

## **The prevalence of diabetic foot at risk (diabetic foot neuropathy and peripheral vascular disease) in a selected Kenyan population**

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### **ABSTRACT**

**Objective:** *To determine prevalence of foot at risk (diabetic foot neuropathy and peripheral vascular disease) in diabetic patients attending an outpatient clinic in Kenya.*

**Methods:** *This was a cross-sectional study done in Nakuru county hospital. Patients attending diabetic clinic were recruited with diabetic foot neuropathy and peripheral vascular disease as the main outcome measures.*

**RESULTS:** *Out of the 433 patients screened, 406 met the inclusion criteria and were recruited consecutively between May and August 2011. The mean age was 52.4 years with standard deviation of 17.5. Females were 53% with majority of patients (63.4%) above 40 years. The overall prevalence of foot at risk was 76.1%. Of these 43.4% had peripheral neuropathy, 29.4% peripheral vascular disease with 27.2% having both.*

**Conclusion:** *The prevalence of diabetic foot at risk is high. This emphasizes the need for care of the diabetic foot to reduce this high risk and prevent progression to ulceration/amputation.*

### **KEY WORDS**

Diabetic foot at risk, peripheral neuropathy, peripheral vascular disease, Ankle brachial Pressure Index

## **1.0 Introduction**

Diabetes mellitus has bedeviled mankind since antiquity. Faced with such a daunting challenge scientists and clinicians have sought various modalities to prevent complications. The current global prevalence of diabetes is estimated at 415 million and this is expected to rise to 642 million by 2040 (Rahelic, 2016). In Kenya, the prevalence of diabetes is estimated to be 3.3%(Sanitation, July 2010).

Diabetic foot which entails a range of preventable foot complications ranging from diabetic foot at risk to ulceration and gangrene commonly befalls victims of this condition. Studies have reported that foot ulceration occurs in 15% of diabetic patients during their lifetime (Al-Maskari & El-Sadig, 2007) with diabetic foot being the leading cause of lower extremity amputations (Aragon-Sanchez et al., 2010; Papazafiropoulou et al., 2009; Van Damme et al., 2001). Targeting patients at increased risk for developing foot ulcer is believed to constitute a cost effective strategy to control progression to end-stage complications (Al-Maskari & El-Sadig, 2007). Evidence suggests that early detection and treatment of diabetic foot complications could reduce the prevalence of ulceration by 44 to 85 % (11, 12).

The diabetic foot at risk is one that has developed any of the features of neuropathy or peripheral arterial disease (PAD) before ulceration. Given the inconsistencies associated with the symptoms of PAD, the measurement of ankle-brachial pressure index (ABPI) is an objective relatively simple, non-invasive and inexpensive technique employed in the evaluation of PAD(Ogbera, Adeleye, Solagberu, & Azenabor, 2015).

Considering the magnitude of the problem and paucity of data on diabetic foot at risk, we undertook a prevalence study on diabetic foot at risk to help in designing preventive programs.

## **2.0 Research Design and Methods**

This was a cross-sectional study conducted for three months between May and August 2011at the rift valley provincial general hospital (RVPGH). RVPGH is a referral and teaching hospital with 622 bed capacity located in the county of Nakuru, Kenya. It serves Nakuru and surrounding counties through the referral system. The diabetic clinic attends to an average of 40 to 50 patients per week with physician consultation, health education and investigations as necessary.

Sample size (n) was calculated using the formula  $n = Z^2PQ/L^2$ with prevalence, P estimated at 50% and allowable error, L at 5%. This gave a sample size of 384 with addition of 10% in case of dropouts.

We included diabetic patients of all ages on follow up in the diabetic clinic at the RVPGH who satisfied the inclusion criteria (type 1 or 2 diabetes with no ulcer or previous amputation).Patients who had progressed beyond foot at risk, declined to give consent, or known to have peripheral neuropathy or vascular disease from causes other than diabetes were excluded. A total of 433 patients with diabetes mellitus in the out-patient clinic diagnosed earlier by National Diabetes Data Group Criteria("Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance. National Diabetes Data Group," 1979) were screened by the two principal investigators and two trained nurses. Those who satisfied the inclusion criteria were recruited after informed consent and data collected. 93.8% of the number screened who satisfied the inclusion criteria were recruited into the study.

For each of the recruited subjects, we collected information on patient's demographics, hypoglycemic medication, duration of diabetes (estimated from year of diagnosis), and the mode of treatment from either the patient or available hospital records were documented. A physical examination was then performed. Only patients with diabetic foot Wagner stage 0 (diabetic foot at risk) were included. Those with stage 1 (superficial ulcer) and beyond were excluded.

Physical examination entailed two main components; determination of peripheral vascular status using Ankle brachial pressure index (ABPI) and peripheral neuropathy using Semmes Weinstein monofilament sensory testing, foot deformities and associated callosities.

Ankle brachial Pressure Index (ABPI) was used in this study in the assessment of peripheral vascular diseases.  $ABPI = P_{Leg} / P_{Arm}$ , where  $P_{Leg}$  is the systolic blood pressure of dorsalis pedis or posterior tibial arteries and  $P_{Arm}$  is the highest of the left and right arm brachial systolic blood pressure. Ankle pressures were obtained using pressure cuff and hand held Doppler in both limbs. Brachial pressures were also obtained using the same procedure in both arms. The ABPI was then calculated. The lower value if there was any difference between the two limbs was adopted.

Peripheral neuropathy was assessed for both peripheral sensory and motor neuropathies. Foot sensation was tested using 10g Semmes Weinstein Monofilament.

Sensation was tested at four points on the plantar surface of the foot; plantar aspects of great toe and metatarsal heads of first, second and fourth toes. The monofilament was applied at these points until it buckled and patient was asked to report on the sensation at each point. Normal person should be sensitive to the monofilament that buckles at a force of 10g.

The monofilament was first applied on the patient's forehead so the patients know what to expect. This modality was then tested at four sites on the sole of feet and findings recorded as present or absent. The patient was not allowed to see if and where the examiner applies the filament. This was accomplished by asking the patient to close the eyes.

The monofilament was applied perpendicular to the skin surface. Sufficient force was used to cause the filament to bend/buckle.

Protective sensation of the foot was recorded as present or absent. Patient with peripheral sensory neuropathy is considered to be at risk of ulceration.

Motor neuropathy was assessed by examining for presence of foot deformities i.e. hammers toes, claw toes, and hallux valgus. Associated plantar and dorsal callosities were also recorded.

Using the clinical information obtained, the diabetic foot at risk was classified as neuropathic, ischemic or neuroischaemic. Foot was categorized as ischemic when peripheral vascular disease was present with ABPI of less than 0.9 or more than 1.2 and neuropathic when there was peripheral sensory neuropathy or foot deformities and neuroischaemic when both neuropathic and evidence of peripheral vascular disease were present.

### **2.1 Data collection and management**

Data was collected using a standard data sheet. Data collected included patient demographics, type of hypoglycemic medication, duration of diabetes, sensation, presence of foot deformities (claw toes, hammer toes and hallux valgus) and associated callosities.

Data was coded and entered in SPSS version 20 for analysis. The baseline characteristics were summarized and presented as means/medians and proportions. Associations were tested using chi square test for categorical variables (proportions) and student t-test for continuous variables (means). Associations between different parameters were tested. All statistical tests were performed at 5% level of significance (95% confidence interval).

### **ETHICAL CONSIDERATIONS**

This study was approved by Nakuru county hospital-Egerton university ethics and research committee.

Informed consent was obtained from the patients who accepted to participate in the study.

#### **Conflict of interest**

The authors have no conflict of interest to declare.

### **3.0 RESULTS**

Four hundred and thirty three participants were recruited into the study over a three month period (May to August 2011). Twenty seven patients were dropped out of the study because their feet had progressed beyond foot at risk with ulceration. The data from the remaining four hundred and six patients was analyzed as summarized in fig. 1.

#### **Baseline characteristics**

Baseline characteristics of the study are as summarized in table 1

#### **Diabetic foot at risk**

Presence of diabetic foot at risk was assessed using ABPI, presence of foot deformities and foot sensation. By computation of the above three characteristics, 76.1% of the patients had diabetic foot at risk.

ABPI was considered abnormal for any value less than 0.9 or more than 1.2.

#### **Peripheral Neuropathy**

Presence of foot deformities was used to determine motor neuropathy and abnormal sensation for peripheral sensory neuropathy. Computation of the two gave overall peripheral neuropathy.

The commonest foot deformity was claw toes (23%) followed by hammer toes at 17% with hallux valgus least common (3%). 7% of the patients had both hallux valgus and claw toes.

Peripheral sensory neuropathy was found in 8.9% of the patients.

43.4% and 29.4% of the patients with diabetic foot at risk had neuropathy and peripheral arterial disease respectively while 27.2% had both (neuroischaemic foot).

### **Foot deformities and callosities**

The presence of foot deformity has a strong association with the presence of foot callosities with a strong statistical significance ( $p = 0.01$ ). 137 (66.5%) of the patients with foot deformity had presence of callus which predisposes to foot ulceration.

### **Sex and diabetic foot at risk**

The effect of sex was assessed in relation to diabetic foot at risk plus integral parameters. The findings are summarized in table 3. Male sex had statistically significant association with abnormal ABPI ( $p = 0.01$ ). However, overall foot at risk and deformity has no statistically significant association with sex.

### **Duration since diagnosis of diabetes mellitus**

Duration of diabetes since diagnosis was grouped into less than and more than 10 years. There was no significant association between duration of diabetes (less or more than 10 years) and peripheral sensory neuropathy, deformity and abnormal ABPI as summarized in table 3. Likewise there was no significant difference in duration since diagnosis of diabetes and diabetic foot at risk (all  $p$  values are  $>0.05$ ).

### **Age and diabetic foot at risk**

The effect of age was assessed in relation to diabetic foot at risk plus integral parameters as summarized in table 2.

Diabetic foot at risk and presence of foot deformity have statistically significant association with age ( $p = 0.0$  and  $p = 0.01$  respectively). However, sensation and abnormal ABPI have no statistical significance.

### **Type of hypoglycemic medication**

Most of the patients were on either oral hypoglycemic medication (169, 42%) or insulin (217, 53%) with only a small number being on diet alone (14, 3%).

## **4.0 DISCUSSION**

The study was done on diabetic patients attending outpatient diabetic clinic to determine the prevalence of diabetic foot at risk.

We found the prevalence of diabetic foot at risk to be 76.1%. Male sex had statistical significance with peripheral vascular disease ( $p = 0.01$ ) while female sex was associated with lack of sensation ( $p = 0.02$ ). Deformities ( $p = 0.01$ ) and overall diabetic foot at risk ( $p = 0.02$ ) correlated with increasing age. Duration since diagnosis of diabetes had no significant association with diabetic foot at risk ( $p = 0.28$ )

To our knowledge, this is the first study in the east African region specifically on the prevalence of diabetic foot at risk. However, there are many studies both globally and in the region on various aspects of diabetic foot and its complications. They have all reported the high prevalence of diabetic foot complications (Al-

Maskari & El-Sadig, 2007; Ashok, Ramu, Deepa, & Mohan, 2002; Ogbera et al., 2015; Premalatha, Shanthirani, Deepa, Markovitz, & Mohan, 2000). Al-Maskari et al (Al-Maskari & El-Sadig, 2007) in their study on risk factors for diabetic foot complications found 39% and 12% prevalence of peripheral neuropathy and peripheral vascular disease respectively. This compares with our study which found a prevalence of 43% for peripheral neuropathy and 29% for peripheral arterial disease with 27% having both. A study done by Nyamu et al (Nyamu, Otieno, Amayo, & McLigeyo, 2003) at Kenyatta National Hospital reported similar findings.

Previous studies have found higher prevalence of peripheral vascular disease among diabetic than non-diabetic patients in both population and hospital based studies ("The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group," 1993; Orchard & Strandness, 1993). Although comparison could not be done in our study because we had no control group, it emphasizes diabetes as an independent risk factor for peripheral vascular disease.

In a neighboring country Uganda, a study done by Mwebaze on peripheral arterial disease among adult diabetic patients attending an outpatient diabetic clinic found a 39% prevalence of PAD (Mwebaze & Kibirige, 2014). This compares well with our study which found 36.7% of patients with abnormal ABPI.

The sensitivity of ABPI is 90% with a corresponding 98% specificity for detecting hemodynamically significant stenosis >50% in major leg arteries (McDermott et al., 2000). ABPI is a recognized bedside screening technique for detecting peripheral arterial disease (Jayaprakash et al., 2011). A study by Premalatha et al in south India, with 1,262 participants aged > 20 years using Doppler to detect PAD with a cut value of 0.9, found the prevalence of PAD among diabetics to be 6.3 % (Premalatha et al., 2000). This compares well with our study which found an 8.1 % prevalence of PAD (ABPI less than 0.9). Of the 170 patients with abnormal ABPI in our study, 140 (82%) had high ABPI above 1.2 and the rest had ABPI below 0.9. A high ABPI is indicative of medial arterial calcification which is associated with diabetes (Quigley, Faris, & Duncan, 1991). A high ABPI index suggests incompressibility of the vessels. However it is imperative to note that the handheld Doppler equipment does not give waveform pattern hence may fail to detect the PAD when Monckebergs sclerosis is present (Ogbera et al., 2015). High ABPI has the potential of misleadingly high figures in detected PAD. PAD is major contributory factor in the development of ulceration, and its presence is a strong predictor of non-healing ulcer and amputation (Markakis, Bowling, & Boulton, 2015).

Peripheral neuropathy has been reported as a common complication of diabetes mellitus by various studies (Ashok et al., 2002; Ogbera et al., 2015). A study by Salvotelli *et al* in an Italian population found a prevalence of 30.5% on clinical assessment (Salvotelli et al., 2015). Our study found a higher prevalence of 43% neuropathic foot. This can be explained by poor health seeking practices and poor glycemic control in our third world country set up. However, a study done in Nigeria reported a higher prevalence rate of 56%. (Ogbera et al., 2015)

Ledoux et al in a study on foot deformities in diabetic patients found a prevalence of 23.9% for hallux valgus and 46.7% for hammer/claw toes (Ledoux et al., 2005). Our study found 40% prevalence of hammer/claw toes which compares with Ledoux *et al* study but a lower prevalence of hallux valgus at 3%. A number of our recruited patients walk barefoot which possibly explains the lower prevalence of hallux valgus. High heeled

shoes with narrow toe box are a risk factor for hallux valgus. Deformities ( $p = 0.01$ ) and overall diabetic foot at risk ( $p = 0.02$ ) correlated with increasing age. This association between ageing and the occurrence of neuropathy has been reported in many pertinent studies.(Ashok et al., 2002; Booya et al., 2005; Tesfaye et al., 1996)

In this study, foot deformities had significant correlation with callus formation ( $p = 0.01$ ). Clinical observation suggests that neuropathic foot ulceration frequently occurs beneath plantar callosities because callus acts as a foreign body elevating plantar pressures(Young et al., 1992). A study by Makoundou *et al* found callus removal decreases the peak plantar pressures by 58% which significantly decreases the risk of ulceration (Pataky et al., 2002). A study by Makoundou recommends aggressive callus removal in patients with neuropathy and peripheral vascular disease.

### **Limitations of the study**

There were a number of limitations in this study. First, laboratory parameters like glycemic level, glycosylated hemoglobin, dyslipidemias and albuminuria which are important risk factors were not considered due to funding constraints. These are important when designing preventive programs because of their possible significant role in development and progression of diabetic foot at risk. Secondly, co morbidities like hypertension which is critical especially with peripheral arterial disease were not documented. Thirdly, anthropometric measurements and determination of body mass index was not done. Lastly, we did not document waveform patterns while examining for PAD and pulse oximetric toe pressure which is more reliable to demonstrate peripheral arterial disease was not done.

### **5.0 Conclusion**

This study confirms the high burden of peripheral neuropathy and PAD in patients with diabetes mellitus. Screening should be done by all clinicians in every contact with these patients. ABPI and use of Semmes Weinstein monofilament are simple yet effective tools in improving diagnostic pick-up and we encourage clinicians to adopt them. Education on diabetic foot care for both clinicians and patients is crucial for early diagnosis so as to prevent progression to foot ulceration. Regular podiatric care is essential.

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### **Author contributions**

Both authors actively participated in designing the study, data collection and writing of this manuscript.

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**Table 1. Summary of the baseline characteristics**

Characteristic		Total	Male	Female
Age	Mean (Years)	52.4	53.2	51.6
	SD	17.5	18.5	16.5
Age group	Less than 40 years	108 (26.6%)	55 (28.9%)	53 (24.5%)
	41 - 60 years	163 (40.1%)	64 (33.7%)	99 (45.8%)
	More than 60 years	135 (33.3%)	71 (37.4%)	64 (29.6%)
Medication	Insulin	217 (53.4%)	112 (58.9%)	105 (48.6%)
	Oral hypoglycemic agent	168 (41.4%)	67 (35.3%)	101 (46.8%)
	Diet	14 (3.4%)	6 (3.2%)	8 (3.7%)
	Both Insulin & OH	6 (1.5%)	5 (2.6%)	1 (0.5%)
Duration of diabetes	<1 year	67 (16.5%)	29 (15.3%)	38 (17.6%)
	1 - 5 yrs	166 (40.9%)	77 (40.5%)	89 (41.2%)
	6 - 10yrs	95 (23.4%)	42 (22.1%)	53 (24.5%)
	>10yrs	78 (19.2%)	42 (22.1%)	36 (16.7%)
ABPI	Mean	1.1	1.1	1.1
	SD	0.19	0.19	0.19
ABPI values	Normal (0.9 - 1.2)	235 (57.9%)	97 (51.1%)	138 (63.9%)
	Arterial disease ( <0.9)	30 (7.4%)	17 (8.9%)	13 (6.0%)
	Arterial calcification ( >1.2)	140 (34.5%)	76 (40.0%)	64 (29.6%)
Sensation	Yes	370 (91.1%)	180 (94.7%)	190 (88.0%)
	No	36 (8.9%)	10 (5.3%)	26 (12.0%)
Foot deformities	Hammer toes	70 (17.2%)	29 (15.3%)	41 (19.05)
	Claw toes	94 (23.2%)	45 (23.7%)	49 (22.7%)
	Hallux valgus	13 (3.2%)	7 (3.7%)	6 (2.8%)
	Both Hallux Valgus & Claw toes	29 (7.1%)	17 (8.9%)	12 (5.6%)
	None	200 (49.3%)	92 (48.4%)	108 (50.0%)

**Table 2. Effect of sex, duration since diagnosis of diabetes and age on diabetic foot at risk**

Characteristic		Sex		p value	ODDS RATIO	95% Confidence Interval
		Male	Female			
Any deformity	Yes	98 (51.6%)	108 (50%)	0.75	1.03	0.86 – 1.24
	No	92 (42.6%)	108 (50%)			
PSN+	Yes	10 (5.3%)	26 (12%)	0.02	0.71	0.57 – 0.89
	No	180 (94.7%)	190 (88%)			
Abnormal ABPI	Yes	96 (50.5%)	79 (36.7%)	0.01	1.31	1.08 – 1.59
	No	94 (49.5%)	136 (63.3%)			
Foot at risk	Yes	148 (77.9%)	161 (74.5%)	0.43	1.09	0.89 – 1.34
	No	42 (22.1%)	55 (25.5%)			
<b>Duration since diagnosis of diabetes</b>						
Characteristic		> 10 years	<10 years	P value		
PSN+		7 (9%)	29 (8.8%)	0.97	1.003	0.85 – 1.19
Presence of deformity		44 (56.4%)	162 (49.4%)	0.27	1.06	0.81 – 2.18
Abnormal ABPI		40 (51.3%)	135 (41.2%)	0.11	1.08	0.98 – 1.20
Diabetic foot at risk		63 (80.8%)	246 (75%)	0.28	1.06	0.96 – 1.18
<b>Age and diabetic foot at risk</b>						
Characteristic		<50 years	>50 years	P value	ODDS RATIO	95% Confidence Interval
PSN+		12 (7.5%)	24 (9.8%)	0.44	1.57	0.88 – 2.78
Presence of deformity		65 (40%)	151 (57%)	0.01	1.57	1.21 – 2.03
Abnormal ABPI		97 (60%)	133 (54%)	0.21	1.19	0.92 – 1.54
Diabetic foot at risk		112 (70%)	191 (80%)	0.02	1.44	1.12 – 1.86

<sup>†</sup>PSN -Peripheral Sensory neuropathy

**Figure 1. Summary of patient distribution**

