Previous amputation:				
Yes	5 (100)	1 (20)	3 (80)	0.116
No	95 (100)	2 (40)	94 (60)	
Smoking:				
Yes	1 (100)	0 (0.0)	1 (100)	0.860
No	99 (100)	3 (3)	97 (97)	
Alcohol intake:				
Yes	9 (100)	0 (0.0)	9 (100)	0.58
No	31 (100)	3 (3.3)	97 (96.7)	
BMI:				
Underweight	9	1 (11.1)	8 (88.9)	0.328
Normal	28 (100)	1 (3.6)	27 (96.4)	
Overweight	40 (100)	0 (0.0)	40 (100)	
Obese	23 (100)	1 (4.3)	22 (95.7)	
Foot deformity:				
Present	6 (100)	1 (16.7)	5 (83.3)	0.043
Absent	94 (100)	2 (2.1)	92 (97.9)	
Impaired vision:				
Present	14 (100)	0 (0.0)	14 (100)	0.119
Absent	56 (100)	3 (5.4)	53 (94.6)	
Hypertension:				
Present	60 (100)	2 (3.3)	58 (96.7)	0.811
Absent	40 (100)	1 (2.5)	39 (97.5)	

Table 4.10: Univariate analysis of biochemical characteristics associated with lower extremity amputations among study subjects

Characteristic	**Total Population (%) N=100**	**Lower extremity amputation present N=3 (%)**	**Lower extremity amputation absent N=97(%)**	**p-value**
Serum Creatinine (µmol/l):				
Abnormal (>120)	14(100)	1 (7.1)	13 (92.9)	0.241
Normal (≤ 120)	86(100)	2 (2.3)	84 (97.7)	
eGFR (mL/min/1.73 m^2):				
Abnormal (<60)	27 (100)	2 (7.4)	25 (92.6)	0.116

Normal (≥60)	73 (100)	1 (1.4)	72 (98.6)	
Serum Urea (mmol/l):				
Abnormal (>8.3)	3 (100)	1 (33.3)	2 (66.7)	0.002
Normal (≤8.3)	97 (100)	2 (2.1)	95 (97.9)	
Total Cholesterol (mmol/l):				
Abnormal (>6.5)	7 (100)	0 (0.0)	7 (100)	0.629
Normal (≤6.5)	93 (100)	3 (3.2)	90 (96.8)	
Triglycerides (mmol/l):				
Abnormal (> 1.7)	32 (100)	2 (6.2)	30 (93.8)	0.191
Normal (≤1.7)	68 (100)	1 (3)	67 (97)	
HDL Cholesterol (mmol/l):				
Abnormal (<1.03)	22 (100)	0 (0.0)	22 (100)	0.350
Normal (≥1.03)	80 (100)	3 (3.8)	75 (96.2)	
LDL Cholesterol (mmol/l):				
Abnormal (>4.9)	3 (100)	0 (0.0)	3(100)	0.757
Normal (≤ 4.9)	97 (100)	3 (3.1)	94 (96.9)	

4.3.2 Risk factors and predictors of diabetic lower extremity amputations

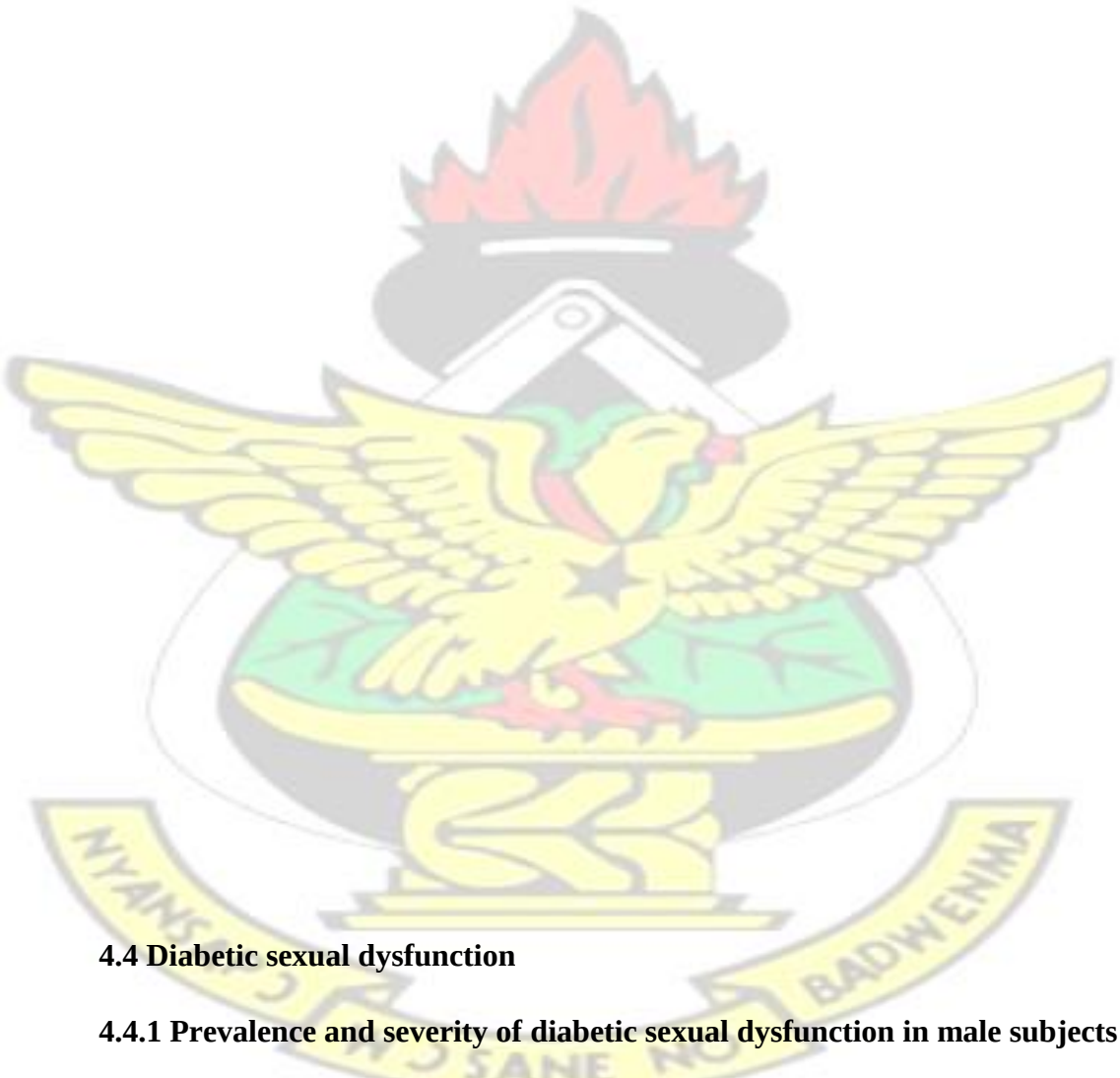
The independent variables (Serum urea and foot deformity) with p<0.05 on the univariate analysis were considered for multivariate analysis so as to control for confounder risk factors. The logistic regression model was statistically significant, $X^2(4) = 6.712$, $p < 0.034$. The model explained 27.5.3% (Nagelkerke R^2) of the variance in lower extremity amputations and correctly classified 97% of the cases. Patients with high serum urea levels were 45 times more likely to exhibit lower extremity amputations than those with normal levels of serum urea. Foot deformity could not maintain statistical significance in the multivariate logistic regression analysis (p=0.052) as shown in Table 4.11.

Table 4.11: Multivariate analysis of factors associated with lower extremity amputation among study subjects

Characteristic	aOR	95% CI	p-value

Foot deformity:			
Absent	1		
Present	18	0.976-33.889	0.052
Serum urea (mmol/l):			
Normal (≤8.3)	1		
Abnormal (>8.3)	45	2.015-1004.773	0.016

The reference group is the first group in each category.



4.4 Diabetic sexual dysfunction

4.4.1 Prevalence and severity of diabetic sexual dysfunction in male subjects

The male participants were assessed using the seven domains for measuring sexual dysfunction which included impotence (erectile dysfunction), premature ejaculation, non-sensuality, non-communication, avoidance, infrequency and dissatisfaction to determine

sexual dysfunction prevalence. Of the 31 male diabetics who completed the sexual dysfunction questionnaires 17 (54.8%) had sexual dysfunction out of which 2 (6.5%) had severe sexual dysfunction. Sexual dysfunction prevalences in male diabetics recorded in Korle Bu Teaching Hospital, Komfo Anokye Teaching Hospital and Tamale Teaching Hospital were 35.3%, 29.4% and 35.3% respectively**.**

Dysfunction was also high in all domains as shown in Table 4.12, impotence, premature ejaculation, infrequency, non-communication, non-sensuality, avoidance and dissatisfaction were present in 71.4%, 64%, 63.6%, 73.7%, 65.2%, 64.7% and 83.3% of the diabetics respectively.

It was also observed that premature ejaculation (p= 0.036), non-communication (p= 0.008), non-sensuality (p=0.049) and dissatisfaction (p=0.011) were significantly correlated with sexual dysfunction whilst impotence (p=0.092), infrequency (p= 0.124) and avoidance (p= 0.224) were insignificantly correlated with sexual dysfunction. Impotence (12.9%), premature ejaculation (12.9%) and non-communication (12.9%) had higher level of severity than the other four domains of sexual dysfunctions as shown in Table 4.13.

Table 4.12: Sexual dysfunction domains stratified by sexual dysfunction in male diabetics

Domain	**Total Population**	**Sexual dysfunction**	**No Sexual dysfunction**	**P-value**
N=31(%)	**N=17(%)**	**N=14(%)**		
Impotence:				
Present	14 (100)	10 (71.4)	4 (28.6)	0.092

Absent	17 (100)	7 (41.2)	10 (58.8)	
Premature ejaculation:				
Present	25 (100)	16 (64)	9 (36)	0.036
Absent	6 (100)	1 (16.7)	5 (83.3)	
Infrequency:				
Present	22 (100)	14 (63.6)	8 (36.4)	0.124
Absent	9 (100)	3 (33.3)	6(66.7)	
Non-communication:				
Present	19 (100)	14 (73.7)	5 (26.3)	0.008
Absent	12 (100)	3 (25)	9 (75)	
Non-sensuality:				
Present	23 (100)	15 (65.2)	8 (34.8)	0.049
Absent	8 (100)	2 (25)	6 (75)	
Avoidance:				
Present	17 (100)	11 (64.7)	6 (35.3)	0.224
Absent	14 (100)	6 (42.9)	8 (57.1)	
Dissatisfaction:				
Present	12 (100)	10 (83.3)	2(16.7)	0.011
Absent	19 (100)	7 (36.8)	12 (63.2)	

Table 4.13: Severity of sexual dysfunction in male diabetics

Domain	Severely Abnormal	Abnormal	Normal
Impotence	4 (12.9%)	10 (31.3%)	17 (54.8%)
Premature ejaculation	4 (12.9%)	21 (67.7%)	6 (19.4%)
Infrequency	3 (9.7%)	19 (61%)	9 (29%)
Non-sensuality	3 (9.7%)	20 (64.5%)	8 (25.8%)
Non-communication	4 (12.9%)	14 (48.4%)	12 (38.7%)
Avoidance	2 (6.5%)	15 (48.4%)	14 (45.2%)
Dissatisfaction	4 (12.9%)	8 (25.8%)	19 (61.3%)

As shown in Table 4.14, the mean age in diabetics with sexual dysfunction was higher than the mean age in diabetics without sexual dysfunction but the difference was insignificant (p=0.752). Sexual dysfunction prevalence did not differ significantly among the ethnic groups (p=0.110); Ewes recorded a 100% prevalence of sexual dysfunction. It

was observed that sexual dysfunction was reported mostly in married males (55.2%) (p=0.361). The study also revealed that 60% of the male subjects who were Muslims had sexual dysfunction as compared to 52.4% of Christians (P=0.690). Majority (75%) of the men with no form of education had sexual dysfunction but the difference was insignificant (p=0.518). Men who were self- employed recorded the highest prevalence of sexual dysfunction (p= 0.728).

Table 4.15 shows that majority (58.3%) of male subjects with diabetes duration ranging from 5-10 years presented with sexual dysfunction (p= 0.672). There was no correlation between smoking and sexual dysfunction (p=0.263); the only diabetic who was a smoker had no sexual dysfunction. It was seen that 66.7% of those who were alcohol drinkers had sexual dysfunction as compared to 52% of those who were not alcohol drinkers (p=0.517). Regarding BMI, 61.5% of the subjects who were overweight reported sexual dysfunction (p=0.417). Majority (72.7%) of the male subjects with impaired vision had sexual dysfunction (p=0.138). It was also revealed that 55.6% of male subjects with hypertension presented with sexual dysfunction as compared to 53.8% of subjects without hypertension (p= 0.925). Among the biochemical parameters, serum creatinine (P=0.613), eGFR (p=0.101), serum urea (P=0.887), triglycerides (P=0.469) and high density lipoprotein cholesterol (p=0.517) were not significantly associated with lower extremity amputations (Table 4.16). None of the male subjects had abnormal level of total cholesterol and low density lipoprotein cholesterol.

Table 4.14: Univariate analysis of socio-demographic characteristics associated with sexual dysfunction in male diabetics

Characteristic	Total Population N=31(%)	dysfunction N=17(%)	No Sexual dysfunction N=14(%)	p-value
Age (mean±S.D)	54.74±12.791	55.41±13.505	53.93±12.319	0.752

Ethnicity:				
Northerner	8 (100)	6 (75)	2 (25)	0.110
Ga/Adangbe	5 (100)	4 (80)	1 (10)	
Ewe	1 (100)	1 (100)	0 (0.0)	
Akan	17 (100)	6 (35.3)	11 (64.7)	
Marital status:				
Single	1 (100)	0 (0.0)	1 (100)	0.361
Married	29 (100)	16 (55.2)	13 (44.8)	
Divorced	1 (100)	0 (0.0)	1 (100)	
Religion:				
Muslim	10 (100)	6 (60)	4 (40)	0.690
Christian	21 (100)	11 (52.4)	10 (47.6)	
Level of education:				
JHS	10 (100)	4 (40)	6 (60)	0.518
SHS	6 (100)	3 (50)	3 (30)	
Tertiary	7 (100)	4 (57.1)	3 (42.9)	
None	8 (100)	6 (75)	2 (25)	
Employment status:				
Employed	9 (100)	5 (55.6)	4 (44.4)	0.728
Self-employed	19 (100)	11 (57.9)	8 (42.1)	
Not employed	3 (100)	1 (33.3)	2 (66.7)	

Table 4.15: Univariate analysis of medical history, lifestyle and physical

characteristics associated with sexual dysfunction in male diabetics

Characteristic	Total Population N=31(%)	Sexual dysfunction N=17(%)	No Sexual dysfunction N=14(%)	p-value
Duration of diabetes:				
<5	7 (100)	4 (57.1)	3 (42.9)	0.672
5-10	12 (100)	7 (58.3)	5 (41.7)	
11-15	7 (100)	4 (57.1)	3 (42.9)	
16-20	4 (100)	1 (25)	3 (75)	
>20	1 (100)	0 (0.0)	1 (100)	
Smoking:				
Yes	1 (100)	0 (0.0)	1(100)	0.263
No	30 (100)	17 (56.7)	13(43.3)	
Alcohol intake:				
Yes	6(100)	4(66.7)	2(33.3)	0.517
No	25(100)	13(52)	12(48)	
BMI:				
Underweight	29 (100)	0 (0.0)	2 (100)	0.417
Normal	13 (100)	6 (46.2)	7 (53.8)	
Overweight	13 (100)	8 (61.5)	5 (38.5)	
Obese	3 (100)	1 (33.3)	2 (66.7)	
Impaired vision:				
Present	11 (100)	8 (72.7)	3 (27.3)	0.138
Absent	20 (100)	9 (45)	11 (55)	
Hypertension:				
Present	18 (100)	10 (55.6)	8 (44.4)	0.925
Absent	13 (100)	7 (53.8)	6 (46.2)	

Table 4.16: Univariate analysis of biochemical characteristics associated with sexual dysfunction in male diabetics

Characteristic	Total Population N=31(%)	Sexual dysfunction N=17(%)	No Sexual dysfunction N=14(%)	p-value
Serum Creatinine (µmol/l):				
Abnormal (>120)	8 (100)	5 (62.5)	3 (37.5)	0.613
Normal (≤ 120)	23 (100)	12 (52.2)	11 (47.8)	
eGFR (mL/min/1.73 m^2):				
Abnormal (<60)	9 (100)	7 (77.8)	2 (22.2)	0.101
Normal (≥60)	22 (100)	10 (45.5)	12 (54.5)	
Serum Urea (mmol/l);				
Abnormal (>8.3)	2 (100)	1 (50)	1 (50)	0.887
Normal (≤8.3)	29 (100)	16 (55.2)	13 (44.8)	
Triglycerides (mmol/l):				
Abnormal (> 1.7)	7 (100)	3 (42.9)	4 (57.1)	0.469
Normal (≤1.7)	24 (100)	14 (58.3)	10 (41.7)	
HDL Cholesterol (mmol/l):				
Abnormal (<1.03)	6 (100)	4 (66.7)	2 (33.3)	0.517
Normal (≥1.03)	25 (100)	13 (52)	12 (48)	

4.4.2 Risk factors and predictors of sexual dysfunction in males

The independent variables with $p<0.05$ on the univariate analysis were to be considered for multivariate analysis so as to control for confounder risk factors but none was associated with male sexual dysfunction in the univariate analysis, thus multivariate logistic regression analysis was not ran.

4.4.3 Prevalence and severity of sexual dysfunction in females

The female participants were assessed using the seven domains for measuring sexual dysfunction which included anorgasmia, vaginismus, non-communication, infrequency, female avoidance, female non-sensuality and female dissatisfaction to determine sexual dysfunction prevalence. The prevalence of sexual dysfunction among the female diabetics was 68.1% out of which 4.3% had severely abnormal. Sexual dysfunction prevalences in female diabetics recorded in Korle Bu Teaching Hospital, Komfo Anokye Teaching Hospital and Tamale Teaching Hospital were 40.4%, 21.3% and 38.3% respectively**.**

As shown in Table 4.17, anorgasmia, vaginismus, non-communication, infrequency, female avoidance, female non-sensuality and female dissatisfaction were present in 82.2%, 86%, 79.6%, 74%, 82%, 80% and 92.7% of the diabetics respectively. Anorgasmia (p= 0.001), vaginismus (p=0.000), non-communication (p=0.000), female avoidance (p=0.000), female non-sensuality (p=0.032) and female dissatisfaction (p=0.000) were significantly associated with sexual dysfunction whilst infrequency (p=0.089) was insignificantly associated with sexual dysfunction. Non-communication (13%) had a higher level of severity than the other six domains of sexual dysfunctions as shown in Table 4.18.

Table 4.17: Sexual dysfunction domains stratified by sexual dysfunction in female diabetics

Domain	Total Population N=69 (%)	Sexual dysfunction N=47(%)	No Sexual dysfunction N=22 (%)	P-value
Anorgasmia:				
Present	45 (100)	37 (82.2)	8 (17.8)	0.001
Absent	24 (100)	10 (41.7)	14 (58.3)	
Vaginismus:				
Present	50 (100)	43 (86)	7 (14)	0.000
Absent	19 (100)	4 (21.1)	15 (78.9)	
Non-communication:				
Present	54 (100)	43 (79.6)	11 (20.4)	0.000
Absent	15 (100)	4 (26.7.4)	11 (73.3)	
Infrequency:				
Present	50 (100)	37 (74)	13 (26)	0.089
Absent	19 (100)	10 (52.6)	9 (47.4)	
Female Non-sensuality:				
Present	50 (100)	41 (82)	9 (18)	0.000
Absent	19 (100)	6 (31.6)	13 (68.4)	
Female avoidance:				
Present	35 (100)	28 (80)	7 (20)	0.032
Absent	34(100)	19 (55.9)	15 (44.1)	
Female dissatisfaction:				
Present	41(100)	38 (92.7)	3 (7.3)	0.000
Absent	28(100)	9 (32.1)	19 (67.9)	

Table 4.18: Severity of sexual dysfunction in female diabetics

Domain	Severely Abnormal	Abnormal	Normal

Anorgasmia	4 (5.8%)	41 (59.4%)	27 (34.8%)
Vaginismus	6 (8.7%)	44 (63.8%)	19 (27.5%)
Non-communication	9 (13%)	45 (65.2%)	15 (21.7%)
Infrequency	5 (7.2%)	45 (65.2%)	19 (27.5%)
Female avoidance	4 (5.8%)	31 (44.9%)	34 (69.3%)
Female non-sensuality	5(7.2%)	45 (65.2%)	19 (27.5%)
Female dissatisfaction	4 (5.8%)	37 (53.6%)	28 (40.6%)

As indicated in Table 4.19, the mean age in diabetics with sexual dysfunction was higher than the mean age in diabetics without sexual dysfunction but it was statistically insignificant (p=0.403). Sexual dysfunction prevalence did not differ significantly among the ethnic groups (p=0.855); majority (71.4%) of the northerners had sexual dysfunction. It was observed that females who were divorced had the highest prevalence of sexual dysfunction (80%) but the difference was insignificant (p=0.862). The study also revealed that 69.2% of the female subjects who were Muslims had sexual dysfunction as compared to 67.4% of Christians (P=0.877). Furthermore, majority (69.7%) of the women with no form of education had sexual dysfunction (p=0.813). Women who were employed recorded the highest prevalence (72.7%) of sexual dysfunction (p= 0.381).

Table 4.20 shows that, 77.8% of female subjects with diabetes duration ranging from 11-15 years presented with sexual dysfunction (p= 0.673). None of the female subjects smoked. It was also seen that 66.7% of those who were alcohol drinkers had sexual dysfunction as compared to 68.2% of those who were not alcohol drinkers (p=0.956). Regarding BMI, subjects who were obese recorded the highest prevalence (80%) of sexual dysfunction (p=0.548). Also, 72.7% of female subjects with impaired vision had sexual dysfunction as compared to 63.9% of those without impaired vision

(p=0.431). It was also revealed that 66.7% of female subjects with hypertension presented with sexual dysfunction as compared to 70.4% of subjects without hypertension (p= 0.747). None of the biochemical variables were significantly associated with sexual dysfunction in diabetic females (Table 4.21).

Table 4.19: Univariate analysis of socio-demographic characteristics associated with sexual dysfunction in female diabetics

Characteristic	Total Population N=69(%)	dysfunction N=47(%)	N=22(%)	-value dysfunction P
Age (mean±S.D)	53.40±14.236	54.49±12.995	51.08±16.676	0.403
Ethnicity:				
Northerner	28 (100)	20 (71.4)	8 (28.6)	0.855
Ga/Adangbe	4 (100)	2 (50)	2 (50)	
Ewe	4 (100)	3 (75)	1 (25)	
Akan	33 (100)	22 (66.7)	11 (33.3)	
Marital status:				
Single	8 (100)	5 (62.5)	3 (37.5)	0.862
Married	54 (100)	37 (68.5)	17 (31.2)	
Divorced	5 (100)	4 (80)	1 (20)	
Widowed	2 (100)	1 (50)	1 (50)	
Religion:				
Muslim	26 (100)	18 (69.2)	8 (30.8)	0.877
Christian	43 (100)	29 (67.4)	14 (32.6)	
Level of education:				
Primary	3 (100)	3 (100)	0 (0.0)	0.813
JHS	16 (100)	11 (68.8)	5 (31.2)	
SHS	8 (100)	5 (62.5)	3 (37.5)	
Tertiary	7 (100)	4 (57.1)	3 (42.9)	
Informal	2 (100)	1 (50)	1 (50)	
None	33 (100)	23 (69.7)	10 (30.3)	
Employment status:				
Employed	11 (100)	8 (72.7)	3 (27.3)	0.381

Self-employed	43 (100)	31 (72.1)	12 (27.9)
Not employed	15 (100)	8 (53.3)	7 (46.7)

Table 4.20: Univariate analysis of medical history, lifestyle and physical characteristics associated with sexual dysfunction in female diabetics

Characteristic	**Total Population N=69(%)**	**Sexual dysfunction N=47(%)**	**No Sexual dysfunction N=22(%)**	**P-value**
Duration of diabetes:				
<5	29 (100)	21 (72.4)	8 (27.6)	0.673
5-10	20 (100)	11 (55)	9 (45)	
11-15	9 (100)	7 (77.8)	2 (22.2)	
16-20	7 (100)	5 (71.4)	2 (22.2)	
>20	4 (100)	3 (75)	1 (25)	
Alcohol intake:				
Yes	3 (100)	2 (66.7)	1 (33.3)	0.956
No	66 (100)	45 (68.2)	21 (31.8)	
BMI:				
Underweight	7 (100)	5 (71.4)	2 (28.6)	0.548
Normal	15 (100)	9 (60)	6 (40)	
Overweight	27 (100)	17 (63)	10 (37)	
Obese	20 (100)	16 (80)	4 (20)	
Impaired vision:				
Present	33 (100)	24 (72.7)	9 (27.3)	0.431
Absent	36 (100)	23 (63.9)	13 (36.1)	
Hypertension:				
Present	42 (100)	28 (66.7)	14 (33.3)	0.747
Absent	27 (100)	19 (70.4)	8 (29.6)	

Table 4.21: Univariate analysis of biochemical characteristics associated with sexual dysfunction in female diabetics

Characteristic N=69(%)	Total Population	Sexual dysfunction N=47(%)	No Sexual dysfunction N=22(%)	P-value
Serum Creatinine (µmol/l):				
Abnormal (>120)	6 (100)	5 (83.3)	1 (16.7)	0.403
Normal (≤ 120)	63 (100)	42 (66.7)	21(33.3)	**eGFR (mL/min/1.73 m^2):**
Abnormal (<60)	18 (100)	12 (66.7)	6 (33.3)	0.878
Normal (≥60)	51 (100)	35 (68.6)	16 (31.4)	
Serum Urea (mmol/l):				
Abnormal (>8.3)	1 (100)	0 (0.0)	1 (100)	0.491
Normal (≤8.3)	68 (100)	46 (67.6)	22 (32.4)	
Total Cholesterol (mmol/l):				
Abnormal (>6.5)	7 (100)	4 (57.1)	3 (42.9	0.511
Normal (≤6.5)	62 (100)	43(69.4)	19 (30.6)	
Triglycerides (mmol/l):				
Abnormal (> 1.7)	25 (100)	18 (72)	7 (28)	0.602
Normal (≤1.7)	44 (100)	29 (65.9)	15 (34.1)	**HDL Cholesterol (mmol/l):**
Abnormal (<1.03)	16 (100)	10 (62.5)	6 (37.5)	0.582
Normal (≥1.03)	53 (100)	37 (69.8)	15 (30.2)	
LDL Cholesterol (mmol/l):				
Abnormal (>4.9)	3 (100)	2 (66.7)	1 (33.3)	0.956
Normal (≤ 4.9)	66 (100)	45(68.2)	21 (31.8)	

4.4.4 Risk factors and predictors of sexual dysfunction in females

None of the independent variables was associated with sexual dysfunction in the females in the univariate analysis and thus were not considered for multivariate logistic regression analysis.

4.4.5 Comparism of diabetic sexual dysfunction between males and females

Association between sexual dysfunction in males and females was not significant (p= 0.257) as shown in Figure 4. 2. Among the subjects 47 (68.1%) of the females had sexual dysfunction whilst 17 (54.8%) of the males had sexual dysfunction.

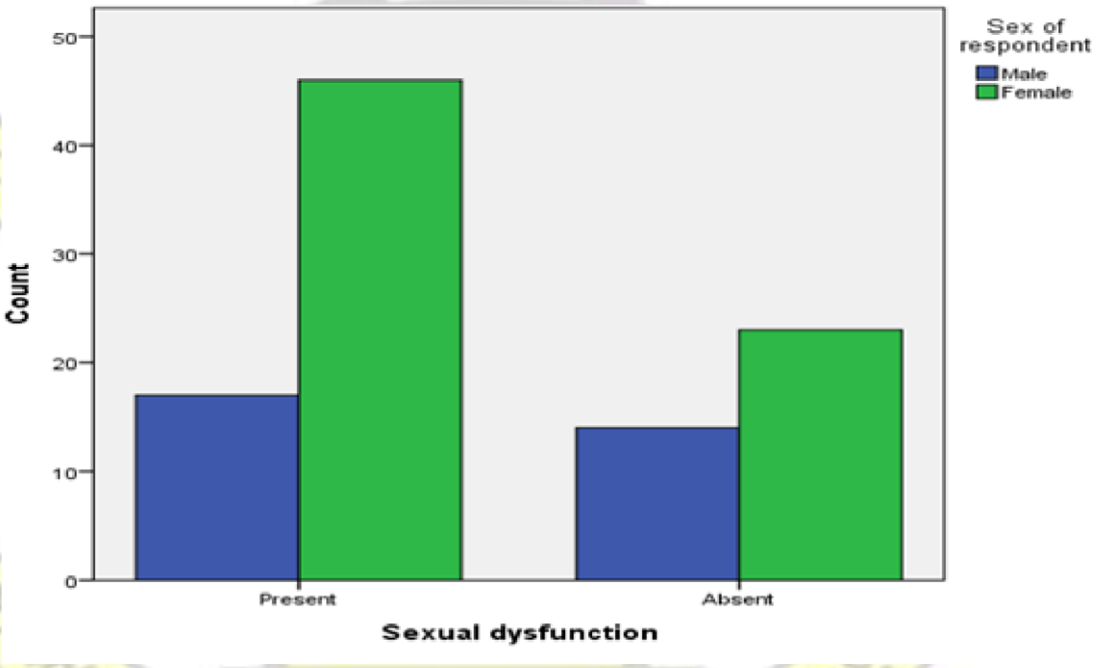


Figure 4.2: Sexual dysfunction categories by gender

CHAPTER FIVE

5.0 DISCUSSIONS

Diabetic foot ulcers, lower extremity amputations and sexual dysfunction result in human suffering, economic burden and mortality. These diabetes-related complications are currently on the rise following the continual rise in diabetes prevalence in Ghana and the world at large. Thus the present study was aimed at assessing the prevalence, risk factors and predictors of these complications to improve preventive strategies and care for diabetics.

In the present study, the prevalence of foot ulcers was 11%. This is higher than the prevalence reported in a retrospective study in Ghana, where the prevalence was 3.8% (Amissah and Amoako-Boateng, 2014). Similarly, the prevalence in the current study was also higher than prevalences reported in other countries including Egypt, Kenya, Jordan and Saudi Arabia where the prevalences were found to be 1.2%, 4.6%,

2.05% and 3.3% respectively (El-Nahas *et al.*, 2008; Nyamu *et al.*, 2003; Bakri *et al*., 2012; Al-Rubeaan *et al*., 2015). However, the finding of this study is comparable to studies done in India, Ethiopia, and Tanzania, where the prevalences were found to be 14%, 14.8% and 15% respectively (Reddy *et al.*, 2015; Deribe *et al.*, 2013; Achiwanga and Njelekela, 2015). It is worth noting that the results of the present study are among diabetics at three hospitals as compared to the results of the above previous studies that are among diabetics at one hospital. The variation in the prevalences of foot ulcers could also be due to differences in subject characteristics and the methodology used. The high prevalence of foot ulcers reported in the present study may be due to the fact that the study was carried out in tertiary hospitals that receive the largest referrals of patients in Ghana. Referral patients commonly present with a lot of complications including diabetes complications. Furthermore, the high prevalence recorded could also be attributed to inadequate knowledge on foot care by patients. Thus foot care education for diabetic patients may help curtail this problem.

In this study the association between BMI and foot ulcers was not significant (p=0.180, Table 4.4). Correlation between body mass and diabetic foot ulcers is thought to be due to the impact of body mass on plantar pressure (Tang *et al.*, 2015), but evidence has shown that body mass is poorly associated with plantar pressure (Cavanagh *et al.*, 1991) which explains the finding of the current study. Similarly, Kafrawya *et al*. (2014) and Altenburg *et al.* (2011) revealed that BMI is not a predictor of diabetic foot ulcers. In contrast, other studies showed a correlation between BMI and higher risk for foot ulceration (Pinzur *et al*., 2005; Zaine *et al*., 2014).

In the present study, there was no significant difference between diabetics with and without foot ulcers in terms of hypertension. This finding was confirmed by some studies

(Hellar and Mbembati, 2011; Nyamu *et al*., 2003). In contrast, other studies (Khan *et al*., 2011; Rizka and Ameen, 2013; Kibachio *et al*., 2013) have shown that hypertension is related to diabetic foot ulcers. The difference in findings may be due to differences in the methodology used and population characteristics (Bergqvist *et al.*, 2013).

Tseng (2003) in a study to determine the risk factors of foot ulcers observed that duration of diabetes was a significant risk factor for diabetic foot ulcers. Similarly, AlRubeaan *et al*. (2015) also revealed that foot ulcer prevalence is correlated with diabetes duration. This relationship was also confirmed by Shahi *et al*. (2012). In contrast, the present study showed no correlation (p=0.261) between diabetes duration and foot ulcers. The sample size of the present study is smaller than that of the previous studies and this might have decreased the chance of detecting the differences between the groups as described by Patel *et al*. (2003).

In the current study, impaired vision was found to be significantly associated with foot ulcers in the univariate analysis (p=0.042) and this may be due to the effect of impaired vision on the ability of patients to successfully prevent or treat lesions on their feet leading to foot ulceration (Gils and Stark, 2006). This finding is in line with that of Aziz (2010), Rizka and Ameen (2013) and Kafrawya *et al*. (2014) who also found an association between impaired vision and diabetic foot ulcers. However, impaired vision could not maintain statistical significance in the multivariate analysis, thus not an independent predictor of foot ulcers in diabetics. In contrast, Boyko *et al*. (1999) found impaired vision to be an independent predictor of foot ulcers in diabetics in a multivariate analysis. Impaired vision was self-reported in the present study and may account for the difference in finding as disease prevalence differs when assessed by medical criteria versus self-reported diagnoses (Vellakkal *et al.*, 2013).

Diabetics with renal dysfunction have a high risk of developing ischemia or neuropathy (Michael *et al.*, 2000) which often results in diabetic foot ulcer. This is in line with the finding of the present study as high levels of serum creatinine and chronic kidney disease (eGFR<60 mL/min/1.73 m^2**)** were associated with diabetic foot ulcer risk in the univariate analysis. The finding of the present study is in consonance with studies by Apelqvist and Agardh (1992), Fernando *et al*. (2009) and Al-Rubeaan *et al*. (2015) who also identified renal dysfunction to be associated with diabetic foot ulcers risk in univariate analysis. However, in the multivariate analysis, serum creatinine levels and chronic kidney disease did not maintain significance and thus, not predictors of diabetic foot ulcers. Similarly, a study by Shahi *et al*. (2012) confirmed that renal dysfunction is not a predictor of diabetic foot ulcer risk.

The current study further identified smoking as an insignificant risk factor for diabetic foot ulcers. Smoking has been described theoretically as a cause of peripheral vascular disease in diabetics which often results in foot ulcers (American Diabetes Association, 2014), contrarily, smoking has been identified in a study not to be related to peripheral vascular disease (Premalatha *et al*., 2000), hence the finding of the present study. Similarly, Altenburg *et al*. (2011) indicated that smoking is not a predictor of foot ulceration. The finding of the present study is also supported by other studies (Sriyani *et al*., 2013; Boyko *et al*., 1999). Contrarily, other studies showed a correlation between smoking and diabetic foot ulcers as Musa and Ahmed (2012) and Kafrawya *et al.* (2014).

Majority (50%) of the diabetics with foot ulcers in this study were having foot deformities (Contractured toe, prominent metatarsal heads, halux valgus, Table 4.4.) and there was significant difference between diabetics with and without foot ulcers in terms of

foot deformities (p=0.002) in the univariate analysis. In the multivariate logistic regression analysis, foot deformities maintained statistical significance (p=0.016). Diabetics with foot deformities were 18.39 times more likely to exhibit foot ulcers than diabetics without foot deformities. The finding of this study is in consonance with previous studies (Abbott *et al*., 2002; El-Nahas *et al*., 2008; Khan *et al*., 2011; Kafrawya *et al.,* 2014). This may be as a result of the role of foot deformities in the etiology of foot ulcers. Foot deformities are known to increase plantar peak pressure in the feet leading to skin breakdown resulting in ulcers (Lavery *et al*., 1995).

Dyslipidemia has been identified to play a role in the etiology of peripheral vascular diseases, one of the main causes of diabetic foot ulcers, but this relationship is inconsistent, as dyslipidemia has also been reported not to be linked to diabetic peripheral vascular disease (Premalatha *et al*., 2000). This may explain why the present study did not identify dyslipidemia as a risk factor for diabetic foot ulcers. Similarly, Hellar and Mbembati (2011) reported no association between dyslipidemia and foot ulcers in diabetics. In contrast, Tseng (2003) concluded that dyslipidemia is significantly correlated with diabetic foot ulcer risk.

It has also been revealed in the current study that treatment modalities such as diet, insulin and oral hypoglycemic agents are not correlated with foot ulcer prevalence in diabetics. This finding is in line with that of Musa and Ahmed (2012). Contrarily, a study by Shahi *et al*. (2012) indicated that insulin use is significantly associated with foot ulcers in diabetics, possibly because of the role of insulin in nerve degeneration as described by Gibbons and Freeman (2010). The present study and that of Musa and Ahmed (2012) investigated a small sample size as compared to that of Shahi *et al.* (2012) which may

account for the difference in finding as small sample size decreases the chance of detecting differences between groups (Patel *et al.,* 2003).

The current study found no link between alcohol intake and foot ulcers in diabetics. The finding of the present study has been confirmed in a study by Sriyani *et al.* (2013) who showed that alcohol intake is not associated with foot ulcer risk in diabetics. Similarly, Achiwanga and Njelekela (2015) also confirmed that alcohol use does not increase foot ulcer risk in diabetics. In contrast, a study in the United Kingdom showed that alcohol use increases the risk of foot ulcers in diabetics (Altenburg *et al.,* 2011). The study by Altenburg *et al*. (2011) differed in finding possibly because it was a case control study as difference in study designs can result in different outcomes (Bergqvist *et al.,* 2013).

Previous history of foot ulcer was found to be a predictor of diabetic foot ulcers in the present study. Abbott *et al.* (2002) also revealed that previous history of foot ulcer is correlated to increased risk of foot ulcers. The finding of the present study has also been confirmed by Kafrawya *et al.* (2014). This finding may be as a result of the fact that after wound healing following ulceration, the skin plantar to that area usually become less strong to withstand repetitive stress and thus easily breakdown (Helm *et al*., 1991). Contrary to the finding of the present study, other previous studies (Achiwanga and Njelekela, 2015: Boyko *et al*., 1999) reported no link between previous history of foot ulcers and diabetic foot ulcers. Regarding previous history of amputation, it was not found to be significantly associated with foot ulcer risk in the present study. On the contrary Kafrawya *et al*. (2014) showed a link between previous history of amputation and diabetic foot ulcers.

Some previous studies (Leung *et al*., 2001; Iversen, 2009; Wang *et al*., 2014) revealed that increasing age is correlated with increased risk of foot ulcers in diabetics. These findings may be supporting the effect of increasing age on wound healing duration in diabetics (Guo, 2010). In contrast, this relationship was not supported by Kafrawya *et al.* (2014). Similarly, the present study showed no correlation between age and foot ulcers. The methodological differences among the studies at least in part may be responsible for the mixed findings (Bergqvist *et al.*, 2013).

The prevalence of lower extremity amputations was found to be 3% in the present study and is comparable to studies done in Ghana, Thailand, Jordan, Taiwan and United State of America where the prevalences were found to be 1.1%, 1.5%, 1.7%, 1.7%, and 4% respectively (Amissah and Amoako-Boateng, 2014; Krittiyawong *et al*., 2006; Bakri *et al*., 2012; Tseng, 2003; Freeman and Hosey, 1993). However, the study done in Ghana by Amissah and Amoako-Boateng (2014) was a retrospective study that focused on type 2 diabetics >30 years and this may account for the slight difference in prevalence. Similarly, the prevalence in the other studies done in Thailand, Jordan, Taiwan and United State of America might have differed slightly from the present study because of differences in methodology and population characteristics. It is worth mentioning that, a higher prevalence of lower extremity amputations was expected from the present study, in that the hospitals of study receive the largest referrals of diabetics in Ghana as referral patients usually present with a lot of complications. The low prevalence in this study may be due to proper diabetic foot care provided by these hospitals, thus minimizing the chances of a diabetic foot progressing to an amputation.

Body mass index of diabetics was not found to be related to lower extremity amputation in this study. This finding was confirmed by Jung *et al.* (2007). However, these findings were inconsistent with that of Sohn *et al*. (2012) who showed that greater body weight (obesity) was associated with lower extremity amputation. Although diabetic amputations may be correlated with the effect of body weight on plantar pressure, evidence for this correlation is inconsistent (Cavanagh *et al.,* 1991), hence the finding of the present study.

The prevalence of hypertension was higher (3.3%) in diabetics with lower extremity amputation than those without lower extremity amputations (2.5%) in the present study, but this variation in prevalence was statistically insignificant (p=0.811). This finding is consistent with previous studies (Gürlek *et al*., 1998; Jung *et al*., 2007). In contrast, Lee *et al*. (1993) and Moss *et al*. (1992) found a strong correlation between hypertension and lower extremity amputations. These studies employed different study designs and sample sizes which might have resulted in the differences in findings as described by Devillé *et al*. (2002).

Although longer diabetes duration has been linked to nerve damage (neuropathy) as described by the World Health Organization (2015), this link has been proven to be very poor (Mørkrid, 2007), thus justifies the finding of the present study that duration of diabetes is an insignificant risk factor for lower extremity amputations. On the other hand, Jbour *et al*. (2003) and Gallagher *et al*. (2014) indicated a correlation between duration of diabetes and lower extremity amputation.

Previous studies (Jbour *et al*., 2003; Laclé and Valero-Juan, 2012) have indicated that poor vision increases lower extremity amputation risk in diabetics whilst other studies (Gürlek *et al*., 1998; Jung *et al*., 2007) did not find such an association. Similarly, poor

vision was not found to be linked to diabetic lower extremity amputations in this study. The difference in findings may be as a result of the differences in diagnostic criteria for impaired vision (Vellakkal *et al.,* 2013).

Significant difference was observed between diabetics with lower extremity amputations and diabetics without lower extremity amputations with regards to renal dysfunction (abnormal serum urea levels). Similarly, renal dysfunction was identified as a significant risk factor for diabetic lower extremity amputations in a study by Jiang *et al*. (2015). Also Young *et al*. (2003) reported that the presence of renal dysfunction increases the risk of diabetic lower extremity amputations. Renal dysfunction results in the accumulation of high amounts of toxic substances in the blood causing nerve degeneration (National Institute of Neurological Disorders and Stroke, 2015) which may result in amputations.

Smoking and lower extremity amputations were not found to be related in this study. Smoking is thought to be a cause of ischemia (Peripheral vascular disease) which often result in amputations in diabetics, but this is not conclusive as evidence also show that smoking is not linked to ischemia (Premalatha *et al*., 2000). This in part, explains the finding of the present study. In line with the present study, Alder *et al.* (1999) demonstrated that smoking is not related to lower extremity amputations in diabetics. Similarly, a study by Gürlek *et al*. (1998) also revealed that smoking is not related to lower extremity amputation risk in diabetics.

Foot deformities were correlated with lower extremity amputation risk in the univariate analysis in the present study. This finding may be due to the role of foot deformities in increasing plantar peak pressure. The finding of the present study is in consonance with a study by Srinivas *et al*. (2012) who showed that foot deformity

prevalence was higher in diabetics with lower extremity amputations than those without lower extremity amputations. However, in the multivariate analysis, foot deformities could not maintain significance and thus not an independent predictor of lower extremity amputations in diabetics. Similarly, Assumpção *et al.* (2009) revealed that foot deformities are not independently related to diabetic lower extremity amputations.

The role of dyslipidemia in the etiology of atherosclerosis that results in ischemia, the major cause of amputations in diabetics as described by Cassoobhoy (2014) is not consistent as a study by Premalatha *et al*. (2000) showed no correlation between dyslipidemia and ischemia. This may explain why dyslipidemia was not identified as a risk factor for lower extremity amputations in this study. The finding of this study is in line with that of Selby and Zhang (1995) and Rajamani *et al.* (2009).

It was revealed in this study that treatment of diabetes with either diet or medication (insulin/or oral hypoglycemic agents) is not correlated with lower extremity amputations. Similarly, Yekta *et al*. (2011) who investigated 94 diabetics reported that diet or oral hyperglycemic agents treatment is not correlated with lower extremity amputation in diabetics. Contrary to the present study, Krittiyawong *et al.* (2006) in a study involving 9419 diabetics aimed at determining the prevalence as well as the association between insulin use and lower extremity amputations reported that insulin use is a risk factor for lower extremity amputations. This may be due to the role of insulin in nerve degeneration, the main cause of lower extremity amputations in diabetics. The large sample size of the study by Krittiyawong *et al.* (2006) as compared to the present study and that of Yekta *et al*. (2011) may explain the difference in findings as large sample size increases the possibility of detecting differences between groups as confirmed by Patel *et al.* (2003).

Theoretically, alcohol intake has being noted to cause nerve damage which can result in foot ulcers and amputations (American Health Network, 2015) but a study by Mimi *et al.* (2003) reported no connection between nerve damage in diabetics and alcohol intake, thus suggesting an insignificant correlation between alcohol intake and lower extremity amputations as identified by the present study. Similarly, alcohol intake did not show a statistically significant relation to amputation in diabetics in a study by Adam *et al*. (2009). Jung *et al*. (2007) in a study to evaluate the possible predictors of lower extremity amputations in diabetics revealed no relationship between alcohol use and amputation risk in diabetics.

Previous history of foot ulcers was not shown to increase lower extremity amputation risk in this study. In line with the present study, Siddiqui *et al*. (2004) and Monteiro *et al*. (2014) showed that previous history of foot ulcer does not increase lower extremity amputation risk. Contrarily, Rajamani *et al*. (2009) showed that previous history of amputation increases lower extremity amputation risk in diabetics. His finding might have differed from that of current study possibly because his study was limited to type 2 diabetics as difference in study characteristics can lead to different outcomes (McDonagh *et al.*, 2013).

Studies by Sekamatte (2014), Monteiro *et al*. (2014) and Gürlek *et al*. (1998) showed no relationship between age and lower extremity amputations in diabetics. Similarly, the present study found no relationship between age and lower extremity amputation in diabetics. In contrast, Jung *et al.* (2007), Wang *et al*. (2014) and Santos *et al*. (2015) revealed a correlation between age and lower extremity amputations. The study designs and population characteristics differed among the studies and this may account for the difference in findings (Devillé *et al*., 2002).

With respect to sexual dysfunction, it has been observed that the sexual dysfunction prevalence among male diabetics varies among studies. Sexual dysfunction prevalence among male diabetics was found to be 54.8% in the present study which is lower than that observed from studies done in Ghana by Amidu *et al.* (2010) and Owiredu *et al*. (2011) where the prevalences were found to be 70% and 69.3%

respectively. This could be as a result of the fact that the present study was a multicenter study and also investigated a small sample size as compared to that of Amidu *et al.* (2010) and Owiredu *et al*. (2011). However, the prevalence observed in the present study is comparable to that of Unadike *et al*. (2008) in Nigeria where the prevalence was reported to be 58% among diabetic males. In the present study, 6.5% of the male diabetics had severe sexual dysfunction as compared to 4.7% in the study by Owiredu *et al*. (2011). Regarding the sexual dysfunction domains, impotence (12.9%), premature ejaculation (12.9%), non-communication (12.9%) and dissatisfaction (12.9%) recorded the highest severity of sexual dysfunction in the present study as compared to impotence (15.8%) in the study by Owiredu *et al*. (2011). Furthermore, premature ejaculation, nonsensuality, avoidance and dissatisfaction were significantly related to sexual dysfunction in the present study as compared to infrequency, non-communication, non-sensuality, dissatisfaction, and impotence in the study by Owiredu *et al*. (2011). It is worth emphasizing that the result of the present study should be relied on, in that it is a multicenter study, thus the data was derived from different hospitals in Ghana making it unlikely for a coincidental factor in one hospital to affect the results.

Regarding female sexual dysfunction in diabetics, the present study, which is the first to investigate the prevalence of female sexual dysfunction among diabetics in Ghana, reported a prevalence of 68.1%, which is comparable to a prevalence of 73.2% reported

by Singh *et al.* (2009) in India. However, the prevalence reported in the present study is higher than prevalences obtained from other countries. For instance, studies in Jordan, Italy and Kenya reported prevalences of 59.6%, 53.4% and 36% respectively (Ali *et al*., 2008; Esposito *et al*., 2010; Owiti *et al*., 2012). The variation in prevalences observed above could probably be due to methodological and population characteristic differences. Regarding the female sexual dysfunction domains, the most prevalent areas of difficulty were female dissatisfaction (92.7%), vaginismus (86%), anorgasmia (82.2%), female avoidance (82%), female non-sensuality (80%), non-communication (79.6%) and infrequency (74%). In terms of severity of sexual dysfunction, 4.3% had severe dysfunction and the most severe area was non-communication (13%). The high prevalence of sexual dysfunction in the female diabetics observed in the present study was expected, in that the hospitals of study were referral hospitals; hence receive all serious and chronic illnesses, which diabetes complications are not an exception.

Among the subjects, BMI did not relate to sexual dysfunction. In line with the finding of the present study, Hosseinzadeh *et al.* (2014) revealed that obesity is not correlated with sexual dysfunction in women. Similarly, Vafaeimanesh *et al.* (2014) showed no link between obesity and sexual dysfunction in men. In contrast, Owiredu *et al*. (2011) reported that greater body weight (obesity) is a predictor of sexual dysfunction in diabetic men. Obesity has been known to cause sexual dysfunction because of its association with dyslipidemia, the main cause of ischemia (decreased blood flow) resulting in sexual dysfunction, but it is worth noting that this relationship is not conclusive (Premalatha *et al*., 2000), hence the finding of the present study.

Difference in the prevalence of sexual dysfunction between diabetics with and without sexual dysfunction in terms of hypertension was not significant in the current

study. This finding is consistent with other studies (Ziaei-Rad *et al*., 2010; Esposito *et al*., 2010; Vafaeimanesh *et al*., 2014). On the contrary, Sharifi *et al*. (2012) and Peter *et al*. (2012) showed an association between hypertension and sexual dysfunction in diabetics. The methodological differences among the studies may justify the different findings (Bergqvist *et al.*, 2013).

The effect of longer diabetes duration on nerve damage (neuropathy) has been proposed theoretically to be responsible for sexual dysfunction in diabetics as it disrupts blood flow to the genital area (Josylin Diabetes Centre, 2015). On the other hand, the association between duration of diabetes and neuropathy has been reported to be very negligible (Mørkrid, 2007) and thus justifies the finding of the present study. In line with the current study, Ziaei-Rad *et al*. (2010) found no relation between duration of diabetes and sexual dysfunction in both genders. This finding was also confirmed by Esposito *et al*. (2010) and Omidvar *et al*. (2013) who discovered that duration of diabetes has no correlation with sexual dysfunction in women.

Poor vision was not correlated with diabetic sexual dysfunction in this study. Contrarily, Henis *et al.* (2011) identified impaired vision as a predictor of sexual dysfunction in men. Similarly, Ali *et al*. (2008) also identified poor vision as a significant risk factor for sexual dysfunction in diabetic women. The difference in finding may be as a result of the different diagnostic criteria employed in the current study as difference in diagnostic criteria can result in different outcomes (Vellakkal *et al*., 2013).

Studies by Chernyshova *et al*. (1991) and Copeland *et al*. (2012) showed a relationship between renal dysfunction and sexual dysfunction in diabetics. On the other hand, renal dysfunction was not associated with sexual dysfunction in both men and women in the present study. The large sample size as well as the different methodologies

employed in these previous studies may justify the difference in findings (Patel *et al.*, 2003; Devillé *et al*., 2002).

Nerve damage can result in loss of sensation in the genitals which often leads to sexual dysfunction in diabetics. The role of nicotine in nerve tissue damage as described theoretically by Tostes *et al*. (2008) does not hold as a study by Premalatha *et al*. (2000) found no relationship between nicotine and nerve tissue damage. This finding justifies the finding of the current study as smoking was not identified as a significant risk factor for sexual dysfunction. The finding of the present study is in consonance with a previous study among diabetic men by Mutagaywa *et al*. (2014). Similarly, Ali *et al*. (2008) and Esposito *et al*. (2010) also found no relationship between smoking and sexual dysfunction in diabetic women.

The effect of high lipids concentration in the development of atherosclerosis which often results in sexual dysfunction is yet to be fully justified (Premalatha *et al*., 2000). This may explain why there was no difference between diabetics with sexual dysfunction and diabetics without sexual dysfunction in terms of dyslipidemia in the present study. This finding has been confirmed by Sharifi *et al*. (2012) and Mutagaywa *et al.* (2014) who revealed that dyslipidemia is not a significant risk factor for sexual dysfunction in diabetic men. Similarly, Ali *et al*. (2008) showed no correlation between dyslipidemia and sexual dysfunction in women.

Alcohol intake and sexual dysfunction in diabetics were not found to be correlated in this study. A similar finding was reported by Mutagaywa *et al*. (2014) in a study of diabetic men. Peter *et al*. (2012) also reported no correlation between alcoholism and sexual dysfunction in men. In women, alcohol has been known to cause sexual dysfunction (American Health Network, 2015) but no clinical study has been identified linking

alcoholism to sexual dysfunction in women. Theoretically, alcohol is said to be linked to the development of neuropathy, a major cause of sexual dysfunction in diabetics, but this is inconclusive (Mimi *et al*., 2003), hence the finding of the present study.

The present study found no link between age and sexual dysfunction in both genders. This finding was supported by Ziaei-Rad *et al*. (2010) who found no relation between age and sexual dysfunction in both genders. Similar to the present study, Omidvar *et al*. (2013) showed no relationship between age and sexual dysfunction in diabetics. In contrast, it was revealed in a study by Esposito *et al*. (2010) that age and female sexual dysfunction are correlated, possibly because of the different methodology employed (Bergqvist *et al.*, 2013).

This study had some limitations that are worth mentioning. Because of limited resources, the presence of impaired vision was based on self-reported diagnosis. Also, glycated hemoglobin could not be tested for, thus made it impossible to relate glycemic control to diabetic foot ulcers, lower extremity amputations and sexual dysfunction. Moreover, the cross-sectional nature of the study does not provide a good basis for establishing causality as both exposure and outcome were assessed simultaneously.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study assessed the prevalence, risk factors and predictors of diabetic foot ulcers, lower extremity amputations and sexual dysfunction among diabetics attending three hospitals in Ghana. The study showed that the prevalences of diabetic foot ulcers, lower extremity amputations and sexual dysfunction are high among diabetes patients. Severity of sexual dysfunction is also high. Foot deformities and previous history of foot ulcers are independent predictors of diabetic foot ulcers while renal dysfunction (high serum urea levels) is an independent predictor of diabetic lower extremity amputations. None of the independent variables is predictive of sexual dysfunction in diabetics.

6.2 Recommendations

Following the findings from the study, it is recommended that:

1. Health educators should improve foot care knowledge among diabetic patients especially those with previous history of foot ulcers and foot deformities to enhance their practice of diabetic foot self-care to prevent foot ulcers.

2. Healthcare providers should improve quality of care for diabetic foot ulcer patients especially those with nephropathy to minimize the chances of a diabetic foot ulcer progressing to an amputation.
3. Diabetics should be screened for sexual dysfunction in routine clinical practices by healthcare providers for early detection and management possibly through psychotherapy and pharmacotherapy.
4. Interventions geared towards the prevention, early diagnosis and effective management of diabetes should be implemented by healthcare providers to prevent complications such as foot ulcers, lower extremity amputations and sexual dysfunction from setting in.

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APPENDICES

APPENDIX I: QUESTIONNAIRE FOR DATA COLLECTION

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY
COLLEGE OF SCIENCE
DEPARTMENT OF BIOCHEMISTRY AND BIOTECHNOLOGY

A RESEARCH QUESTIONNAIRE

PREVALENCE, RISK FACTORS AND PREDICTORS OF DIABETESRELATED COMPLICATIONS: ULCERS, AMPUTATIONS AND SEXUAL DYSFUNCTION

Serial Number:

INTRODUCTION

I .....,a second year MPhil. Human Nutrition and Dietetics student of the above institution wish to have a conversation with you on the above topic. Please be candid and truthful in your response and be assured that what is being discussed will remain confidential and shall be used for the purpose of this research only. Thank you.

SECTION A: SOCIO-DEMOGRAPHIC CHARACTERISTICS OF RESPONDENT

1. Respondent ID: …….
2. Age of respondent: ……...
3. Sex of respondent:

a. Male[ ]
b. Female[ ]

4. Ethnicity of respondent:
    a. Northerner[ ]
    b. Ga/Adangbe[ ]
    c. Ewe[ ]
    d. Akan [ ]
    e. Others (specify)……..

5. Marital status:
    a. Single [ ]
    b. Married [ ]
    c. Divorced [ ]
    d. Widowed [ ]
    e. Others (specify)……...

6. Religion:
    a. Muslim [ ]
    b. Christian [ ]
    c. Traditionalist [ ]
    d. Others (specify)……..

7. Level of education:
    a. Primary [ ]
    b. JHS [ ]
    c. SHS [ ]
    d. Tertiary [ ]
    e. Informal[ ]
    f. None[ ]

8. Employment status:
    a. Employed [ ]
    b. Self-employed [ ]
    c. Unemployed [ ]

SECTION B: MEDICAL HISTORY

9. How long have you been diagnosed with diabetes?
    a. <5 [ ]
    b. 5-10 [ ]

c. 11-15 [ ]
d. 16-20 [ ]
e. >20 [ ]

10. Diabetes treatment:
    a. Diabetic diet [ ]
    b. Oral hyperglycemic agents
    c. Insulin [ ]
    d. Oral hyperglycemic agents and Insulin [ ]

11. Previous history of foot ulcer:
    a. Yes [ ]
    b. No [ ]

12. Previous history of amputation:
    a. Yes [ ]
    b. No [ ]

SECTION C: LIFESTYLE VARIABLES

13. Do you smoke tobacco?
    a. Yes [ ]
    b. No [ ]

14. Do you drink alcohol?
    a. Yes [ ]
    b. No [ ]

SECTION D: PHYSICAL CHARACTERISTICS AND BIOCHEMICAL PARAMETERS

15. Height(m): ……

16. Weight(kg): …….

17. BMI (kg/m2):……

18. Foot ulcer:
    a. Present[ ]
    b. Absent[ ]

19. Lower extremity Amputation:
    a. Present[ ]
    b. Absent[ ]

20. Foot deformity:
    a. Present[ ]
    b. Absent[ ]

21. Poor vision:
    a. Present [ ]
    b. Absent [ ]

22. Hypertension:
    a. Present [ ]
    b. Absent [ ]

23. Serum creatinine (µmol/l)…….

24. Serum urea (mmol/l)…….

25. eGFR (mL/min/1.73 m^2)……..

26. Dyslipidemia (mmol/l):
    a. Total cholesterol ……..
    b. Triglycerides…….
    c. HDL cholesterol……..
    d. LDL cholesterol……...

SECTION E: ASSESSMENT OF SEXUAL DYSFUNCTION

THE GOLOMBOK RUST INVENTORY OF SEXUAL SATISFACTION (GRISS) QUESTIONNAIRE

Each question is followed by a series of possible answers**:**

NEVER HARDLY EVER OCCASIONALLY USUALLY ALWAYS

Read each question carefully and decide which answer best describes the way things have been for you recently; then chose the corresponding answer. Please answer every question. If you are not completely sure which answer is most accurate, tick the one that you feel is most appropriate. Do not spend too long on each question. Please answer this questionnaire without discussing any of the questions with your partner. In order for you to obtain valid information it is important for you to answer each question as honestly and as accurately as possible.

ALL THE INFORMATION WILL BE TREATED IN THE STRICTEST CONFIDENCE.

Male version (If female skip to Q.54)

		Never	Hardly Ever	Occasionally	Usually	Always
26	Do you have sexual intercourse more than twice a week?					
27	Do you find it hard to tell your partner what you like or dislike about your sexual relationship?					
28	Do you become sexually aroused easily?					
29	Are you able to delay ejaculation during intercourse if you think you may be coming too quickly?					
30	Are you dissatisfied with the amount of variety in your sex life with your partner?					
31	Do you dislike stroking and caressing your partner's genitals?					
32	Do you become tense and anxious when your partner wants to have sex?					
33	Do you enjoy having sexual intercourse with your partner?					

34	Do you ask your partner what she likes and dislikes about your sexual relationship?					
35	Do you fail to get an erection?					
36	Do you feel there is a lack of love and affection in your sexual relationship with your partner?					
37	Do you enjoy having your penis stroked and caressed by your partner?					
38	Can you avoid ejaculating too quickly during intercourse?					
29	Do you try to avoid having sex with your partner?					
40	Do you find your sexual relationship with your partner satisfactory?					
41	Do you get an erection during foreplay with your partner?					
42	Are there weeks in which you don't have sex at all?					
43	Do you enjoy mutual masturbation with your partner?					
44	If you want sex with your partner do you take the initiative?					
45	Do you dislike being cuddled and caressed by your partner?					
46	Do you have sexual intercourse as often as you would like?					
47	Do you refuse to have sex with your partner?					
48	Do you lose your erection during intercourse?					
49	Do you ejaculate without wanting to almost as soon as your penis enters your partner's vagina?					
50	Do you enjoy cuddling and caressing your partner's body?					
51	Do you feel uninterested in sex?					
52	Do you ejaculate by accident just before your penis is about to enter your partner's vagina?					
53	Do you have feelings of disgust about what you and your partner do during lovemaking?					

Female version of GRISS

		Never	Hardly Ever	Occasionally	Usually	Always
54	Do you feel uninterested in sex?					
55	Do you ask your partner what he likes or dislikes about your sexual relationship?					
56	Are there weeks in which you don't have sex at all?					
57	Do you become sexually aroused easily?					
58	Are you satisfied with the amount of time you and your partner spend on foreplay?					
59	Do you find that your vagina is so tight that your partner's penis cannot enter it?					
60	Do you try to avoid having sex with your partner?					
61	Are you able to experience an orgasm with your partner?					
62	Do you enjoy cuddling and caressing your partner's body?					
63	Do you find your sexual relationship with your partner satisfactory?					
64	Is it possible to insert your finger into your vagina without discomfort?					
65	Do you dislike stroking and caressing your partner's penis?					
66	Do you become tense and anxious when your partner wants to have sex?					
67	Do you find it impossible to have an orgasm?					
68	Do you have sexual intercourse more than twice a week?					
69	Do you find it hard to tell your partner what you like and dislike about your sexual relationship?					
70	Is it possible for your partner's penis to enter your vagina without discomfort?					
71	Do you feel there is a lack of love and affection in your sexual relationship with your partner?					
72	Do you enjoy having your genitals stroked and caressed by your partner?					
73	Do you refuse to have sex with your partner?					
74	Can you reach orgasm when your partner stimulates your clitoris during foreplay?					

75	Do you feel dissatisfied with the amount of time your partner spends on intercourse itself?					
76	Do you have feelings of disgust about what you do during					
	lovemaking?					
77	Do you find that your vagina is rather tight so that your partner's penis can't penetrate very far?					
78	Do you dislike being cuddled and caressed by your partner?					
79	Does your vagina become moist during lovemaking?					
80	Do you enjoy having sexual intercourse with your partner?					
81	Do you fail to reach orgasm during intercourse?					

APPENDIX II: PARTICIPANT CONSENT AND INFORMATION FORM

This leaflet must be given to all prospective participants to enable them know enough about the research before deciding to or not to participate

Title of Research: Prevalence, risk factors and predictors of diabetes-related complications: ulcers, amputations and sexual dysfunction

Name(s) and affiliation(s) of researcher(s): This research is being conducted by Ambrose Atosona of the postgraduate Human Nutrition and Dietetics programme, Department of Biochemistry and Biotechnology, Kwame Nkrumah University of Science and Technology, Kumasi.

Background: This study is about diabetes-related complications namely ulcers, amputations and sexual dysfunction. Diabetic ulcers, amputations and sexual dysfunction are long term complications of diabetes that result mainly from nerve damage. These complications come with a lot of human suffering, economic burden and mortality. Thus this study is focused on defining the extent, the associated risk factors and predictors of these complications to help improve preventive strategies and care for diabetics.

Purpose(s) of research: The purpose of this study is to assess the prevalence, risk factors and predictors of diabetes related complications: ulcers, amputations and sexual dysfunction in Ghana.

Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research:

Data will be collected from diabetics with the aid of a structured questionnaire to document information on socio-demographic characteristics, medical history, lifestyle variables (smoking and alcohol intake), physical characteristics and sexual dysfunction.

Socio-demographic characteristics: Information will be collected on level of education, age, sex, ethnicity, marital status, religion and occupation.

Medical history: Information on duration of diabetes, treatment of diabetes, history of impaired vision, nephropathy, and previous history of foot ulcers or amputations will be obtained.

.

Physical examination: Participants will be physically examined for foot ulcers, amputations, deformity (contractured toe, prominent metatarsal heads and halux valgus), hypertension and obesity. Regarding obesity, height (in meters) will be taken using a microtoise and weight (in kilograms) will be measured using a uniscale. The body mass index (BMI) will be derived by dividing the weight by the square of the height and classification of obesity will done according to World Health Organization criteria.

Regarding hypertension, blood pressure will be measured using a digital sphygmomanometer.

Biochemical assessment: Venous blood of participants will be taken for lipid profile and serum creatinine.

Assessment of sexual dysfunction: Sexual dysfunction will be measured using the Golombok Rust Inventory of Sexual Satisfaction (GRISS) questionnaire. All the questions are answered on a five-point scale (never, hardly ever, occasionally, usually, and always) Participants will be required to be candid and truthful in their response. In total100 participants will be recruited into this study throughout the country.

Risk(s): Pain and discomfort as a result of venipuncture (collection of blood from a vein). Participants will also be asked to provide information about sexual function, demographic data (age, income, education, race/ethnicity) and other sensitive information. Stress and feelings of guilt or embarrassment may arise from thinking or talking about these sensitive issues.

Benefit(s): This study when conducted will provide information that can be used to improve preventive strategies and care for diabetics. The results of this study will also be useful to care providers and the general public in the management of diabetic ulcers, amputations and sexual dysfunction to enhance their quality of life.

Confidentiality: Identification numbers will be used to protect the participants' identities, thus no name will be recorded. The records will be stored appropriately and accessible to only those conducting the study. No name will be used in any publication or reports from this study.

Voluntariness: Your participation in this study should be out of your own free will. You are not under any obligation to participate in the study.

Alternatives to participation: If you choose not to participate in the study, your treatment in this hospital will not be affected in any way.

Withdrawal from the research: You have the right to withdraw from the study at any time. You may choose not to answer any question you find uncomfortable or private.

Consequence of Withdrawal: There will be no consequence, loss of benefit to you if you choose to withdraw from the study. Please some of the information that may have been obtained from you before you chose to withdraw cannot be removed anymore. We do promise to make good faith effort to comply with your wishes as much as practicable.

Costs/Compensation: There shall be no compensation to participants

Contacts: If you have any question concerning this study, please do not hesitate to contact Dr. Christopher Larbie, (0243445961), Principal Investigator and Dr. Antonia Tetteh, (0201134416), the head of Biochemistry and Biotechnology Department.

Further, if you have any concern about the conduct of this study, your welfare or your rights as a research participant, you may contact:
The Office of the Chairman
Committee on Human Research and Publication Ethics
Kumasi
Tel: 03220 63248 or 020 5453785

CONSENT FORM
Statement of person obtaining informed consent:
I have fully explained this research to _____ and have given sufficient information about the study, including that on procedures, risks and benefits, to enable the prospective participant make an informed decision to or not to participate.

DATE: _____ NAME: _____

Statement of person giving consent:
I have read the information on this study/research or have had it translated into a language I understand.

I have also talked it over with the interviewer to my satisfaction.

I understand that my participation is voluntary (not compulsory).

I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it.

I understand that I may freely stop being part of this study at any time without having to explain myself.

I have received a copy of this information leaflet and consent form to keep for myself.

NAME_____

DATE: _____ SIGNATURE/THUMB PRINT: _____

Statement of person witnessing consent (Process for Non-Literate Participants):

I_____ (Name of Witness) certify that information given to

_____ (Name of Participant), in the local language, is a true reflection of what l have read from the study Participant Information Leaflet, attached.

INDEPENDENT LITERATE WITNESS' SIGNATURE: _____

PARENT'S SIGNATURE/THUMB PRINT: _____

PARENT'S NAME_____

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICAL SCIENCES / KOMFO ANOKYE TEACHING HOSPITAL
COMMITTEE ON HUMAN RESEARCH, PUBLICATION AND ETHICS

Our Ref: CHRPE/AP/228/15

29th May, 2015.

Dr. Christopher Larbie
Department of Biochemistry
and Biotechnology
College of Science
KNUST-KUMASI.

Dear Sir,

LETTER OF APPROVAL

Protocol Title: ***"Prevalence, Risk Factors and Predictors of Diabetes-Related Complications: Ulcers, Amputations and Sexual Dysfunction."***

Proposed Site: ***Korle-Bu Teaching Hospital (Accra), Komfo Anokye Teaching Hospital (Kumasi) and Tamale Teaching Hospital (Tamale).***

Sponsor: ***Principal Investigator.***

Your submission to the Committee on Human Research, Publications and Ethics on the above named protocol refers.

The Committee reviewed the following documents:

- A notification letter of 20th April, 2015 from the Tamale Teaching Hospital (study site) indicating approval for the conduct of the study in the Hospital.
- Notification letters of 20th April, 2015 from the Department of Biochemistry and Biotechnology seeking permission to conduct the study at the Korle Bu and Komfo Anokye Teaching Hospitals (study sites) respectively.
- A Completed CHRPE Application Form.
- Participant Information Leaflet and Consent Form.
- Research Protocol.
- Questionnaire.

The Committee has considered the ethical merit of your submission and approved the protocol. The approval is for a fixed period of one year, renewable annually thereafter. The Committee may however, suspend or withdraw ethical approval at any time if your study is found to contravene the approved protocol.

Data gathered for the study should be used for the approved purposes only. Permission should be sought from the Committee if any amendment to the protocol or use, other than submitted, is made of your research data.

The Committee should be notified of the actual start date of the project and would expect a report on your study, annually or at the close of the project, whichever one comes first. It should also be informed of any publication arising from the study.

Thank you Sir, for your application.

Yours faithfully,

Rev. Prof. John Appiah-Poku
Honorary Secretary
FOR: CHAIRMAN

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