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Characterization of Patients with Diabetic Foot Ulcers Managed at Moi Teaching and Referral Hospital, Eldoret, Kenya

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Abstract: Background: A diabetic foot ulcer is any break in the epidermis below the ankle, in a person with diabetes mellitus. Among these patients, the lifetime prevalence of developing foot ulcers is 15%. Neuropathy and poor blood circulation create a suitable environment for occurrence of Diabetic Foot Ulcers (DFUs), gangrene and infection. These foot complications in individuals with diabetes mellitus are becoming a major public health problem in Africa and can be attributed to late presentation, poor awareness both among healthcare workers and patients, as well as late referral once they occur. Locally and at Moi Teaching and Referral Hospital (MTRH), there is paucity of publication on this subject, hence the need of this study. Objective: To describe the sociodemographic characteristics and the patterns of diabetic foot ulcers in patients manged at MTRH, Eldoret, Kenya. Methods: A cross sectional study done at MTRH, involved a census of 89 adult patients with diabetic foot ulcers, who met inclusion criteria. They comprised of those seen in the surgical wards and in the diabetic clinic. Data was collected using interviewer administered questionnaires. The Researcher documented crucial information from the history and physical examination. The variables studied were coded and assigned numerical values for quantitative analysis. Data was summarized as mean ± SD and presented using tables, pie charts and graphs. Results: The mean age was 55.3(SD±12.2) years. Female were 37(42%) and males were 52(58%). Formally educated were 80(90%), while 9(10%) had none. Cigarettes smokers were 22 (25%) while 40 (45%) took alcohol. Their Body Mass Index (BMI) values showed that 7(8%) were underweight, 55(62%) were of normal weight, 22(24%) were overweight and 5(6%) were obese. Glycated haemoglobin (HBA_1C) was normal in 40 (45%) and abnormal in 49(55%) patients. Features in association with peripheral neuropathy were: oedema (57%), numbness and pricking sensation (both at 48%), fissures (47%), weakness (42%), dryness (39%), burning sensation (37%) and *Tinea pedis* (8%). Majority (90%) of the patients received appropriate footwear education, and 88.8% received education on self-examination. Comorbidity included: hypertension- 61%, retinopathy- 36% and nephropathy- 27%. The distribution of DFUs based on Wagner classification: Grades 1- 4 were 21.3%, 33.7%, 31.5%, and 13.5% respectively. DFUs were found to be significantly associated with hypertension ($p<0.001$) and retinopathy ($p<0.001$). Conclusion: Majority of the patients were male. Many had abnormal HBA_1C, while all had at least two or more features of peripheral neuropathy. Grade 2 ulcers and hypertension as comorbidity were the most common. Recommendations: Prevention of DFUs through early identification and correction of risk factors like high BMI, high HBA_1C, peripheral neuropathy, smoking cigarettes and alcohol intake should be intensified.

Keywords: Body mass index, Comorbidity, Diabetic foot ulcers, Glycated haemoglobin, Hypertension, Neuropathy, Patterns, Retinopathy, Sociodemographic characteristics, Wagner classification

INTRODUCTION

Foot problems related to diabetes mellitus were first discovered in the 19th century but there was no progress in the management even into the first half of the 20th century (Connor, 2008). Most of these patients presented late and amputation was the common mode of management (Boulton, 2004; Connor, 2008). Despite the time that has passed since then, some countries still apply this management for most of their patients. In a study conducted in Barbados in 2001, 75% of bed occupancy of the surgical ward was of patients with diabetic foot ulcers while a third of them ended up with major amputation (Boulton, 2004; Walrond, 2001).

In Nottingham-England, Pryce - a surgeon – recognized over 100 years ago the connection between diabetes and foot ulceration; reporting that diabetes played an active part in causation of perforating ulcers and that the actual cause of this was peripheral nerve degeneration. The sensory loss associated with foot problems in diabetes was understood from work done in leprosy. Despite the fact that the cause of sensory loss in the two is different, work in leprosy helped in the understanding of foot problems associated with diabetes. In India, the work by Doctor Paul Brand -a surgeon- pioneered research on the causation of foot problems in leprosy (Bergtholdt, *et al.,* 1976). He further added science to the art of foot care by recommending that, to reduce amputation in diabetes, the physicians should remove patients' shoes and socks and to examine the feet (Boulton, 2004). Brand also pioneered research on abnormal foot pressures during walking and described use of thermography to assess areas at risk of breaking down. He taught principles of management of feet that were insensate, emphasizing on the need to offload plantar neuropathic ulcers (Bauman & Brand, 1963; Bergtholdt, *et al.,* 1976; Boulton, 2004; Boulton, *et al.,* 2004). One remark he made was that any patient with a plantar ulcer walking into the clinic without a limp, has neuropathy (Bauman & Brand, 1963; Boulton, 2004).

Sociodemographic characteristics of patients with diabetic foot ulcers reveal that the lesions have often been reported to be predominant among the middle-aged and elderly patients. In sub-Saharan African countries such as Kenya, the number of individuals living to middle and old age has been on the rise (Bastawrous, *et al.,* 2019; Renuga Nagarajan, *et al.,* 2017). These individuals end-up being predisposed to non-communicable diseases such as diabetes and diabetic foot ulcers- its common resulting long-term complication (Bastawrous, *et al.,* 2019).

In Mombasa city of Kenya, it has been reported that majority of diabetic foot ulcer patients were males aged between 50 and 70 years; with a mean age of 58 years while the women were aged between 60 and 80 years with a mean age of 65 years (Muthuuri, 2007). This retrospective study was conducted at a private hospital clinic serving the greater city. These findings did not differ widely from those reported in a separate study (Nyamu, *et al.,* 2003) at the Kenya's national and teaching hospital - Kenyatta National Hospital (KNH) – where the mean age of the 82 patients with Diabetic Foot Ulcers enrolled into the study was 56.9 (± 13.41). This study conducted at KNH enrolled equal proportions of both male and

female patients, hence there were no mean age differences reported by gender. Furthermore, KNH being a national hospital has a larger catchment area compared to the findings reported study conducted in Mombasa (Muthuuri, 2007); making it more powered, representative and with generalizable study findings.

The age range of patients presenting with diabetic foot ulcers can be as wide as 40 to 90 years as has been previously reported in many Kenyan studies (Alla & Azadevo, 2008; Mugambi-Nturibi, *et al.,* 2009; Muthuuri, 2007; Nyamu, *et al.,* 2003). In the United States of America, older studies have reported a mean age of 60 years (McNeely, *et al.,* 1995) while in recent studies, the mean age stands at 61.7 (± 3.7) years (Zhang, *et al.,* 2017). This older mean age has also been attributed to time-dependent risk factors affecting the course and evolution of the disease from the time of diagnosis to the development of diabetic foot ulcers (Nyamu, *et al.,* 2003). Furthermore, the age of diabetes mellitus onset differs across continents. In an Ethiopian study (Deribe, 2014), it was reported that majority of diabetic patients presenting with diabetic foot ulcers were middle-aged to elderly men. In a prospective study conducted in Nigeria (Ogbera, *et al.,* 2008), diabetic foot ulcers patients were averagely aged 59.22 (± 7.36) years with an age range of 47-78 years (Ogbera, *et al.*, 2008). Because of similarity in the sociodemographic and economic status of patients in sub-Saharan Africa, the mean age of patients presenting with diabetic foot ulcers could be similar across various clinical settings across Africa, irrespective of the study design and sampling techniques adopted. Some studies have adopted matched sampling of participants based on gender while others have randomly selected the patients irrespective of their gender. This random sampling technique aims at increasing the likelihood of representativeness of the patients with diabetic foot ulcers. This random sampling approach been locally adopted in a different study at KNH where participants were stratified based on risk categories for diabetic foot ulcerations (Mugambi-Nturibi, *et al.,* 2009). In this particular study (Mugambi-Nturibi, *et al.,* 2009), less than half (39%) of those enrolled were male.

Higher level of formal education has been attributed to better comprehension and adherence to foot care education guidelines offered to diabetic foot ulcers patients (Abbas, *et al.,* 2002; Abbas & Archibald, 2007; Chiwanga & Njelekela, 2015). Higher education level can also improve patient prognosis by not only adhering to treatment but also seeking clarification on various treatment options prescribed. Many patients from Sub-Saharan Africa have been reported to have a minimum of secondary level of academic training (Deribe, 2014; Harrison, *et al.,* 2015). Patients with this level of education can comprehend most treatment guidelines and report any untoward outcomes during their treatment. However, due to disparities in access to education in Africa, there are no universally agreed proportions of access to various levels of education. This creates a need for studies to determine the extent of disparity and its influence in diabetic foot ulcer care and patient outcomes. The nature of meaningful economic engagement diabetes patients are involved in may predispose them to bruises and wounds that may proceed to diabetic foot ulcers (Deribe, 2014). Work related stressors may also increase the likelihood of mental health challenges that could interfere with treatment compliance and patient outcome (Madmoli, *et al.,* 2019). Because of variance in reported findings of the sociodemographic characteristics of diabetic foot ulcers patients, this study aimed at determining the sociodemographic characteristics of patients with diabetic foot ulcers at Moi Teaching and Referral Hospital.

Regarding the patterns of diabetic foot ulcers, it has been documented that the lesions are a combination of the Wagner Classification of the wound, presence of peripheral neuropathy, the patient's body mass index and glycated hemoglobin levels. Because glycated hemoglobin levels are used as indicators of long-term blood sugar control, patients with deranged values have a greater likelihood of developing diabetic foot ulcers and ultimately lower-extremity amputation (Adler, *et al.*, 2010).

The Wagner Classification is a universally accepted grading system for DFUs used more commonly, with five wound grades - based on the wound's severity - used to assess ulcer's depth (Hobizal & Wukich, 2012). Wagner Classification of wounds is adopted to underscore the morbidity attributed to the diabetic foot ulcer disease and assess severity (Mugambi-Nturibi, *et al.*, 2009). In a study conducted at the Kenyatta National Hospital in Kenya, it was revealed that Grade 2 Wagner ulcers were the most common (49.4%), followed by Grade 4 ulcers (23.5%) which presented with the highest neuropathic score and longest mean duration of diabetes (23.6%), and then Grade 3 ulcers at 18.5% (Nyamu, *et al.*, 2003). Similar observations were also reported in Nigeria (Ogbera, *et al.*, 2008) where Grades 2 (25%) and 3 (25%) ulcers were the most prevalent. In this Nigerian study, the authors (Ogbera, *et al.*, 2008) further reported the precipitating factors for diabetic foot ulcers as spontaneous blisters, inappropriate shoes, puncture injury, burns and boils. Furthermore, in a follow-up Nigerian study (Edo, *et al.*, 2013); the severity of the wound progressed with the advancement of the disease. In this study, majority of the patients had Grades 3 (36.1%) and 4 (44.3%) ulcers.

Peripheral neuropathy and peripheral vascular disease have been classified as the main etiological factors for development of diabetic foot ulcers. They have been estimated to have a prevalence of 4% - 84.4% and 2.9% - 79.7% respectively, with rates of amputation ranging between 0.3% and 45% (Abbas & Archibald, 2005; Mugambi-Nturibi, *et al.*, 2009; Sadriwala, *et al.*, 2018). It is the main risk factor underlying development of diabetic foot ulcers in sub-Saharan Africa (Amour, *et al.*, 2019; Mugambi-Nturibi, *et al.*, 2009). In Nigeria (Edo, Edo & Ezeani, 2013), peripheral neuropathy accounted for 42.6% of all the diabetic foot ulcers patients reviewed.

In a Tanzanian study, all the patients who attended the outpatient clinic had varying degrees of peripheral neuropathy (Abbas & Archibald, 2005). It has been noted that patient education and medical supervision that would otherwise promote self-care and address misconceptions are lacking (Boulton, *et al.*, 2004; Hicks, *et al.*, 2020); and this can increase the risk of worsening peripheral neuropathy. Furthermore, although the risk factors of diabetic foot ulcers are known, there have been reports of poor awareness among healthcare workers, poor referrals for specialist care, lack of team work in management, therefore these patients get poor outcomes (Agwu, Dafieware & Ekanem, 2011).

Studies in Nigeria (Ogbera, *et al.*, 2008) and Kenya (Mugambi-Nturibi, *et al.*, 2009) have reported incidences of peripheral neuropathy among diabetic foot ulcers. In Nigeria, 76.5% of the diabetic foot ulcers presented with pricking sensations. Nearly three-quarters (70.6%) of the study participants presented with deformity, 20% had *Tinea pedis* (Ogbera, *et al.*, 2008); while in Kenya (Mugambi-Nturibi, *et al.*, 2009), 36% presented with deformity.

Previous studies have reported varying proportions of smokers, alcohol intake, hypertension, retinopathy, and nephropathy among these patients. In Nigeria (Edo, *et al.*, 2013), half (50.8%) of the patients with diabetic foot ulcers presented with hypertension

while 21.3% had retinopathy. Nephropathy was least prevalent at 1.64% (Edo, *et al.*, 2013). In Saudi Arabia (Musa, *et al.*, 2018), cigarette smoking increased the risk of peripheral neuropathy by 20% (RR = 1.2; 95% CI: 0.2, 6.2), however, this relationship was not statistically significant (***p***=0.833). Alcohol intake significantly increased the risk of pricking sensation in an Austrian study (Kästenbauer, *et al.*, 2001) with a five-fold increased risk of foot ulcers (RR=5.1; 95% CI: 1.1, 24, ***p***-value = 0.0404). In a Pakistani study (Saleem, *et al.*, 2017), no statistically significant risk (RR = 0.977; 95% CI: 0.414, 2.305) of hypertension was associated with diabetic foot ulcers just like in Saudi Arabia (Musa, *et al.*, 2018) where no association and increased risk was reported (RR = 0.5; 95% CI: 0.1–1.7). In another study in Australia by Davies, *et al.,* (2006), lower extremity amputation was significantly associated with peripheral neuropathy. However, they did not isolate the specific features of peripheral neuropathy.

The patient's body mass index has been considered to influence the risk of the development of diabetic foot ulcers especially among those who are overweight due to their higher foot pressure (Deribe, 2014). An Ethiopian study (Deribe, 2014) reported that overweight patients were four-times more likely to present with diabetic foot ulcers compared to those with a normal BMI. According to Davies, *et al.,* (2006) diabetic foot ulcerations are predictors of increased incidence and the biggest risk factor for nontraumatic lower extremity amputations.

Regarding the Glycated Hemoglobin, ***s***tudy conducted in Kenya at the Kenyatta national Hospital (KNH), the mean HbA_1C levels (10.5 ±2.8) were elevated among patients presenting with neuropathic diabetic foot ulcers. However, this elevation was not statistically significant. However, contrasting findings were reported in a study conducted in Pakistan (Saleem, *et al.,* 2017) where no statistically significant association was reported among those with elevated HbA_1C levels and diabetic foot ulcers. This Kenyan study had varying HbA_1C cut-off points as the Pakistani study used a cut-off of 7.5. However, in Pakistan (Saleem, *et al.,* 2017), more than 58% of those who presented with diabetic foot ulcers had elevated HbA_1C levels (OR= 1.582; 95% CI: 0.599, 4.178).

Adler *et al*. noted that individuals with poor glycemic control as seen via measurement of HbA_1C had a higher risk of the DFU progressing and eventually requiring lower extremity amputation. This was due to the effect of hyperglycemia on nerves causing peripheral neuropathy, and the blood vessels causing peripheral arterial disease (Burns & Jan, 2012; Adler, Erqou, Lima & Robinson, 2010).

Because of variance in reported findings of the patterns of DFUs in patients with diabetes mellitus this study aimed at determining these patterns in patients being managed at Moi Teaching and Referral Hospital.

The study therefore is significant as it gives highlight on the characterization of patients with DFUs being managed at MTRH, Eldoret, Kenya. The study therefore provides information on both the sociodemographic characteristics and the patterns of DFUs in patients with diabetes mellitus being managed at MTRH. This information will bridge the existing knowledge gap locally and nationally, and will be utilized by the hospital management and stake holders to strategize on improvement in the care of the diabetes mellitus patients with DFUs.

METHODOLOGY

Study Location: The study was carried out in the diabetic clinics at Chandaria, medical and surgical wards of Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya. The hospital is situated along Nandi Road in Uasin Gishu County, approximately 350 kilometers North-west of Nairobi the capital city of Kenya. It serves Uasin Gishu County, a predominantly agricultural region, Western Kenya, Eastern Uganda and parts of Southern Sudan, a catchment area of 20 million people. It is a training center for Moi University CHS, KMTC and many other institutions. The AMPATH collaborates with MTRH in research activities as well as taking care of patients (MTRH website, 2021).

Study Design: This was a cross-sectional study design. Patients with diabetic foot ulcers, who met inclusion criteria, were recruited until the desired sample size was reached. Patients were interviewed using a standard questionnaire, done by trained Research Assistants supervised by the Principal Investigator. There were two research assistants. They were trained on grading of DFUs and were well oriented concerning the questionnaire.

Study Population: Patients with diabetic foot ulcers managed at MTRH. Among these patients, only those who met the eligibility criteria were included in the study.

Eligibility criteria: Included were patients with diabetic foot ulcers in the diabetic clinic at Chandaria, medical and surgical wards of MTRH, willing to participate in the study. Excluded were patients who did not consent and patients below 18 years of age.

Sample size: The researcher did a census of the patients with DFUs seen at MTRH in order to get the patients who formed the study population. From the hospital records, approximately 120 patients with diabetic foot ulcers were seen annually between 2014 and 2015. A total of 89 patients were recruited for this study. The study period was between 1st May 2017 and 31st April 2019.

Data collection: Patients were enrolled into the study once they were admitted in medical and surgical wards of MTRH as well as those being followed up at the diabetic clinic, and had consented to participate. Data was collected following history taking and a physical examination and was also via interviewer administered questionnaire. The variables studied included: the demographics: age, sex, residence; duration of living with diabetes- according to the Wagner classification; comorbidities- retinopathy, nephropathy and/or hypertension; and stage of the ulcer.

Documentation of the data was guided using the diagrams shown.

Table 1: The BMI and classification

BMI	CLASSIFICATION
< 18.5	Underweight
18.5-24.9	Normal
25.0-29.9	Overweight
30.0-34.9	Obesity (Class 1)
35.0-39.9	Obesity (Class Il)
Above 40	Extreme Obesity (Class Ill)

Table 2: Diabetic Foot classification according to Wagner

Grade	Lesion
0	No open lesions: may have deformity or cellulitis
1	Superficial ulcer
2	Deep ulcer to tendon or joint capsule
3	Deep ulcer with abscess, osteomyelitis or joint sepsis
4	Local gangrene--forefoot or heel
5	Gangrene of entire foot

Figure 1: Wagner Classification of Diabetic foot ulcers

Variables were coded and assigned numerical values for quantitative analysis.

Data Management: There was double data entry into SPSS version 19. Data was checked for consistency, completeness and accuracy. The categorical variables were analyzed using frequencies and percentages. The continuous variables observing Gaussian curve were presented as mean (± standard deviation). Skewed data was presented as median and quartiles.

Ethical Considerations: Permission to carry out the study was sought from IREC (Reference: IREC/2016/131; FAN IREC 1737, Dated 23/09/2016) before the study was carried out. Consent was sought from the patients and confidentiality was maintained. Patients were informed of the purpose of the study and its benefit to them. No patient was coerced

into becoming a participant. Withdrawal from the study was voluntary at any point of the study.

Dissemination of the research findings: through oral presentation (thesis defense), bound book and publication in peer reviewed journal.

Study Limitations: Noncompliance of the patient to treatment might have led to inaccurate collection of data. To mitigate, the Researcher counseled patients on the importance of good glycemic control and compliance with the medical instructions to avoid complications.

Some of the patients might have withheld sensitive information on risk factors, for example, cigarette smoking and alcohol intake history. This was mitigated by building of good rapport with the patients and the assurance that there would be absolute confidentiality with the information gathered.

RESULTS

Sociodemographic Characteristics: A total of 89 patients on management for diabetic foot ulcers were enrolled into the study. Their ages ranged between 27 and 89 years, with a mean age of 55.3 (±12.2) years. There were nearly equal proportions of both gender with the males being the majority at 58.43% (n=52). Majority of the enrolled patients were employed (44.94%) with nearly all (89.89%) attending at least primary school education.

Patterns of Diabetic Foot Ulcers seen at MTRH: The study identified Wagner Classification, Peripheral Neuropathy, Body Mass index and Glycated Hemoglobin levels as the patterns of interest. The risk factors identified for comparison were history of cigarette smoking, alcohol intake and comorbidities such as hypertension, retinopathy and nephropathy.

Wagner Classification of Diabetic foot Ulcers: Diabetic foot ulcers were graded into four categories as per the Wagner classification criteria. The most prevalent was Grade 2 among most (33.7%; n=30) of all the enrolled patients.

Table 3: Distribution of Diabetic Foot Ulcers as per Wagner Classification

Wagner classification	Frequency	Percentage
Grade 1	19	21.3
Grade 2	30	33.7
Grade 3	28	31.5
Grade 4	12	13.5

When the risk factors were matched by the Wagner Classification, history of cigarette smoking increased the risk of a diabetic patient presenting with the risk of Grade 3 ulcers (RR=2.284; 95% CI: 1.288, 4.051). History of alcohol intake increased the risk of presenting with Grade 3 ulcers fifteen times (RR=15.925; 95% CI: 4.021, 63.063) more than those who did not. Comorbidities such as hypertension increased the risk of Grades 3 (RR=2.981; 95% CI: 1.254, 7.106) and 4 (7.130; 95% CI: 0.963, 52.810) while retinopathy only increased the risk of Grade 4 ulcers nearly fourfold (RR= 3.563; 95% CI: 1.163, 10.912). There

was a statistically significant relationship between having comorbidities (hypertension and retinopathy) and an advanced grade of the diabetic foot ulcer at ***p***<0.001 and ***p***=0.002 respectively. Nephropathy increased the risk of Grade 3 ulcers by 50% (RR=1.505; 95% CI: 0.813, 2.783), however, there was no statistically significant association found (***p***=0.361). Lack of foot care education was common among those presenting with both Grade 1 and 4 diabetic foot ulcers, with a statistically significant association reported among those with a Grade 1 diabetic foot ulcer (RR= 1.013; 95% CI: 0.701-1.462, ***p***= 0.005). However, majority of those who had foot care education presented with both Grade 2 and 3 diabetic foot ulcers with a statistically significant association reported among those with Grade 2 diabetic foot ulcers (***p***=0.001) as tabulated.

Table 4: Effect of Risk Factors of Diabetic Foot Ulcers Wagner Classification

Risk Factor		Grade 1		Grade 2		Grade 3		Grade 4		Total	*p*-value
		Yes	No	Yes	No	Yes	No	Yes	No		
Cigarette smoking	Yes	4	18	6	16	12	10	0	22		
	No	15	52	24	43	16	51	12	55		
	RR (95% CI:)		1.054 (0.833-1.334)		1.133 (0.829-1.548)	2.284 (1.288-4.051)			1.218 (1.089-1.362)		0.025
Alcohol	Yes	5	35	6	34	26	14	3	37		
	No	14	35	24	25	2	47	9	40		
	RR		1.225 (0.991-1.515)		1.666 (1.230-2.257)	15.925 (4.021-63.063)			1.133 (0.966-1.329)		<0.001
Hypertension	Yes	5	49	15	39	23	31	11	43		
	No	14	21	15	20	5	30	1	34		
	RR		1.512 (1.139-2.008)		1.264 (0.908-1.760)	2.981 (1.251-7.106)		7.130 (0.963-52-810)			<0.001
Retinopathy	Yes	9	23	3	29	12	20	8	24		
	No	10	47	27	30	16	41	4	53		
	RR	1.603 (0.728-3.531)			1.722 (1.314-2.256)	1.336 (0.725-2.460)		3.563(1.163-10.912)			0.002
Nephropathy	Yes	5	19	8	16	10	14	1	23		
	No	14	51	22	43	18	47	11	54		
	RR		1.009 (0.792-1.285)			1.088 (0.723-1.405)	1.505 (0.813-2.783)		1.154 (1.005-1.324)		0.361
Foot care Education	Yes	17	63	27	53	26	54	10	70		
	No	2	7	3	6	2	7	2	7		
	RR	1.013 (0.71-1.462) ^{no}*p*=0.005		1.013 (0.382-2.861) ^{yes} *p*=0.001		1.463 (0.414-5.168) ^{yes}		1.125 (0.786-1.611) ^{no}			

Risk factors associated with Peripheral Neuropathy: In this study, majority of the patients (57.3%; n=51) presented with edema followed by numbness and pricking in equal proportions (48.3%; n=43). The least occurring risk factors were *Tinea pedis* (7.9%; n=7) and deformities (2.2%; n=2) as shown in Table 5.

Table 5: Proportions of Risk Factors associated with Peripheral Neuropathy

Risk Factor	n (%)
Numbness	43 (48.3%)
Pricking	43 (48.3%)
Burning	33 (37.1%)
Weakness	37 (41.6%)
Dryness	35 (39.3%)
Fissures	42 (47.2%)
Deformity	2 (2.2%)
Tinea Pedis	7 (7.9%)
Edema	51 (57.3%)

This study identified numbness, pricking, burning, weakness, dryness, fissures, deformity, *Tinea pedis* and edema as the indicators of peripheral neuropathy. Cigarette

smoking significantly (***p***=0.038) increased the risk of diabetic foot ulcers patients having *Tinea pedis* four times (RR= 4.061; 95% CI: 0.984, 16.755) compared to non-smokers. Alcohol intake significantly increased the risk of: pricking sensation (RR= 1.701; 95% CI: 1.097, 2.639, ***p***=0.016); weakness (RR=2.013; 95% CI: 1.200, 3.374; ***p***=0.006) and edema (RR=2.246; 95% CI: 1.514, 3.331; ***p***<0.001). Hypertension was significantly associated with weakness (RR=2.016; 95% CI: 1.086, 3.745; *p*=0.015) and edema (RR = 1.713; 95% CI: 1.099, 2.671; *p*=0.008) while nephropathy significantly increased the risk of edema (RR=2.055; 95% CI: 1.527, 2.764; ***p***<0.001) as shown in Table 6.

Table 6: Association between Risk Factors and Peripheral Neuropathy indicators

Risk Factor		Numbness	Pricking	Burning	Weakness	Dryness	Fissures	Deformity	*Tinea Pedis*	Edema
Cigarette smoking	Yes	10	8	8	9	10	4	0	4	
	No	33	35	25	28	25	38	2	3	
	RR (95% CI:)	0.923 (0.550-1.55)	0.696 (0.383-1.266)	0.975 (0.517-1.837)	0.979 (0.550-1.742)	1.218 (0.701-2.118)	0.321 (0.129-0.797)	-	4.061 (0.984-16.755) *p*=0.038	0.937 (0.608-1.443)
Alcohol	Yes	16	25	11	23	6	17			
	No	27	18	22	14	29	25			
	RR (95% CI:)	0.726 (0.460-1.145)	1.701 (1.097-2.639) *p*=0.016	0.613 (0.339-1.106)	2.013 (1.200-3.374) *p*=0.006	0.253 (0.117-0.549)	0.833(0.530-1.310)	-	3.063 (0.627-14.954)	2.246 (1.514-3.331) *p*<0.001
Hypertension	Yes	24	29	21	28	17				
	No	19	14	12	9	18				
	RR	0.819 (0.535-1.253)	1.343 (0.835-2.160)	1.134 (0.643-2.001)	2.016 (1.086-3.745) *p*=0.015	0.612 (0.368-1.018)	1.446 (0.880-2.377)	1.602 (0.333-7.896)	1.602 (0.333-7.896)	1.713 (1.099-2.671) *p*=0.008
Retinopathy	Yes	19	17	16	14	11				
	No	24	26	17	23	24				
	RR (95% CI:)	1.410 (0.928-2.142)	1.165 (0.756-1.793)	1.676 (0.989-2.842)	1.084 (0.655-1.795)	0.816 (0.463-1.440)	1.096 (0.701-1.715)	-	0.297 (0.037-2.358)	1.149 (0.803-1.645)
Nephropathy	Yes	13	12	5	13	2	14			
	No	30	31	28	24	33	28			
	RR	1.174 (0.747-1.844)	1.048 (0.652-1.684)	0.484 (0.211-1.101)	1.467 (0.902-2.386)	0.164 (0.043-0.632) *p*<0.001	1.354 (0.873-2.100)	-	2.031 (0.490-8.419)	2.055 (1.527-2.764) *p*<0.001

Risk Factors Associated with Body Mass Index: Retinopathy was the only risk factor significantly associated (RR=2.545; 95% CI: 1.500, 4.316; ***p***<0.001) with having an abnormal body mass index, as shown in Table 7.

Table 7: Association between Risk Factors and BMI

Risk Factor	BMI Status n (%)		RR (95% CI:)	*p*-value
Cigarette smoking	Normal	15 (68.2%)	1.142 (0.807-1.615)	-
	Abnormal	7 (31.8%)		
Alcohol	Normal	26 (65%)	1.098 (0.793-1.520)	-
	Abnormal	14 (35%)		
Hypertension	Normal	32 (59.3%)	0.902 (0.651-1.249)	-
	Abnormal	22 (40.7%)		
Retinopathy	Normal	12 (37.5%)		
	Abnormal	20 (62.5%)	2.545 (1.500-4.316)	<0.001
Nephropathy	Normal	17 (70.8%)	1.212 (0.872-1.683)	-
	Abnormal	7 (29.2%)		

Risk Factors Associated with Glycated Haemoglobin (HbA_1C): This study identified history of cigarette smoking and alcohol intake, retinopathy and nephropathy as statistically

significant risk factors associated with elevation of glycated hemoglobin levels. Both retinopathy and nephropathy increased the risk more than two-fold (Table 8).

Table 8: Association between Risk Factors and HbA_1C

Risk Factor	HbA_1C Status n (%)		RR (95% CI:)	*p*-value
Cigarette smoking	≤7	15 (68.2%)	1.827 (1.199-2.786)	0.012
	>7	7 (31.8%)		
Alcohol	≤7	23 (57.5%)	1.657 (1.038-2.645)	0.031
	>7	17 (42.5%)		
Hypertension	≤7	22 (40.7%)	0.792 (0.503-1.249)	-
	>7	32 (59.3%)		
Retinopathy	≤7	3 (9.4%)	0.144 (0.048-0.431)	
	>7	29 (90.6%)	2.583 (1.784-3.740)	<0.001
Nephropathy	≤7	17 (70.8%)	2.002 (1.319-3.037)	0.003
	>7	7 (29.2%)		

Table 8 shows that the association between the risk factors and the HbA1C were statistically significant ($p < 0.05$) except for hypertension.

DISCUSSION

Sociodemographic Characteristics of Patients with Diabetic Foot Ulcers at Moi Teaching and Referral Hospital

Diabetic foot ulcers are often predominant among the middle-aged and elderly patients. In this study, the mean age of the patients enrolled was 55.3 (±12.2) years with the oldest being aged 89 years. This finding is in agreement with that of a study conducted in Mombasa (Muthuuri, 2007) where majority of the male patients were aged between 50 and 70 years; with a mean age of 58 years while the women aged between 60 and 80 years with a mean age of 65 years. The differences in the specific proportions and mean age values could be attributed to the study design adopted by Muthuuri, (2007) who used a retrospective as opposed the cross-sectional study design in this study.

In a second Kenyan retrospective study conducted at the Kenyatta National Hospital among 82 patients with Diabetic Foot Ulcers (Nyamu, *et al.*, 2003), the mean age of all the patients was 56.9 (± 13.41) years with equal proportions of both male and female patients. Despite the difference in the study design, the mean age findings were similar because both facilities are national teaching and referral hospitals receiving diabetic foot patients from various regions of Kenya.

The mean age finding in this study also concurs with those in a prospective Nigerian study where patients were aged 59.22 (± 7.36) years with an age range of 47-78 years (Ogbera, *et al.*, 2008). This implies that the mean age of patients presenting with diabetic foot ulcers is similar across various clinical settings across Africa, irrespective of the study design and sampling techniques.

Although most studies adopted matched sampling based on gender, the current study randomly selected the patients irrespective of their gender. This was meant to increase the

likelihood of representativeness of the patients with diabetic foot ulcers. This approach was also adopted by Mugambi-Nturibi, *et al.*, (2009) who had 39% of their patients being male.

Patterns of Diabetic Foot Ulcers seen at Moi Teaching and Referral Hospital

Wagner Classification of Diabetic foot Ulcers: In this study majority (33.7%; n=30) of the patients presented with Grade 2 ulcers as per the Wagner Classification followed by Grades 3 and 1. The least prevalent were Grade 4 ulcers. These findings are in agreement with those of a Kenyan study (Nyamu, *et al.*, 2003) where nearly half (49.4%) of all patients presented with Grade 2 ulcers. This finding was also reported in Nigeria (Ogbera, *et al.*, 2008) where Grades 2 (25%) and 3 (25%) ulcers were the most prevalent. This Nigerian study further reported the precipitating factors as spontaneous blisters, inadequate shoes, puncture injury, burns and boils. Wagner Classification of wounds are adopted to underscore the morbidity attributed to the diabetic foot ulcer disease and assess severity (Mugambi-Nturibi, *et al.*, 2009). The severity of the wound progresses with the advancement of the disease as was evidenced in a Nigerian study where majority of the patients had Grades 3 (36.1%) and 4 (44.3%) ulcers (Edo, *et al.*, 2013).

Risk factors associated with Peripheral Neuropathy Indicators: This study identified numbness, pricking, burning, weakness, dryness, fissures, deformity, *Tinea pedis* and edema as the indicators of peripheral neuropathy. In this study, majority of the patients 57.3% (n=51) presented with edema followed by numbness and pricking in equal proportions 48.3% (n=43). The least occurring risk factors were *Tinea pedis* 7.9% (n=7) and deformities 2.2% (n=2). These proportion varied from those reported in Nigeria (Ogbera, *et al.*, 2008) and Kenya (Mugambi-Nturibi, *et al.*, 2009). In Nigeria, 76.5% had pricking which was higher than the 48.3% reported in this study. Furthermore, higher proportions (70.6%) of deformity were reported in Nigeria compared to the 2.2% in the current study while *Tinea pedis* was at 20% compared to the 7.9% reported (Ogbera, *et al.*, 2008). In Kenya (Mugambi-Nturibi, *et al.*, 2009) 36% presented with deformity in comparison to the 2.2% reported in this study.

Cigarette smoking significantly (***p***=0.038) increased the risk of diabetic foot ulcers patients having *Tinea pedis* four times (RR= 4.061; 95% CI: 0.984, 16.755) compared to non-smokers. This was four times higher than that reported in Saudi Arabia (Musa, *et al.*, 2018), where cigarette smoking increased the risk of peripheral neuropathy by 20% (RR = 1.2; 95% CI: 0.2, 6.2). However, this relationship was not statistically significant (***p***=0.833).

Alcohol intake significantly increased the risk of: pricking sensation (RR= 1.701; 95% CI: 1.097, 2.639, ***p***=0.016); weakness (RR=2.013; 95% CI: 1.200, 3.374; ***p***=0.006) and edema (RR=2.246; 95% CI: 1.514, 3.331; ***p*<0.001**). This finding is in agreement with that conducted in Austria (Kästenbauer, *et al.*, 2001) where daily intake of alcohol significantly increased the risk of foot ulcers by a factor of five (RR=5.1; 95% CI: 1.1, 24, ***p*** = 0.0404).

This study reported that hypertension was significantly associated with weakness (RR=2.016; 95% CI: 1.086, 3.745; ***p***=0.015) and edema (RR = 1.713; 95% CI: 1.099, 2.671; ***p***=0.008) which were risk factors for peripheral neuropathy. This finding contrasts a Pakistani study (Saleem, *et al.*, 2017) which reported no statistically significant risk (RR = 0.977; 95% CI: 0.414, 2.305) of hypertension associated with diabetic foot ulcers just like in Saudi Arabia (Musa, *et al.*, 2018) where no association and increased risk was reported (RR = 0.5; 95% CI: 0.1, 1.7).

Furthermore, numbness increased the risk of peripheral neuropathy by 17% (RR=1.174; 95% CI: 0.747, 1.844**)** while edema increased the risk two-fold (RR=2.055; 95% CI: 1.527, 2.764; ***p*<0.001**). Peripheral neuropathy is a principal risk factor of diabetic foot ulcers. In Nigeria (Edo, *et al.*, 2013), peripheral neuropathy accounted for 42.6% of all the diabetic foot ulcers patients reviewed. In a systematic review on the epidemiology of diabetic foot ulcers in Africa (Abbas & Archibald, 2005), peripheral neuropathy ranged between 4–84.4%. Local studies have reported a prevalence of 42% (Mugambi-Nturibi, *et al.*, 2009) and 47.5% (Nyamu, *et al.*, 2003) at Kenyatta National Hospital.

Previous studies have reported varying proportions of smokers, alcohol intake, hypertension, retinopathy, and nephropathy among these patients. In Nigeria (Edo, *et al.*, 2013), half (50.8%) of the patients with diabetic foot ulcers presented with hypertension while 21.3% had retinopathy. Nephropathy was least prevalent at 1.64% (Edo, *et al.*, 2013).

Risk Factors Associated with Body Mass Index: This study further reports that diabetic foot ulcer patients presenting with retinopathy were more that two-times (RR = 2.545; 95% CI: 1.500, 4.316; ***p*<0.001**) more likely to present with an abnormal BMI. This finding conforms with that in Ethiopia (Deribe, 2014) where overweight patients were four-times more likely to present with diabetic foot ulcers compared to those with a normal BMI.

Association between Glycated Hemoglobin (HbA_1C): Retinopathy was significantly associated with elevated (>7) glycated hemoglobin levels (***p*<0.001**) compared to those with a normal HbA_1C. In a different Kenyan study conducted at the Kenyatta National Hospital (KNH), the mean HbA_1C levels (10.5 ±2.8) were elevated among patients presenting with neuropathic diabetic foot ulcers. However, this elevation was not statistically significant. This finding of this study further contrasts that conducted in Pakistan (Saleem, *et al.*, 2017) where no statistically significant association was reported among those with elevated HbA_1C levels and diabetic foot ulcers. These two studies had varying HbA_1C cut-off points as the Pakistani study used a cut-off of 7.5. However, in Pakistan (Saleem, *et al.*, 2017), more than 58% of those who presented with diabetic foot ulcers had elevated HbA_1C levels (OR= 1.582; 95% CI: 0.599, 4.178).

CONCLUSION

This study demonstrated that diabetic foot ulcers affected diabetic patients across a wide age spectrum and both genders. However, majority of those affected were elderly males.

Many patients had abnormal HBA_1C, while all had at least two or more features of peripheral neuropathy. Most patients with diabetic foot ulcers seen were classified as either Grade 2 or more with edema being the most common risk factor associated with peripheral neuropathy. Retinopathy increased the risk of having an elevated body mass index and glycated hemoglobin values.

RECOMMENDATIONS

There is need for early identification of diabetic foot ulcers especially among those predisposed to developing them- the elderly (over 70 years) and males who may require the professional to create a good rapport with them in order to obtain correct and comprehensive information.

Patient and health professional education on the risk factors associated with development of DFUs, as well as the Wagner system of grading them should be continuous in order to reduce the proportions of patients presenting with diabetic foot ulcers with a poor prognosis. Patients with risk factors (high BMI, high HBA_1C, peripheral neuropathy, smoking cigarettes and alcohol intake) should be managed aggressively through multidisciplinary approach to holistically address treatment continuum to prevent progression into undesirable complications, so as to improve the patients' quality of life.

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