East African Medical Journal Vol. 80 No. 1 January 2003
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ABSTRACT

Background: **Diabetic foot ulcers contribute significantly to the morbidity and mortality of patients with diabetes mellitus. The diabetic patients with foot ulcers require long hospitalisation and carry risk of limb amputation. The risk factors for developing diabetic foot ulcers are manageable. In Kenya there is paucity of data on such risk factors.**

Objective: **To determine the prevalence of diabetic foot ulcers and the risk factors in a clinic-based setting .**

Design: **Cross-sectional study.**

Setting: **Kenyatta National Hospital, Kenya.**

Subjects**: Patients with both type 1 and 2 diabetes mellitus who had active foot ulcers in both outpatient and inpatient units.**

Main outcome measures: **Diabetic foot ulcers glycated haemoglobin, neuropathy, peripheral vascular disease and fasting lipid profile.**

Results**: One thousand seven hundred and eighty eight patients with diabetes mellitus were screened and 82(4.6%) were found to have foot ulcers. The males and females with diabetic foot ulcers were compared in age, duration of foot ulcers, blood pressure, glycaemic control, neurological disability score and their proportion. Diabetic foot ulcers occurred mostly in patients who had had diabetes for a long duration. The types of (occurence) ulcers were neuropathic (47.5%), neuroischaemic (30.5%) and ischaemic (18%). The neuropathic ulcers had significantly poorer glycaemic control compared to other types and the longest duration (23.3 weeks). Ischaemic ulcers had significantly higher total cholesterol and diastolic blood pressure compared to other ulcer types. Wagner stage 2 ulcers were the commonest (49.4%) but stage 4 ulcers had their highest neuropathic score (7.8/10) and longest duration (23.6weeks). Aerobic infective pathogens were isolated from 73.2% of the ulcers.**

Conclusion: **The prevalence of diabetic foot ulcers was 4.6% in this tertiary clinic. The risk factors of diabetic foot ulcers in the study were poor glycaemic control, diastolic hypertension, dyslipidaemia, infection and poor self-care. These findings are similar to studies done in other environments and they are modifiable to achieve prevention, delay in formation or improved healing of foot ulcers in patients with diabetes. Therefore, specific attention should be paid to the management of these risk factors in patients with or without diabetes foot ulcers in this clinic.**

INTRODUCTION

Diabetic foot ulcers contribute significantly to morbidity and mortality of patients with diabetes(1). It is estimated that approximately 2.5% of all diabetic patients will develop foot problems yearly(2). Studies in the United Kingdom have shown that foot problems in diabetic patients were responsible for 20% of all diabetic admissions to hospitals(3,4).

Diabetic foot ulcers may require long hospitalisation(5) or end up in amputation of the index limb. Muyembe *et al*(6) observed that about 25% of lower extremity amputation in a Kenyan provincial hospital were due to diabetic foot ulcers matching only road traffic accidents. Most patients with diabetic foot ulcers living in developing countries present to healthcare facilities fairly late with advanced foot ulcers for diverse reasons. Such reasons include poor economic capabilities in cost-shared healthcare systems, inadequate knowledge of self-care, socio-cultural reasons and poor and inadequate diabetes healthcare. Sano *et al* (7) showed that diabetic patients in Ouagadougou, Chad had a delay period of one month after onset of foot ulcer before presenting to a health facility.

Edmund *et al* (8) demonstrated that 40 to 50% of lower extremity amputations due to diabetic foot ulcers could be prevented by meticulous foot care and patient education.

This study was intended to determine the prevalence, patterns and risk factors of diabetic foot ulcers amongst patients with mellitus who were attending or using Kenyatta National Hospital health facilities.

MATERIALS AND METHODS

This study was conducted prospectively from July 1998 to January 1999. The protocol for the study was approved both by the Department of Medicine and the Ethical Review Committee of Kenyatta National Hospital.

A total of 1788 patients with diabetes mellitus from in-patients and out-patients diagnosed earlier by National Diabetes Data Group Criteria(9) and were on treatment as per hospital records or by WHO criteria(10) were screened by meticulous clinical examination, especially inspection and palpation (from both inpatient and outpatient pool of patients) for diabetic foot ulcer. Eighty two (4.6%) of the total number screened satisfied the inclusion criteria for the study. Diabetic foot ulcers was operationally defined as a breach on the normal skin occurring as induration, ulceration or change of colour on the foot for duration equal to or more than two weeks. Only patients with active foot ulceration(s) were included in the study.

For each of the recruited subjects, a history was obtained and it detailed the patient's demographics including the age, gender, marital status, area of usual residence and the level of formal education. Smoking, alcohol use, occupation, presence of trauma at onset of ulcer and progression was asked for. The duration of the foot ulcer and patient's awareness of the presence of the ulcer was noted. History regarding the diabetes including duration of disease (estimated from year of diagnosis), and the mode of treatment from either the patient or available hospital records were documented. The presence of intermittent claudication and neuropathic pains was noted. History of prior education on foot care and previous healed foot ulcers were asked for.

A physical examination was then performed. Height and weight were measured the standard ways. Height was expressed in metres and weight was expressed in kilograms. The body mass index (BMI) was then calculated as BMI=Weight(kg)/ Height in Kg/M^2

Patients were categorised as shown below(11)

-Not obese BMI of less than 25
-Mild obesity: BMI: 25 – 29.9
-Moderate obesity: BMI 30-40
-Gross obesity: BMI Greater than 40

The blood pressure was measured with the adult cuff standard technique. An average of two readings was used for final records.

Examination of the eye was performed and the presence of cataract and retinal changes on fundoscopic examination were noted. Both feet were examined and the site, state and the stage of foot ulcers were documented. The presence of the high risk non-ulcer lesions were also described. The lesions were staged on the Wagner's classification as follows(12).

- Stage 0- Foot at risk
- Stage 1- Superficial ulcer
- Stage 2- Deep ulcers without bone involvement or abscess.
- Stage 3- Abscess with bone involvement (as shown by X-ray)
- Stage 4- Localized gangrene e.g. toe(s), heel
- Stage 5- Gangrene of whole foot.

Peripheral neuropathy was assessed by elucidating the presence or absence of vibration sense using the 128Hz tuning fork the medical and lateral malleoli and documented. The pressure sensation (monofilament testing) was done using 10g monofilament (5.07). (A normal person should be sensitive to the monofilament that buckles at a force of 10g). This modality was tested on various sites on the sole of feet and findings recorded as present or absent. Examining the deep tendon reflexes, the Achilles tendon reflex was tested using a standard patella hammer and technique and graded as either present (normal), detectable only after enhancement, or absent. Perception of pain by application of a pinprick on various sites on the feet was tested for and classified as present or absent.

Thereafter, the neurological disability scoring (NDS) system(13) was used and was awarded to each foot according to the neurological findings and the sum-scored obtained. The NDS scoring system is as outlined below. In a situation where prior foot amputation had been performed, the score awarded to the examined foot was doubled.

	Right		Left	
Sensation	Normal	Abnormal	Normal	Abnormal
Pain (pin prick)	0	1	0	1
Vibration (tuning fork)	0	1	0	1
Pressure (monofilament)	0	1	0	1
Achilles Tendon Reflex	Right		Left	
Grading				
Present	0		Present	0
Reinforced	1		Reinforced	1
Absent	2		Absent	2

Range of neuropathy score:0-10
Classification:
0-2= No neuropathy
3-5= Mild neuropathy
5-8= Moderate neuropathy
>9= Severe neuropathy

Peripheral vascular disease: The dorsalis pedis and posterior tibial arterial pulses were palpated with the patient in supine position, by one of the investigators (P.N.N), the standard way and graded as normal impaired or absent. Blanching on elevation, dependence rubor and delayed capillary refill were examined. The examined limb was elevated for 30 seconds and blanching looked for by comparing with the other contralateral limb, it was then lowered to a dependent position and any reactive hyperaemia noted. Slight pressure was then applied on the nail beds and pulp of the toes until pallor was noted then it was released and the refill time (disappearance of pallor) determined. No lower limb arteriography had been done in any of the patients at time of inclusion or re-visit.

The other dermatological and/or high risk lesions looked for were dryness, cracks, fissures, ingrown and/or improperly trimmed nails, oedema, tinea pedis and/or tinea unguum, foot deformities e.g. Charcot joints, hammer toes, pes cavus and callosites and/or corns. X-rays were done to stage the ulcers of the patients.

Using the clinical information obtained, the type of the foot lesion was determined and classified as neuropathic, ischaemic or neuroischaemic. Foot ulcers were categorised as ischaemic when peripheral vascular disease was present but the neurologic disability score was ≤2 neuropathic when there was neurological disability scoring≥ 3 but no obvious peripheral vascular disease as defined above and neuroischaemic when both neurologic disability score≥3 and evidence of peripheral vascular disease were present.

After the history and full clinical assessment of the patients in fasted state of about 10 hours, 5 mls of venous blood was drawn from the cubital vein. A 3mls blood sample placed in a plain bottle was sent for lipid assays(total cholesterol, HDL-C, LDL-C and triglycerides).

The lipid assays were done using the cholesterol oxidase and esterase calorimetric method in the Technicon RA-1000 machine. Total cholesterol HDL-C and triglycerides were directly assayed while LDL-C was calculated using the Friedwalds formula: LDL=T.Chol-T.G/2.2-HDL mmols/I(14).

Another 2 mls sample of blood was placed in an EDTA bottle and stored at 4˚C and processed weekly for glycated heamoglobin. The glycated heamoglobin (HbAlc) was analysed using the calorimetric end-point method on the IMx machine whose normal non-diabetic range is 4.4-6.4%HbAlc. The results were then reported in percentage graded as per assay test recommendation as:

HBAlc≤ 7% good metabolic control

HBAlc> 7<10% fair control

HBAlc≥ 10% poor metabolic control.

A pus swab was obained from the ulcers using the standard techniques prior to any ulcer cleaning and avoiding other contamination at all stages. The samples were delivered to the laboratory within half an hour. The specimens were cultured in blood agar and McConkey media under aerobic conditions for 24 to 48 hours.

Sensitivity to certain antibiotics was tested by incubating the organism in the Mueller Hinton agar with various sensitivity disks for a further 24 hours. Except for very superficial ulcers, X-rays of the involved foot were obtained and any bone involvement or deep sitting abscess was noted.

The data was summarised in tabular form and the mean and standard deviation were calculated for such variables as age and duration of disease.The data was then presented in the form of diagrams, tables, bar charts and histograms as appropriate. Qualitative data were entered in form of percentages and where appropriate associations were made. Student's t-test was used to compare the differences in means.

RESULTS

One thousand seven hundred and eighty eight patients with proven diabetes mellitus were screened and 82 (4.6%) were found to have diabetic foot ulcers. The males and females included in the study were comparable in their mean ages. The proportion of smokers recorded may be an under reporting. The males had better formal education than the females (p=0.017). The areas of residence were similar for both males and females, suffice it to say that most of the urban dwelling patients resided mainly in urban slums (Table 1).

A small proportion of (8.5%) were newly diagnosed diabetic patients. Mean duration of diabetes was 7.98± 6.86 years while the mean duration of foot ulcers disease was 16.36 weeks. The duration of foot ulcers in females was comparatively longer than in males.

The mean blood pressure, both systolic and diastolic were similar in both sexes and they were also within normal range. However, the body mass index was in females, though not to statistically significant proportions.

While most of the population of diabetics studied were type 2, there is an observed high proportion of patients on insulin. This reflects not more of type 1 diabetes included in the study but more patients of type 2 diabetes exhibiting beta cell failure over time and sepsis of foot ulcers thus requiring insulin for their glycaemic control(Table 2).

Table 1

Sociodemographic characteristics of patients included in the study

	Population(%)	Males (n=41) (%)	Females (n=41) (%)	P-value
Age (years)mean (SD)	56.9 (13.41)	57.2 (15.1)	56.5 (11.5)	NS
No. of years in school Mean (SD)	3.09 (4.22)	4.85 (4.19)	2.95 (4.09)	P=0.017*
Smoking: Yes	9 (11)	9 (22)	-	-
No	72 (89)	32 (78)	41 (100)	-
Rural residence: n (%)	43 (52.4)	20 (48.8)	23 (56.1)	
Urban residence: n (%)	39 (47.6)	21 (51.2)	18 (43.9)	-

*Significant at p<0.05

Table 2

Summary of clinical characteristics of the population included in the study

Characteristic		Population	Male	Female	P-value
Duration of diabetes mellitus (years). Mean (SD)		7.98(6.86)	8.352(7.79)	7.37(50.72)	0.642 NS
Duration of foot ulcer (weeks). Mean (SD)		16.36(34.3)	13.0(15.2)	19.6(42.6)	0.63l NS
Blood pressure (mmHg).	Systolic	143(20.3)	143.4(20.4)	143.4(20.4)	0.815 NS
Mean (SD)	Diastolic	85(13.7)	84.4(12.2)	86.3(15.1)	0.607 NS
Vascular dysfunction	Present	49%			
	Absent	51%			
Body mass index (kg/m2)					
Mean (SD)		24.9(5.2)	24.1(4.6)	25.7(5.7)	0.226 NS
Neurological disability score Mean (SD)		6.50(3.4)	6.41(3.6)	6.58(3.33)	0.932 NS
Mode of diabetic control	Diet only n(%)	4(4.9%)			
	Oral agents only(%)	32(39.0%)			
	Insulin only n(%)	39(47.6%)			
	Newly diagnosed n(%)	7(8.5%)			

Prop = Proportion; NS=Not Significant

Table 3

Laboratory findings of the population included in the study

Characteristic	Population:mean (SD)	Males: mean (SD)	Females:mean (SD)	P-value
Glycated Hb (HbAlc%)	9.63 (2.85)	9.22(2.95)	10.02(2.71)	0.072 NS
Total Cholesterol TC (mmol/l)	4.69 (1.55)	4.69(1.73)	4.7(1.34)	0.929 NS
Triglycerides TG's mmol/l	2.02 (1.04)	2.00(0.91)	2.05(1.16)	0.840 NS
Low density Lipoprotein (LDL-C) mmol/l	2.92 (1.11)	2.97(1.23)	2.87(1.11)	0.913 NS
High density Lipoprotein (HDL-C) mmol/l	1.18 (0.42)	1.19(0.45)	1.17(0.39)	0.876 NS
Ratio	4.0	3.94	4.02	

The quality of glycaemic control in the study population was relatively poor, but poorer in females compared to males. However, the difference did not attain significant proportions (Table 3).

There was major clustering of patients in the age range 40-79 years, accounting for about 90% of all patients seen with diabetic foot ulcers.

The proportion of patients with extremes of age were fewer possibly because type 1 diabetes is rare in Kenya and the very elderly die for various other reasons (Figure 1).

Figure 1

Proportion of patients with diabetic foot ulcers by age

Figure 2

Proportion of diabetic foot ulcers by duration of diabetes

Figure 3

Major sites of diabetic foot ulcers as seen in the patients included in the study

Table 4

Location of foot ulcer

Side	Male (n=41)	Female (n=41)	P-value
Right	21	13	0.0249*
Left	10	22	
Both	10	6	

* Statistically significant p<0.05

Males had foot ulcers more on the right while females had their foot ulcers on the left p=0.0249), this observation was statistically significant. No explanation could be derived from the study because it did not control for dominant limb and other related risks.

Table 5

Types of diabetic foot ulcers and proportion of patients included in the study

Type of ulcer	Proportion (%)	Mean HbAlc (%)
Neuropathic	47.5	10.5(2.8)*
Ischaemic	18.0	8.3(1.37)
Neuroischaemic	30.5	9.4(2.4)
Unclassified	4.0	6.5(0.29)

*Significant difference p<0.05

Neuropathy was the more predominant risk factor in the ulcers, where it was detected in 78% of patients. while ischaemia featured in 48.5% of patients. Patients with mainly neuropathy had higher mean HbAlc than patients with predominant ischaemia p<0.05 (Table 5). Four percent were categorised as unclassified ulcers, they probably had other causes which were not possible to determine in the study in because of lack of detailed neurologic and vascular studies.

Table 6

Diabetic foot ulcer type and selected parameters

Parameter	Neuropathic ulcer	Ischaemic	Neuroischaemic
Proportion of patients	(47.5%)	(18%)	ulcer (30.5%)
Mean duration of diabetes (years)	8.32 (6.18)	8.78 (9.57)	8.08 (1.18)
Mean duration of ulcers (weeks)	23.29 (48.73)*	6.28 (5.70)	12.08 (11.13)
Mean HbAlc (%)	10.5 (2.8)	8.3 (1.37)	9.4 (2.4)
Mean total cholesterol (mmol/l	4.75 (1.37)	5.23 (1.02)*	4.84 (1.43)
Mean triglycerides (mmol/l)	1.85 (0.68)	2.05 (1.38)	2.35 (1.26)
Mean SBP (mm/Hg)	141.3 (22.55)	146.2 (17.46)	
DBP (mm/Hg)	81.8 (13.53)	89.2 (13.05)*	

Values expressed as mean (standard deviation)
*Significant p<0.05

Neuropathic ulcers had lasted longer than ischaemic ulcers. The patients with ischaemic ulcers had significantly higher diastolic blood pressures and mean total cholesterol than those with neuropathic ulcers, (Table 6).

Table 7

Diabetic foot ulcer stages and some selected parameters determined in the study

Parameter	Ulcer stage and proportion of patients			
	Stage I (7.4%)	Stage 2 (49.4%)	Stage 3 (18.5%)	Stage 4 (23.5%)
Mean HbAlc(%)	9.92	9.10	10.54	9.81
Mean NDS	2.83	6.20	6.50	7.8
Mean duration of ulcer (weeks)	6.2	17.5	7.0	23.6

Wagner stage 2 ulcers were the most prevalent, at 49.4% followed by stage 4, 23.5% and stage 3, 18.5%. The Wagner stage 4 ulcers had the highest observed neuropathy score, relative to other stages and the longest mean duration of 23.6 weeks (Table 7).

DISCUSSION

The prevalence of diabetic foot ulcers amongst diabetic patients at the Kenyatta National Hospital was 4.6% which was comparable to 5.4% found in a community study in Cape Town, South Africa(15). Studies in the UK found prevalence of 5%(16) and 7.4%(17). The figures are comparable, but if the differences were significant, this may be a reflection of regional variations in prevalence of diabetes mellitus and the local operating risk factors of diabetic foot ulcer disease.

Diabetic foot ulcers were responsible for 11.4% of all the admissions of patients with diabetes in both medical and surgical wards of the hospital in this study. Neil *et al* (16) found approximately 20% of all diabetes-related admissions in the UK were due to diabetic foot ulcer disease. The admission criteria may certainly be different, whereupon, Kenyan patients with diabetic foot ulcers were unlikely to be hospitalised unless they were septicaemic or the limb was threatened. This was because there are diseases like malaria, HIV/AIDS and meningitis amongst others, which are likely to require urgent hospitalisation more than an indolent diabetic foot ulcer.

The mean age of the patients was 56.9 years. The majority had type 2 diabetes with a mean duration of diabetes of 7.98 years. Margueritte *et al* (18) in Seattle, USA, found a comparable mean age of 60 years. These studies were conducted in different centers that offer diabetes care of different qualities. This comparable mean age may suggest certain time-dependent risk factors in the evolution and course of diabetic foot ulcer disease which are common to diabetes in whatever environment. Age of onset of diabetes is also different in continents.

The Seattle study of Margueritte *et al* (18) found the mean duration of diabetes to be 13.2 years compared to 7.98 years in this study. This may imply the differences in the quality of diabetes care where Seattle patients, on average have longer duration of diabetes exposure before they develop foot ulcers. It is possible that better diabetes care that they receive delays the onset of foot ulcer disease. However, this explanation is not wholesome because in this study, 8.5% of the patients were newly diagnosed diabetes, with diabetes foot ulcer as their first presentation. This again emphasises the role of diabetes, per se, as a major risk factor of foot ulcer disease. Overt trauma was reported in 48.8% of patients in this study, but this may not play a major role relative to microtrauma caused by poor or inappropriate footwear. During the study, it was observed that the quality of footwear of most patients was undesirable, having a relatively hostile interior. It was, therefore not surprising that the ventral foot (heel to toes) had the most ulcer lesions probably because of weight-bearing pressure and consequent microtrauma.

McLigeyo and Otieno's study on diabetic foot ulcer's(19) found the mean duration of diabetes to be five years, of foot ulcers was 34 weeks, while in this study, we found mean duration of diabetes of 7.98 years and of ulcers of 16.36 weeks. It is likely that in the 10-years interval of the two studies, diabetes care in the hospital improved , though still sub-optimal as 19.5% had bilateral foot ulcers, 5% had previous amputations and 36% had previous ulcers. Causative risk factors of neuropathy (78%), ischaemia (48.5%) and infection (100%) that were found were similarly seen in other studies (19-21) albeit in different proportions. Exclusive neuropathy occurred in 47.5% compared to 50% found by Sosenko *et al*(21) and Thomsens *et al*(22). This study used exclusive clinical method to evaluate both neuropathy and peripheral vascular disease which may be either a weakness (limit broader comparability of results) or strength (a more practical scenario in a resource-poor setting) of this study.

Poor knowledge of foot care was just as common; for example, about 10% of patients did not even realise they had foot ulcers suggesting that they never inspected their feet or cleaned them well.

Glycaemic control was observed to be generally

poor in this group of patients where only 18.3% of the patients had HbAlc equal to or less than 7%. Females had poorer glycaemic control compared to the males. Women still remain underprivileged in this environment whereupon most of them depend on husbands for maintenance. This may extend to healthcare as well. Their mean duration of ulcers was observed to be longer (19.6 weeks) compared to males (13 weeks). If this observation of poor glycaemic control is common in this study population, it is therefore not unexpected that clinical neuropathy occurred in over 75% of the patients. Neuropathy is a microvascular complication enhanced by poor glycaemic control, and delayed by good glycaemic control(23). The patients with neuropathy had longer mean duration of ulcers, more advanced ulcers stage and higher mean glycated haemoglobin. Importance of good glycaemic control is implied and emphasized by these findings as a key aspect of primary intervention in diabetic foot ulcer management.

Patients with peripheral vascular disease had significantly higher diastolic pressure, while systolic pressures were not elevated above reference range. Previous studies have had conflicting results with some failing to show any association between blood pressure and diabetic foot ulcers(24-26) while Ogbuawa *et al* (27) found hypertension to be an independent risk factor for macrovascular disease and subsequent foot ulceration.

There were 73.2% of the diabetic foot ulcers that grew aerobic bacteria while 26.8% were aerobic culture negative. Advanced Wagner stage ulcers were aerobic culture negative but clinically were septic which suggested deep-seated anaerobic microbes that were not addressed bacteriologically in this study. This aspect of the foot ulcers is addressed elsewhere.

In conclusion, diabetic foot ulcers occurred at a prevalence of 4.6% in this group of diabetic patients using this health facility. Neuropathy occurred most frequently either singly or with peripheral vascular disease. Most patients who had inadequate knowledge on foot care and inappropriate footwear, were also in poor glycaemic control and had infected foot ulcers. They presented late to the healthcare facility for care and obtained sub-optimal diabetic care. These are potentially modifiable risk factors in diabetic foot ulcer disease that can and should be addressed in follow-up of these patients and others at risk of developing foot ulcers.

Such interventions of good glycaemic control and education on foot care prevent or delay development of diabetic foot ulcers. Early and expedious appropriate intervention on foot ulcers would also prevent unnecessary limb wastage. It is important to remember that good glycaemic control, education on foot care and appropriate footware are practical and achievable cost-effective measures for primary management of diabetes foot ulcers even in the developing countries.

ACKNOWLEDGEMENTS

To the nursing staff at the diabetic clinic and in-patient wards of Kenyatta National Hospital for their assistance during the study. We are also grateful to the laboratory staff for running the specimens and most of all, the patients for availing themselves for the care and participation in this study.

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