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Clinical Predictors Of Imminent Diabetic Foot Ulcer Among Diabetes Mellitus Patients In Dar Es Salaam And Zanzibar.

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Abstract
Background*: Diabetic foot ulcer (DFU) is a lesion that involves breakage in the skin with loss of epithelium that extends to the dermis and deeper layers involving muscle and bone which tend to develop due to factors associated with diabetes; hyperglycemia, presence of calluses, foot deformities, peripheral neuropathy, and vasculopathy. The management of diabetic foot ulcers requires a multidisciplinary approach; and is burdensome on the health care systems due to its chronic nature and potential complications. Diabetic foot ulcer has caused financial distress to the government in treating diabetic foot ulcer and its consequences; such as lower limb amputation which is irreversible, costly, and devastating to the quality of life of the patients, since diabetic foot ulcer patients have a low work productivity which in turn causes them to remain unemployed. DFU leads to increased morbidity and mortality due to complications like sepsis. Identification of the clinical predictors of imminent diabetic foot ulcer among diabetes mellitus patients is pivotal for the prevention and prompt identification of diabetic foot ulcer. This study aimed to identify and outline the clinical predictors of imminent diabetic foot ulcer among diabetes mellitus patients in Dar es Salaam and Zanzibar.*
Hence, identifying the clinical predictors of imminent diabetic foot ulcer such as; peripheral neuropathy for example which usually goes unnoticed because of its oblivious nature will therefore have no room for excuse and further prevent the development of diabetic foot ulcer. Correspondingly it allows health care systems to distribute access to health care rather than focusing on treating DFU significantly. It will also enable the government's economic burden placed on managing DFU to temper down. The quality of life of patients will improve in terms of physical, mental, and social health hence, reducing morbidity and mortality.
Methods*: a descriptive cross-sectional study was conducted among diabetes mellitus patients attending diabetic clinics in Dar es Salaam and Zanzibar. Questionnaires were used to collect demographic data and clinical characteristics of study participants. Random blood glucose and skin scrape tests were done using standard methods.*
Results*: A total of 202 participants (72 males and 130 females) were studied. The overall mean age of the study participants was 55.3± 16.7 years with a range of (13-83 years). The majority of the participants resided in Dar es Salaam, with 164 (81.2%) individuals, while 38 (18.8%) were from Zanzibar. Out of the 202 study participants, the proportion of diabetic foot ulcer was 40.6%, with the clinical predictors of imminent diabetic foot ulcer; peripheral neuropathy (47%), calluses (43.1%), hyperglycemia (34.2%) foot deformities (20.8%) and peripheral vasculopathy (10.4%).*
Conclusion*: findings from this study provide evidence for the existence of clinical predictors of imminent diabetic foot ulcer among diabetes mellitus patients in which peripheral neuropathy, calluses, hyperglycemia, foot deformities, and peripheral vasculopathy predominate.*
Keywords*: Diabetic foot ulcer, clinical predictors, neuropathy, vasculopathy*

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I. Background

Diabetic foot ulcer is a microvascular complication of uncontrolled diabetes mellitus defined as a lesion that involves breakage in the skin with loss of epithelium that may extend to the dermis and deeper layers involving muscle and bone[1]. It comprises a spectrum of causes namely; poor foot care practices, peripheral neuropathy, peripheral vascular disease, infections and foot deformities[1]. The leading cause is infections which may range from superficial cellulitis to chronic osteomyelitis and wade into gangrene and hence amputation[2]. There are 3 stages to the development of DFU; callus formation is the first stage; as a result of neuropathy which can be either motor leading to physical deformity of the foot, or sensory resulting in sensory loss and ongoing trauma[3]. The second stage is autonomic neuropathy which leads to dry skin and finally trauma to the callus resulting in subcutaneous hemorrhage, eroding of skin, and formation of ulcer[3]. Lastly, atherosclerosis also plays

a great role in developing DFU due to occlusion of blood vessels in the lower limb leading to a poor vascular supply hence, poor healing and development of gangrene and necrosis over time[3]. The organisms causing diabetic foot ulcer; *Staphylococcus aureus* being the most common followed by *Escherichia coli, and Enterococcus*[4] Globally, diabetes mellitus individuals have a high prevalence of diabetic foot ulcer[3] and these numbers are increasing due to the rising incidence of diabetes mellitus yearly[3,5]. The worldwide prevalence of DFU ranges from 3 to 13%[6] and causes ulcerations and amputations[7]. It is estimated that 15% of diabetics will suffer from diabetic foot ulceration in their lifetime. 50-70% of all lower limb amputations (LLA) are due to DFU and 25-50% will need an amputation on their first visit[8]. The prevalence of DFU in the United States ranges from 1 - 4.0%, 20.4% in the Netherlands, 13% in North America, and 5.5% in Asia[6]. Hospitalized patients due to DFU is more than 80%[9]. Poor foot care is one of the risk factors for developing DFU[10]. Other risk factors include long duration of diabetes mellitus[11], foot ulceration, poor glycemic and lipid control, and previous amputation[12]. Diabetic foot ulcer in Africa is the leading cause of mortality comprising more than 50% and imposes a great burden on the economy due to the late presentation of symptoms of the diabetes mellitus patients[13]. The prevalence is estimated to be 7.2% in Africa, with a prevalence of 13% in Cameroon and 9.5% in Nigeria[6]. In Tanzania 3.2% of diabetes mellitus patients were found to have DFU and peripheral neuropathy and poor foot care practices were among the major risk factors[14]. The objectives of this study were to; determine clinical predictors of imminent DFU among DM patients in Dar es Salaam and Zanzibar; determine the proportion of DM with DFU, determine the proportion of hyperglycemia, assess adherence to recommended foot care, determine the proportion of DM patients with risky feet conditions (i.e. peripheral neuropathy, peripheral vasculopathy, calluses, foot lesions, foot deformities), identify microorganisms in foot lesions of DM patients. Hence, Identifying clinical predictors like peripheral neuropathy can prevent diabetic foot ulcers, reducing healthcare costs and improving patients' quality of life physically, mentally, and socially, thereby lowering morbidity and mortality rates.

II. Methods

Study design and sampling

A descriptive cross-sectional study was conducted among diabetes mellitus patients in diabetic clinics. A cluster sampling technique was used to select the hospitals; the hospitals were divided into public and private hospitals in both Dar es Salaam and Zanzibar. The diabetic clinics in each of these clusters were listed down and by simple random sampling one clinic was selected in each of the clusters i.e. one clinic from the private cluster and one clinic from the public cluster in Dar es Salaam and Zanzibar; one clinic was selected from the private cluster and one from the public cluster by simple random sampling. Study participants were obtained by non-probability convenience sampling technique. The study population included all diabetes mellitus patients who agreed to consent and excluded severely ill patients unable to communicate and diabetes mellitus patients with bilateral lower limb amputation not related to diabetes mellitus i.e. trauma. The sample size was calculated using Fisher's formula; $n = Z^2 p (1-p) / \varepsilon^2$, where, Z = 1.96 for 95% CI, ε= margin of error (precision): for this study taken as 0.05, p = 15% was obtained from a previous study[14]. The calculated sample size was approximately **196 ± 10.**

Data collection instrument

The sociodemographic variables were obtained using a specially structured questionnaire and included gender, age, residence, marital status, level of education, occupation, and employment status. For clinical data; type of diabetes mellitus, duration of diabetes mellitus, family history of diabetes mellitus, presence of foot ulcer, current intake of alcohol, current cigarette smoking, and type of treatment for diabetes mellitus were also obtained using a questionnaire. Foot care practices were assessed by asking a number of questions that were included in the specially structured questionnaire. It comprised of questions regarding risk factors, complications, treatment, and prevention of DFU with responses of 'yes' and 'no'. The 60-second screen for high-risk diabetic foot 2012[15] was used to assess diabetes mellitus patients. This screening test comprises 4 parameters that check for foot health; LOOK for integrity of skin, nails, footwear, and foot deformity, TOUCH for temperature and range of motion, ASSESS for pedal pulses, erythema, rubor and sensation (using a 10g Semmes–Weinstein monofilament tested on ten sites; pulp of the 1st and 3rd toes and the heads of 1st, 3rd and 5th of the metatarsophalangeal joints). Random blood glucose test was done using standard methods and OneTouch® glucometer[16], made in California. Skin scrape test was performed for DM patients who had foot lesions by using a surgical blade to scrape off superficially over infected lesions. The scrapings were placed onto plain paper, labeled, and sent to the laboratory for a KOH test, gram stain, and culture & sensitivity test to detect pyogenic and fungal microorganisms. The bacteria were allowed to grow on a special media that allowed the growth of the given specimen. Culture was done on petri dishes and culture media was used. As for the sensitivity test, the Disc diffusion method was used in which a paper disc was concentrated with various antibiotic solutions.

Ethical clearance was sought from the HKMU Institutional Research and Ethics Committee for conducting this study. Permission for data collection was obtained from the responsible administrative authorities of Dar es Salaam city and Zanzibar. The procedures and aim of this research were clearly explained to the study participants. Consent forms were given to all participants to read and fill out the declaration. The study did not cause any serious harm to the study participants. Participants were informed of a slight pain during finger prick for the measurement of random blood glucose levels which resolved in few minutes after the test. Confidentiality was maintained and codes rather than names were used.

Data entry and analysis

The collected data was then entered, cleaned for errors, and analyzed using SPSS Version 23. Data was described using mean ± SD, or medians for continuous variables. The relationship between the independent and dependent variables was assessed using the Chi-squared test. A p-value < 0.05 was considered to represent a statistically significant difference between variables.

III. Results

Demographic characteristics of study participants

Table 1: Demographics characteristics of diabetes mellitus patients attending diabetic clinics in Dar es Salaam and Zanzibar (N=202)

Variable	**Value**
Age (years), mean ± SD	55.3 ± 16.7
Sex, n (%)	
Male	72 (35.6)
Female	130 (64.4)
Residence, n (%)	
Dar es Salaam	164 (81.2)
Zanzibar	38 (18.8)
Marital status, n (%)	
Single	33 (16.3)
Married	155 (76.7)
Divorced	14 (7.0)
Education, n (%)	
No formal education	17 (8.4)
Primary	105 (52.0)
Secondary	53 (26.2)
College and above	27 (13.4)
Occupation, n (%)	
Office work	29 (14.4)
Farming	10 (5.0)
Others	163 (80.6)
Employment, n (%)	
Unemployed	72 (35.6)
Self employed	61 (30.2)
Employed	24 (11.9)
Retired	45 (22.3)
Religion, n (%)	
Muslim	116 (57.4)
Christian	86 (42.6)

SD, Standard Deviation.

Clinical characteristics of study participants.

Table 2: Clinical characteristics of diabetes mellitus patients attending diabetic clinics in Dar es Salaam and Zanzibar (N=202)

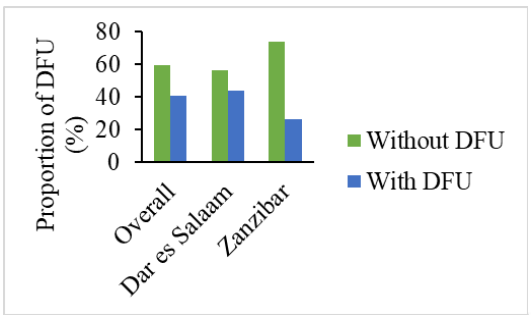
Variable	Value
Diabetes Mellitus Type, n (%)	
Type 1	28 (13.9)
Type 2	174 (86.1)
Type of Diabetes treatment, n (%)	
Diet & Exercise	11 (5.4)
Oral Hypoglycemics	131 (64.9)
Insulin Therapy	53 (26.2)
None	7 (3.5)
Co-morbidity type, n (%)	
None	71 (35.1)
Hypertension	96 (47.5)
Chronic Kidney Disease, n (%)	7 (3.5)
Human Immunodeficiency Virus n (%)	4 (2.0)
Others	24 (11.9)
Diabetic Foot Ulcer status, n (%)	
Present	82 (40.6)
Absent	120 (59.4)
Random Blood Glucose (mmol/L), mean ± SD	10.4 ± 5.6
SD, Standard Deviation.	

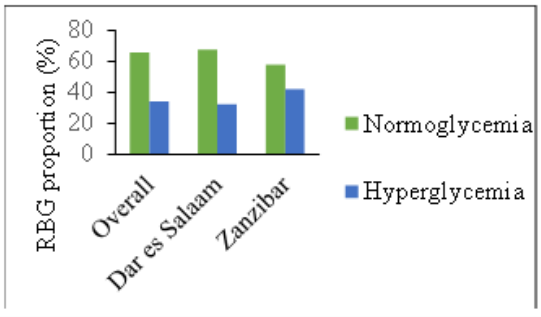
Proportion of diabetes mellitus patients who practice recommended foot care

Table 3: Proportion of diabetes mellitus patients who practice recommended foot care in Dar es Salaam and Zanzibar

Type of diabetic Foot care	Proportion of patients who practice diabetic foot care					
	Overall (n=202)		Dar es Salaam (n=196)		Zanzibar (n=38)	
	Yes, n (%)	No, n (%)	Yes, n (%)	No, n (%)	Yes, n (%)	No, n (%)
Daily foot examination	150 (74.3)	52 (25.7)	119 (72.6)	45 (27.4)	31 (81.6)	7 (18.4)
Moisturizing foot	145 (71.8)	57 (28.2)	117 (71.3)	47 (28.7)	28 (73.7)	10 (26.3)
Trimming nails carefully	109 (54.0)	93 (46.0)	94 (57.3)	70 (42.7)	15 (39.5)	23 (60.5)
Walking barefoot	121 (59.9)	81 (40.1)	106 (64.6)	58 (35.4)	15 (39.5)	23 (60.5)
Placing foot near fire	45 (22.3)	157 (77.7)	37 (22.6)	127 (77.4)	8 (21.1)	30 (78.9)
Seeking medical care for foot changes	161 (79.7)	41 (20.3)	129 (78.7)	35 (21.3)	32 (84.2)	6 (15.8)
Changing socks daily	167 (82.7)	35 (17.3)	132 (80.5)	32 (19.5)	35 (92.1)	3 (7.9)
Checking footwear before wearing	158 (78.2)	44 (21.8)	130 (79.3)	34 (20.7)	28 (73.7)	10 (26.3)

Proportion of hyperglycemia, peripheral neuropathy, peripheral vasculopathy, calluses and foot deformity.





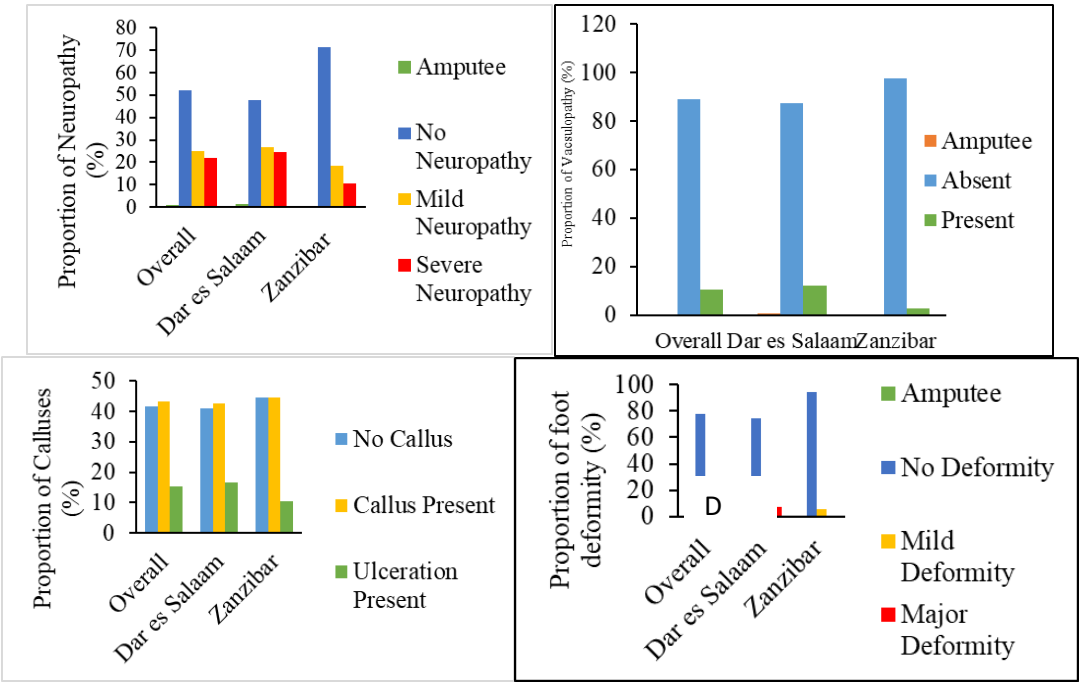


Figure 1: Clinical predictors of DFU; proportion of DFU (A), proportion of hyperglygemina (B), proportion of neuropathy (C), proportion of vasculopathy (D), proportion of calluses (E), proportion of foot deformities (F)

Proportion of microbial growth isolated from the foot lesions of diabetes mellitus patients

The microorganisms present in the foot lesions of the participants were obtained using a skin scrape test categorized based on the test done into the following categories: KOH test (52%) indicating the presence of certain microorganisms, bacterial growth (5%), and fungal growth (19%). In Dar es Salaam, the proportions were 28.6%, 5%, and 17%, respectively. In Zanzibar, the proportions were 8% had KOH positive and 2% had a fungal growth (See table 4).

In the KOH test, fungal elements were isolated and the common elements included; septate hyphae which included branching and non-branching forms, dermatophytes, anthrospores, mycelium strands, and budding yeast cells. These elements were sensitive to topical antifungal cream clotrimazole if their culture was found to be negative.

As for bacterial growth, the common bacteria isolated were; *Staphylococcus aureus* sensitive to Nafcillin, Cloxacillin, Erythromycin, and Clindamycin and resistant to tetracycline, *Alkaligenes species* sensitive to Cefaclor, Amikacin and Doxycycline and resistant to Amoxycillin, Tetracycline and Cotrimoxazole, *Proteus species* resistant to Amoxycillin, Cephazidine, Cephalexin and Ciprofloxacin and sensitive to Tetracycline and Imipenem. Klebsiella species senstitive to Amoxycillin, Cephazidine, Cefotaxime, Cefoprime and Ciprofloxacin and resistant to Tetracycline and Imipenem.

Fungal growth had two main species isolated; *Candida albicans* and *Aspergillus niger* sensitive to Amphotericin B, Nystatin, and Griseofulvin.

Table 4: Proportion of microbial growth among diabetes mellitus patients in Dar es Salaam and Zanzibar

	KOH test		Bacterial growth		Fungal growth	
	Positive	Negative	Positive	Negative	Positive	Negative
Overall, n (%)	52 (52.7)	150 (74.3)	5 (2.5)	197 (97.5)	19 (9.4)	183 (90.6)
Dar es Salaam, n (%)	44 (28.6)	120 (73.2)	5 (3)	159 (97)	17 (10.4)	147 (89.6)
Zanzibar, n (%)	8 (21)	30 (78.9)	0	0	2 (5.3)	36 (94.7)

KOH, potassium hydroxide.

Table 5: Association between DFU status and participant's demographic characteristics in Dar es Salaam and Zanzibar

Variable	Attribute	DFU Status		$\chi 2$	P-value
		YES, n (%)	NO, n (%)		
Sex	Male	37 (51.4)	35 (48.6)	5.41	0.02*

	Female	45 (34.6)	85 (65.4)		
Residence	Dar es Salaam	72 (43.9)	92 (56.1)	3.96	0.047*
	Zanzibar	10 (26.3)	28 (73.7)		
Marital status	Single	5 (15.2)	28 (84.8)	11.2	0.004**
	Married	72 (46.5)	83 (53.5)		
	Divorced	5 (35.7)	9 (64.3)		
Employment	Unemployed	16 (22.2)	56 (77.8)	19.1	< 0.0001***
	Self employed	26 (42.6)	35 (57.4)		
	Employed	15 (62.5)	9 (37.5)		
	Retired	25 (55.6)	20 (44.4)		
Religion	Muslim	42 (36.2)	74 (63.8)	2.18	0.14
	Christian	40 (46.5)	46 (53.5)		

DFU, Diabetic Foot Ulcer; *,**,***statistically significant at $p < 0.005$, $p < 0.001$ and $p < 0.0001$ respectively

Table 6: Association between DFU status and participant's clinical characteristics in Dar es Salaam and Zanzibar

Variable	Attribute	DFU Status		$\chi 2$	P-value
		YES, n (%)	NO, n (%)		
DM type	Type 1	5 (17.9)	23 (82.1)	6.97	0.008**
	Type 2	77 (44.3)	97 (55.7)		
DM duration	Newly diagnosed	3 (42.9)	4 (57.1)	3.58	0.31
	< 5 years	37 (47.4)	41 (52.6)		
	5-10 years	15 (30.6)	34 (69.4)		
	> 10 years	27 (39.7)	41 (60.3)		
Co-morbidities	Yes	64 (50)	64 (50)	12.8	< 0.0001***
	No	18 (24.3)	58 (75.7)		
Fungal growth	Yes	63 (34.4)	120 (65.6)	30.7	< 0.0001***
	No	19 (100)	0 (0)		
Bacterial growth	Yes	77 (39.1)	120 (60.9)	7.7	0.01*
	No	5 (100)	0 (0)		
Type of treatment	Diet and exercise	3 (27.3)	8 (72.7)	5.1	0.168
	OHDs	59 (45)	72 (55)		
	Insulin therapy	16 (30.2)	37 (69.8)		
	None	4 (57.1)	3 (42.9)		
Peripheral neuropathy	No neuropathy	32 (30.5)	73 (69.5)		
	Mild neuropathy	26 (51.0)	25 (49.0)		
	Severe neuropathy	24 (52.2)	22 (47.8)	9.3	0.01*
Calluses	No callus	10 (11.9)	74 (88.1)		
	Light callus	50 (78.1)	14 (21.9)		
	Heavy callus	6 (26.1)	17 (73.9)	69.6	< 0.0001***
	Ulceration present	16 (51.6)	15 (48.4)		

DM, Diabetes Mellitus; DFU, Diabetic Foot Ulcer; OHDs, Oral Hypoglycemic Drugs, *,**,***statistically significant at $p < 0.005$, $p < 0.001$ and $p < 0.0001$ respectively

IV. Discussion

Clinical predictors of imminent diabetic foot ulcer among diabetes mellitus patients were investigated in this study and included; the level of glycemic control, recommended foot care practices, presence of risky feet (i.e. peripheral neuropathy, peripheral vasculopathy, presence of calluses and foot deformities), and the microorganisms present in the foot lesions of diabetes mellitus patients.

This study shows that an overall proportion of 40.6% of diabetes mellitus patients had diabetic foot ulcer. This proportion is above the range reported globally in 2017 which was found to be 3 to 13%[6]. This study found the prevalence of DFU in Dar es Salaam to be 43.9% which is much higher compared to a study done in 2015 by Chiwanga et.al. (15%), the discrepancy in the results may be explained by the differences in the much larger sample size used, almost double[14]. The prevalence in Zanzibar was found to be 26.3% and to the best of our

knowledge, the prevalence of DFU in Zanzibar has not been reported. However, in a study done in Sudan, Nigeria, and Pakistan the prevalence was found to be 18.1%, 41%, and 66.7% respectively[10]. This variation can be explained by discrepancies in the sample size, geographical location, age variation and sociocultural variations. The discrepancy between Dar es Salaam and Zanzibar, with a lower proportion in Zanzibar, was hypothetically thought to be due to the majority of Muslims present in Zanzibar and the act of foot washing as part of their ablution for their daily prayers at least five times a day would render protective for the development of diabetic foot ulcer. However, this study showed there was no statistically significant association between religion and the development of foot ulcer in Dar es Salaam and Zanzibar i.e. a total of 36.2% of Muslims developed DFU and 46.5% of Christians had DFU ($p = 0.14$). This is similar to a study conducted in Ethiopia by Alewiya Y et.al in which they found more Christians (44.9%) than Muslims (28.3%) with DFU but there was no statistically significant difference[17].

The proportion of males (51.4%) was higher than females (34.6%) in the development of diabetic foot ulcer with a statistically significant association ($p = 0.02$) and can be explained by higher foot pressures in males than females due to their physique. These figures are similar to a study done in Bugando Medical Center, 54.4% males and 45.6% females[18] but differ in a study done by Yazdanpanah where by majority were females ($p = 0.002$)[19].

Diabetes mellitus patients in this study who developed DFU were married (46.5%) compared to 15.2% being single and there was a statistically significant association ($P = 0.004$). Diabetes mellitus patients who were employed 62.5% were found to have DFU compared to unemployed 22.2% with $p < 0.0001$. This can be attributable to long standing or sitting hours or even limited time to break between work tasks leading to increased pressure and friction in the feet.

This study concluded that patients with type 2 diabetes mellitus (44.3%) were more prone than type 1 (17.9%) to develop DFU ($p = 0.008$) which can be explained by the fact that type 2 diabetes is associated with co-morbid conditions and obesity which causes insulin resistance[20]. A total of 64 (50%) patients with DFU had other co-morbidities ($p < 0.001$) and this is due to endothelial dysfunction, vascular inflammation, and also dyslipidemia[21]. Treatment options amongst the diabetes mellitus patients concluded that patients not on any treatment were 57.1%, compared to those using oral hypoglycemic drugs (45%) and insulin therapy (30.2%), there was no statistically significant association between treatment options and development of DFU. In regards to the duration of diabetes mellitus, there was no statistically significant association between the two ($p = 0.31$) while in a study conducted in Sudan, it was concluded that the duration of diabetes was the only risk factor for developing DFU[11].

This study revealed that poor glycemic control i.e. hyperglycemia was not among the clinical predictors of imminent DFU since there was no statistical significance ($p > 0.05$). The overall proportion of hyperglycemia among diabetes mellitus patients was found to be 34.2% (mean RBG 10.4mmol/L ± 5.6mmol/L) which is much lower compared to a study done in Sudan by Ahmed O et.al.[11] in which a much higher proportion (85%) of hyperglycemia was found amongst diabetes mellitus patients but it was not statistically significant ($p = 0.39$). The discrepancy between the two studies can be explained by the fact that this study used a random blood glucose test which is not very much reliable based on how long the patient has been fasting as well as the tendency of patients not to eat before visiting the clinic but the study done in Sudan used a glycated hemoglobin (HbA1c) test and found no statistically significance[11].

The proportion of diabetes mellitus patients who practiced recommended foot care in this study was 74.3% and this can be explained by the sessions held once a week by individual diabetic clinics where knowledge is provided to the patients on foot care. This prevalence of foot care practice is much higher compared to a study done in Ethiopia[22] (46.4%) and in Dar es Salaam by Chiwanga et al[14], the study concluded patients who had their feet examined by a health care provider (27.5%) rather than recommended daily foot examination by the patient.

Another clinical indicator that was investigated was the presence of peripheral neuropathy. A total of 47% of diabetes mellitus patients were found to have peripheral neuropathy, 51.2% in Dar es Salaam and 28.9% in Zanzibar. The overall proportion is similar to a study conducted by Chiwanga et al in Dar es Salaam who used the Modified Neuropathy Disability Score in which 44% of diabetes mellitus patients have peripheral neuropathy[14]. A study by Alex R et al who used similar monofilament testing to detect the presence of peripheral neuropathy concluded that 18.9% of diabetes mellitus patients were found to have peripheral neuropathy[23]. This can be explained by the fact that diabetes mellitus causes damage to nerves directly due to poor glycemic control, and atherosclerosis of the vessel wall[28] but also emboli and thrombi may be a cause[24,25]. Hence, the formation of an atheroma leads to obstruction and a reduced blood supply[24].

The proportion of peripheral vasculopathy among diabetes mellitus patients was found to be 10.4%. This figure is similar to a study conducted by Yazdanpanah et.al that concluded 10% of diabetes mellitus patients had absent pulses[19]. This can be attributable to risk factors such as atherosclerosis prevalent in diabetes mellitus causing stenosis of blood vessels hindering blood flow to the lower limbs[3]. However, using a doppler ultrasound would yield a higher specificity for determining peripheral vasculopathy[26,27].

Calluses were present in 43.1% of the diabetes mellitus patients, of which 42.7% were from Dar es Salaam and 44.7% from Zanzibar ($p < 0.0001$). A study done in Ethiopia concluded that diabetes mellitus patients who had calluses were 12.67 times more likely to develop DFU than those without[28]. This can be explained by the initial stage of DFU development which is callus formation that occurs as a result of motor neuropathy or sensory neuropathy leading to abnormal pressure of the foot and hence the skin reacting to this phenomenon by increasing keratinization that leads to open ulcerations[3].

Foot deformities were present in 20.8% of patients in Dar es Salaam and Zanzibar overall. This proportion is much higher than a study done by Alex R et al[23] that concluded 6.8% had foot deformities. Peripheral neuropathy and peripheral vasculopathy are both attributable to the formation of foot deformities in patients with diabetes mellitus[29].

The microorganisms present in the foot lesions of diabetes mellitus patients were detected from a skin scrape test which was then sent for KOH test, bacterial and fungal culture. There was a statistically significant association between the development of diabetic foot ulcer and bacterial growth ($p = 0.01$) and fungal growth ($p < 0.0001$). The microorganisms isolated were *Staphylococcus aureus*, *Proteus species*, and *Klebsiella species* were similar to a study done between 2008 and 2010 by PL Chalya et al. in the surgical ward of Bugando Medical Center[18]. In this study, fungal culture revealed the presence of *Aspergillus niger* and *Candida albicans*. A study done in India by Jain SK concluded that 42 minor amputations were attributable to *Staphylococcus, Klebsiella*, and *Proteus species* among others.

V. Conclusion

Findings from this study provide evidence for the existence of clinical predictors of diabetic foot ulcer among diabetes mellitus patients which include; hyperglycemia, poor foot care practices, peripheral neuropathy, peripheral vasculopathy, calluses, and the presence of foot deformities.

Acknowledgments

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Conflict of interest

All authors declare there are no conflicts of interest for this study.

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