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STRATIFICATION OF PERSONS WITH DIABETES INTO RISK CATEGORIES FOR FOOT ULCERATION

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ABSTRACT

Background: **Patients with diabetes mellitus are at a higher risk of lower extremity complications as compared to their non-diabetic counterparts.**
Objective: **To study risk factors for diabetic foot ulcer disease and stratify patients with diabetes into risk categories for foot ulceration.**
Design: **Cross-sectional descriptive study over five months period.**
Setting: **Diabetic outpatient clinic, at the Kenyatta National Hospital.**
Subjects: **Two hundred and eighteen ambulatory subjects with diabetes mellitus without active foot lesions.**
Results: **The prevalence of previous foot ulceration was 16% while that of previous amputation was 8%. Neuropathy was present in 42% of the study subjects and was significantly associated with age, male gender, duration of diabetes, random blood sugar, systolic blood pressure and the presence of foot deformity. Peripheral arterial disease was present in 12% and showed significant association with male gender. Foot deformities were observed in 46% of study subjects and were significantly associated with age, male gender, and presence of neuropathy. Subsequently 57% were categorised into IWGDF group 0 - no neuropathy, 10% were placed in group 1- neuropathy alone, 16% were put in group 2 - neuropathy plus either peripheral arterial disease or foot deformity and 17% were placed in risk group 3 - previous foot ulceration/amputation.**
Conclusion: **More than one third (33%) of diabetic patients were found to be at high risk for future foot ulceration (lWGDF groups 2 and 3). Published evidence exists that shows improved outcomes with interventions targeting individual patients with diabetes at high-risk of foot ulceration. Long term prospective studies to determine outcomes for the different risk categories should be carried out locally.**

INTRODUCTION

By the year 2010 it is estimated that 221 million people will be affected with diabetes globally (1). It is thought that the life time risk of developing a foot ulcer in a diabetic patient (type 1 or 2) is approximately 15% (2).

Diabetic foot ulcers are responsible for frequent and prolonged admission periods (3). Epidemiological studies suggest that foot ulcers precede about 85% of non-traumatic lower extremity amputations in individuals with diabetes (4). The five year mortality following amputation has been found to be between 39%-68% in various studies (5-7). In a 1999 study, the prevalence of diabetic foot ulcers at Kenyatta National Hospital was 46 per 1000 diabetic patients, with foot ulcers accounting for 12% of all diabetic admissions. The morbidity attributable to diabetic foot ulcer disease was underscored by the finding that the mean ulcer duration was 17 weeks and that 50% of patients presented with Wagner stage 2 ulcers whilst 25% had advanced Wagner stage 4 ulcers (8).

Diabetic foot ulcers are a cause of potentially preventable morbidity, tragic sequelae, notably lower extremity amputation with its grave socio-economic consequences, and mortality.

Several reports indicate that adequate foot examinations are often not performed in diabetic patients (9-l0). A lack of clear understanding of the most important criteria to include in a screening

examination may be contributory (11). Furthermore, with the increasing number of patients with diabetes, it is difficult to provide in-depth preventive foot services for every patient with the disease owing to constraints in resources (12,13).

Allocation of appropriate intervention modalities in high risk diabetic patients has been shown to decrease the rate of re-ulceration by up to 60% and lower extremity amputation by up to 85% (13).

Risk stratification allows prioritisation of resources to high risk populations where they will have the greatest impact.

MATERIALS AND METHODS

For each patient, the demographic history was taken and the patient's clinic record consulted. A simple questionnaire was then administered to collect data concerning previous ulceration, amputation, peripheral vascular disease, neurological deficit, and foot care knowledge. Height was measured against a vertical scale to the nearest half centimetre, with the patient standing erect and without shoes. Weight was measured to the nearest half kilogram with the patient in light clothing, without shoes and using a standard weighing chair in the clinic. BMI was calculated as the weight in kilograms divided by the square of the height in metres and the degree of obesity classified as follows (14).

BMI (kg/m^2)	Degree of obesity
<25	Non obese
25-29.9	Overweight
30-39.9	Obese
>40	Very obese

Blood pressure was measured with the patient in the supine position after a rest period of 5 minutes, using standard procedure. Hypertension was defined as follows:

Category	Systolic BP (mmHg)	Diastolic BP (mmHg)
Optimal	<120	<80
Normal	<130	<85
High normal	130-139	85-89
Hypertension		
Stage 1	140-159	90-99
Stage 2	160-179	100-109
Stage 3	>180	> 110
Isolated systolic hypertension	> 140	<90

The feet were then examined:

Inspection: The patient was observed while walking from one end of the examination room to the other and any abnormality of gait due to pain or deformity recorded. With the patient standing, the feet and the ankles were inspected for hind foot deformities (valgus/varus), pes planus, pes cavus, toe deformities (hallux valgus, claw toe, mallet toe, hammer toe) and prominent metatarsal heads. With the patient supine, the condition of the nails and skin was noted as was the presence of swellings. The presence of callosities was recorded. The presence of high risk lesions such as fungal infections was also recorded.

*Palpation:*The hind-foot, mid-foot and fore-foot were palpated to accurately localise any tenderness, swelling or deformity. The passive range of movement of the ankle joint, sub-talar and mid-tarsal joints was then assessed and each recorded as normal, or restricted. The individual toes were assessed to identify any restriction of movement, and this was recorded as normal or restricted. The posterior tibial pulse and the dorsalis pedis were then assessed and graded as normal, reduced or absent. The presence of blanching on elevation, rubor on dependance and delayed capillary refill was then assessed.

Neurological exam: For each foot the Achilles tendon reflex was tested using a standard patella hammer and a standard technique. The score below was assigned:

Absent (2 points for each foot)
Present with reinforcement (1 point for each foot)
Present without reinforcement (0 points)

Vibration sense was tested using a 128HZ tuning fork over the lateral and medial maleoli and the perception graded as:

Normal (0 points)
Absent or reduced (1 point for each foot)

Pressure sensation was then tested using a 5.07 (10-g) monofilament. This was done at six points on the foot and recorded as normal or abnormal.

Pinprick sensation was assessed on the feet using a disposable pin and graded as:

Normal - (0 points)
Absent or reduced - (1 point for each foot)

Temperature sensation was assessed using a cold tuning fork after immersion in cold water, on the dorsum of the feet and the sensation graded as:

Normal - 0 points
Reduced (1 point for each foot)

The neurological disability score was then determined and scored as:

0 to 2 - no neuropathy
3 to 5 - mild neuropathy
6 to 8 - moderate
9 to 10 – severe.

The score was doubled in patients with previous unilateral foot amputation.

Ankle Brachial Index (ABI) determination: A hand held Doppler probe (8 MHz) was held over the three pedal arteries (posterior tibial, dorsalis pedis, perforating peroneal) in turns while a blood pressure cuff wrapped around the ankle was inflated. The pressure at which the Doppler signal disappears was recorded as the systolic pressure in the artery as it passed under the cuff. The ratio of the highest pedal pressure to the highest brachial artery pressure determined by the Doppler method was recorded as the Ankle Brachial Pressure Index and interpreted as follows:

> 1.30	Non compressible vessel
0.91 - 1.30	Normal
0.41 - 0.90	Mild-moderate peripheral arterial disease
0.00 - 0.40	Severe peripheral arterial disease

A random blood sugar (RBS) level was then determined by aseptic pin prick using a standard glucometer.

Risk stratification: Patients were then placed into one of the following IWGDF risk categories:

Group	Category
0	No neuropathy
1	Neuropathy present Deformity absent PAD absent
2	Neuropathy present, plus either deformity or PAD or both
3	Previous ulcer Previous amputation

Statistical analysis: Data was collected into a specially designed pro-forma and coded before input into a statistical computer package (SPSS version 12). Descriptive statistics were applied to continuous and categorical data from which measures of central tendency and proportions were derived. Inferential statistics were applied to determine associations between age, gender, blood sugar, measures of obesity and neuropathy / peripheral arterial disease/ foot deformity. Where comparisons were made a p - value of less than 0.05 was taken to be statistically significant.

RESULTS

A total of 218 ambulatory patients with diabetes mellitus were enrolled into the study. The baseline characteristics of the study participants are summarised in Table 1.

Table 1
Baseline characteristics by foot complication

Characteristic	Foot complication (ulcer and/or amputation)	No foot complication
Number, n,	174	44
Age, years (mean ± SD)	58.5±8.9	55.9±9.8
Male %	39	55
Duration of diabetes (years) (mean ± SD)	16.1±4.1	13.8±5.4
RBS (mmol/l) (mean ± SD)	11.7±3.9	10±3.4
BMI (kg/m^2)(mean ± SD)	26.2±2.8	24±3.7
ABl	1.0±0.1	1.1 ±0.3
NDS	2.6±2.6	1.32±0.8
Deformity (%)	36	82
SBP (mmHg) (mean ± SD)	135±20	144±12
Current smoking (%)	1.1	2.3

Data presented as mean (SD); NDS = Neurological Disability Score; ABI = Ankle Brachial Index

The distribution of key variables in the different groups is represented in Table 2

Table 2
Patient characteristics in the different key ulceration risk categories

Characteristic	Neuropathy		Peripheral arterial disease		Deformity	
	Present	Absent	Present	Absent	Present	Absent
Number, n,	92	126	26	192	98	120
Age (years) (mean±SD)	62.4±8.5*	56±8.7	58.7±10	57.6±8.9	59.6±10*	56.7±7.8
Male %	58	33	33*	38	42	43
Duration of diabetes (yrs) (mean ± SD)	18.0±4.4*	14.6±4.2	16.4±3.8	15.5±4.6	15.7±5	15.6±4
RBS(mmol/1) (mean±sd)	12.9±4.3*	10.6±3.5	12.8±3.3	11.l±3.8	11.l±4.3	11.5±3.5
BMI(kg/m^2)(mean±SD)	26.3±3.4	25.6±3	27.2±2.6	25.6±3.2	25.5±3.2	26.1±2.7
ABI	0.99±0.16	1.03±0.13	0.8±0.06	1.03±0.12	1.02±0.16	1.01±0.l3
NDS			4.5±3	2.0±2.2	2.3±1.9*	2.3±2.2
Deformity (%)	54*	41	35	46		
SBP(mmHg)	143±16*	134±19	139±21	137±19	141±17	134±19

Data presented as mean (SD); NDS = Neurological Disability Score; ABI = Ankle Brachial Index. *significant correlations p<0.05

Subsequently the patients were stratified into the following IWDGP groups as shown in Table 3

Table 3
IWGDF categories

IWGDF group	Percentage of study subjects in each group
0 No neuropathy	57
1 Neuropathy alone	10
2 Neuropathy + PAD or deformity	16
3 Previous ulcer/ amputation	17

DISCUSSION

The prevalence of neuropathy in this study was 42% (92/218). Neuropathy was assessed through the use of the Neurological Disability Score. Using the same tool, Mwendwa *et al* (14) found a prevalence of peripheral neuropathy of 28% among patients with short-term type 2 diabetes (<2 years) at Kenyatta National Hospital. However the mean duration of diabetes in their study group was 10.3 months in comparison to 15.9 years in this study. The mean age of the study population in the study of Mwendwa *et al* (14) was 53.7 years old as compared with the older age group in the present study with mean of 58 years old. Also the current study had more males i.e. (42%) versus (37%) in Mwendwa *et al* (14). Male gender has been shown to be strongly associated with neuropathy. Thus, the older age group, larger number of males, coupled with the increased duration of diabetes could have contributed to the higher prevalence of neuropathy in this particular study. The prevalence of neuropathy has been shown to vary widely among countries. Inter-observer variations have also occurred within similar populations. A comparative study of diabetic patients with foot lesions in Germany, India and Tanzania found that around 80% in each centre had peripheral neuropathy, but only 12 to 13% had evident peripheral arterial

disease in Tanzania and India respectively, compared to 48% in Germany (15). The basal characteristics of the populations of study may vary amongst study subjects but evidence suggests that foot lesions in developing countries are largely neuropathic in origin. Wikbald *et at* (16) in Tanzania found a prevalence of neuropathy in their patients of 28.1%, PVD 12.50%, while Elbagir *et al* (17) in Sudan found peripheral neuropathy of 37%, PVD-10%. Other studies have documented prevalence of peripheral neuropathy including, 27.8% in the San Louis Diabetic Study (18) 28% in EURODIAB (19), 60% in a Turkish study (20), and 66% in the Rochester Study (21). A recent study reported from the middle-east found a high prevalence of 82% in Iran (22). The varying prevalence has been attributed to the lack of standardisation on the determination of neuropathy.

Equally important is the varying characteristics within/amongst the study populations. In this study male gender was found to be significantly associated with neuropathy, (p = 0.01). This finding is similar to Mwendwa *et al* (14), the DCCT (21) and the San Louis valley diabetes study (16) Pickett (24) showed that females have higher nerve conduction speeds than males. Age was significantly associated with neuropathy in this study. The duration of diabetes was also significantly associated with the prevalence of neuropathy. Although studies that have demonstrated the strong link between poor glycaemic control and neuropathy have used the HBA_{1c} as the marker for glycaemic control, this study was able to demonstrate that in our population the random blood sugar, a surrogate marker of metabolic control, is significantly associated with neuropathy (p = 0.011). The DCCT (21) showed a 60% reduction in the incidence of neuropathy among type 1 diabetic subjects in the group randomized to intensive glycaemic control. In type 2 diabetics the UKPDS (23) estimated that each 1% reduction in the HBA_{1c} was associated in a 35% relative reduction of all micro-vascular complications.

In this study, the prevalence of neuropathy was significantly increased with rise in systolic pressure (p = 0.034). EURODIAB (19) found that hypertension was associated with an odds ratio of 1.92 (p<0=0.0001) of incident neuropathy. The UKPDS reported that all microvascular outcomes were reduced by between 24-56% by modest BP reduction to a mean of 144/82mmhg (23).

The prevalence of peripheral arterial disease (PAD) was 12% (26/218). The tool used was the Ankle Brachial Pressure Index as determined by the Doppler method. Nyamu *et al* (8), using clinical assessment found a prevalence of 52% in patients with diabetic foot ulcers. In Sudan, Elbaghir *et al* (17) reported a prevalence of 10%. Wikbald *et al* (16) in Tanzania found a prevalence of 12%. In the UK, the Edinburg artery study (25) estimated the prevalence to be as high as 20.1%. In this study the association between peripheral arterial disease and age did not reach statistical significance although there was a trend towards increased occurrence with increasing age. Male gender was significantly associated with peripheral arterial disease (p=0.001). Since the pathogenesis involves atherosclerosis, this finding is in keeping with published evidence that shows a strong link between male gender and atherosclerotic manifestations. A positive association between peripheral arterial disease and random blood sugar could not be demonstrated in this study. Although it has been shown that advanced glycaemic end products may have a role in the pathogenesis of peripheral arterial disease in diabetics, (26) very few controlled studies have investigated the association between glycaemic control and peripheral arterial disease. The atherosclerosis risk in communities study (27) found a positive, graded, and independent association between A_{1c} and PAD risk in diabetic adults. This association was stronger for clinical (symptomatic) PAD, whose manifestations may be related to microvascular insufficiency, than for low ABI. Although the mean Ankle Brachial Index was lower for patients with a BMI of more than 25kg/m^2, the association between Ankle Brachial Index and Body Mass Index was not statistically significant (p=0.138). To the authors' knowledge, no published well controlled studies thus far have demonstrated an unequivocal link between ABI and BMI. Systolic blood pressure was not associated with Ankle Brachial Index in this study (p = 0.407). The Edinburg artery study (25) showed that raised systolic blood pressure was associated with an odds ratio of 1.22 of developing peripheral arterial disease.

The study concluded that increased mean levels of systolic blood pressure and triglycerides may help to explain the higher prevalence of PAD in diabetic subjects. The prevalence of foot deformities in this study was 46%. Female gender had a significant statistical association with foot deformities (p = 0.012). Females have generally been shown to have more foot deformities (28,29) likely owing to the use of foot wear with restricted toe boxes and high heels. In our local setup, particularly in the rural areas, women are engaged in cultivation, fetching of firewood and water, and other activities that may result in accumulation of deformities particularly where they walk barefoot or wear inappropriate footwear. However, Abbas and Husam (32) in Basra has recently documented male gender as a risk factor for foot abnormalities in his study population. It is likely that foot deformities as a whole are more determined by gender roles as opposed to gender/sex per se. However, the higher risk deformities, i.e. claw toe, hammer toe and prominent metatarsals were more frequent in males who had significant neuropathy, and thus this may

explain the increased prevalence of foot ulcers in men. As expected, deformity was significantly associated with advancing age which no doubt provides a greater opportunity for acquisition and accumulation of deformities. An important finding in this study also shown by Nyamu *et al* (8) is the significant association between foot deformity and neuropathy. Although it is generally held that neuropathy, by causing imbalance between the toe flexors and extensors may ultimately lead to claw toe deformity, very few studies have investigated the role of neuropathy in the causation of foot deformity. Carine *et al* (31), in their study, concluded that although important relationships between motor nerve conduction deficit and muscle weakness were demonstrated, it was still not clear whether abnormal nerve function, leading to a decrease in muscle strength, could be responsible for the development of foot deformities.

In conclusion, diabetes mellitus confers dramatic increase in risk of foot ulceration; however, available evidence suggests that this risk may be reduced by screening risk satisfaction and appropriate intervention measures (32-35). This study categorised 33% of the participant patients at intermediate to high risk groups of foot ulcerations. The non modifiable risk factors of foot ulceration documented in this study were; age, duration of diabetes, deformities and gender. However, the modifiable risk factors found in the study included; poor glycaemic control, inadequate education (of clinicians and patients) on foot care, neuropathy, high systolic blood pressure and peripheral artery disease (albeit at low prevalence). It is equally important to note that then risk stratification, is practical in a routine care selling ambulatory patients with diabetes.

More than one third of diabetics (33%) are at high risk for future foot ulceration. Long term prospective studies should be carried out in a similar population locally to determine the risk of ulceration in the different categories since these may differ from studies done in the west.

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