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The Foot at Risk in Nigerians With Diabetes Mellitus-The Nigerian Scenario

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Diabetic foot ulceration is a major source of morbidity and mortality in patients with diabetes mellitus. Diabetics are 40 times more likely to suffer a lower-limb amputation than those without the condition and as such the importance of this DM complication cannot be over-emphasized. This study sets out to describe and determine the prevalence of the "foot at risk" for ulceration in diabetic patients in an urban out patient clinic in Lagos, Nigeria.

Subjects and Methods: This was a cross-sectional study carried out at the Diabetes Clinic of the Lagos University Teaching Hospital, Lagos, Nigeria for a period of one year (2001-2002). One thousand, one hundred and forty patients with diabetes mellitus (DM) were screened to obtain a number of 474 with the foot at risk for ulceration. The "foot at risk" in people with diabetes mellitus (DM) refers to the foot with intact skin which may have bony deformities or pre-ulcerative lesions such as claw toes, hammer toes, hallux valgus, prominent metatarsal heads, callus formation, bunion, bunionnette, charcot/bony prominences, dry skin, warm foot with prominent vessels, previous ulceration and or amputation, onychomycosis, features of neuropathy and vasculopathy. Data was analyzed using the Statistical package for the social sciences (SPSS) version 10.

Results: The prevalence of DM patients with the foot at risk in this study (41.5%) was high. Of the 474 study subjects with the "foot at risk" for ulceration, 9(1.9%) had type 1 DM and 465 (98.1%) had type 2 DM. More than half of the patients were elderly (>61years) and either overweight or obese. The duration of diabetes and the mean fasting plasma glucose was higher in patients with type 1 DM but this difference was not statistically significant. In both types of diabetes, more than 50% of the subjects had poor glucose control.

Conclusions: The 41.5% prevalence of the foot-at-risk for ulceration among Nigerian patients with diabetes mellitus is high. In a resource poor country like Nigeria, in order to prevent foot ulceration, preventive measures should be targeted mainly at the high risk group.

Key Words: Diabetes mellitus, Diabetes foot ulceration, Foot-at-risk, Ischemia, Neuropathy.

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Introduction

Of the many complications affecting people with diabetes mellitus (DM), diabetes mellitus foot ulceration (DMFS) is one of the most devastating; it has been estimated that DMFS develops in 15% of diabetic patients.[1] This all-important DM complication is the single most common cause of prolonged hospitalization amongst people with diabetes.[2-3] Studies from Nigeria and elsewhere attest to

this.[1,2] The economic cost occasioned by DMFS is equally considerable.[4]

Risk identification is therefore fundamental for effective preventive management of the foot in people with diabetes. It is estimated that relatively simple and comparatively inexpensive interventions may decrease the amputation rate up to 85%.[5] Early and simple identification of the foot at risk for ulceration would prompt early effective treatment and forestall the development of DMFS.

Reported studies on DMFS among Nigerian diabetics are scant. The majority of the few available studies were retrospective and served mainly to determine the pattern of presentation of DMFS.[2,3] Diabetic foot lesions constitute an important cause of morbidity and mortality in Nigerian diabetics[2,6-9] and therefore deserve an in-depth study. Such a study is needed, as it would be of clinical and scientific relevance. Besides the scientific value of anticipated results, the information would be of practical relevance to clinicians caring for and beneficial to people with diabetes mellitus. Thus this study set out to determine the frequency of "foot at risk" among our patients with Diabetes Mellitus (DM) and also to highlight the potential risk factors for foot ulceration.

Materials and Methods

This was a cross-sectional study carried out at the Diabetes Clinic of the Lagos University Teaching Hospital (LUTH), Lagos, Nigeria. In order to determine the frequency of "foot-at risk", participants were recruited from patients receiving diabetes care at the Diabetes Clinic of LUTH, Lagos Nigeria as outpatients. The "Foot At Risk" refers to the foot in diabetic subjects with intact skin which may have bony deformities or preulcerative lesions such as claw toes, hammertoes, hallux valgus, prominent metatarsal heads, callus formation, bunion, bunionette, charcot/bony prominences, dry skin, warm foot with prominent vessels, features of neuropathy and vasculopathy and a history of previous ulceration and/or amputation.[10]

For purposes of history taking, interviewer administered questionnaires were distributed by medical personnel in the unit. However, physical examination was carried out by the authors and the resident doctors of the Endocrine and Metabolic Unit and the Opthalmology Unit of LUTH.

The sample size for the assessment of the prevalence of the foot-at-risk was determined using Epi info version 6.04. The level of confidence was set at 95%, while the power was set at 80%. The ratio of those with "at risk foot", to those with "non risk foot" was taken to be 1.6. This ratio was obtained from the known prevalence of DMFS in Nigerian diabetics which is 0.9 -8.3%.[8,11] These gave a sample size of 474. To obtain this requisite number with the "foot at risk" for ulceration, screening of 1140 patients with DM was carried out; exclusion criteria included diabetic patients with a history of malignant disease, history of receiving cytotoxic drugs, of significant alcohol ingestion, congenital abnormalities of the foot and haemoglobinopathies and all pregnant women with DM.

Each subject's medical history was obtained. Medical history included features of peripheral vascular disease (intermittent claudication, cold feet and rest pain), autonomic neuropathy (postural dizziness, nocturnal diarrhoea, gustatory sweating, erectile dysfunction and anihydrosis of the lower limbs), sensorimotor polyneuropathy (paraesthesia, numbess) and visual impairment. The duration of pedal ulceration, previous history of pedal ulceration and amputation were noted.

Demographic and anthropometric data were documented. As part of the general physical examination, foot deformities such as bony prominences, callus, hallux valgus, hammertoes, onychogryphosis bunions, bunionnetes, and evidence of previous foot surgery were sought for. The hands were examined for the presence of limited joint mobility.

Neurological Assessment

This was done following the guidelines for the usage of the Semmes Weinstein monofilament, 128Hz tuning fork, pin, patellar hammer and cotton wool. The presence of a symptom and/ or a sign of peripheral nerve dysfunction was diagnostic of neuropathy. The signs included lost or impaired vibration sensation, touch pressure, pain, fine touch and joint sensation. The absence of ankle reflex as the only sign elicited was not diagnostic.[10]

Vascular assessment

This included inspection for loss of skin appendages and toenail hypertrophy. Palpation was done for the pedal pulses and Doppler's ultrasonography (this was done for only those with clinical features suggestive of peripheral vascular disease) for the documentation of the brachial and ankle systolic blood pressure readings. From these, the Ankle brachial pressure index ratio was calculated.

The diagnosis of peripheral vascular disease (PVD) was made in the presence of clinical features of intermittent claudication, rest pain and/or impalpable pedal pulses in the absence of oedema, the presence of dry gangrene or an ABPI of < 0.9.[10,12]

Ocular assessments and laboratory analyses

Fundoscopy was carried out in dilated and sometimes in undilated pupils.

Means of fasting plasma glucose readings got over a period of 3-6 months were documented. For each group of subjects analyzed, the weighted means[13] of the glucose readings were used for analysis. A fasting plasma glucose level of less than 120mg% indicated good glycaemic control.

Urinalysis was carried out using a 9 parameter urinary strip (Ames co). At least two positive readings for the presence of proteinuria indicated DM nephropathy.

Data were analyzed using Statistical package for social sciences SPSS and Epi-info version 6.4. The test statistics used included unpaired student's t test and Chi squared test. The student's t test was used to test for differences between quantitative variables and Chi squared test was used to test for associations and comparisons of proportions.

The research proposal was approved by the Research and Ethics Committee of the Lagos University Teaching Hospital, Idi-Araba. Informed written consent obtained from the study subjects.

Results

Clinical characteristics of patients with the "foot-at-risk"

The clinical characteristics of the patients with the "foot at risk" are shown in Table 1. There were more males than females. Of the total number of subjects, 262(55%) of the total number of patients were elderly (>61 years of age) and these were all patients with type 2 DM.

Period prevalence of foot at risk

Eight hundred and twenty six subjects with diabetes who met the screening criteria were screened for risk factors of "foot ulceration".

Table 1. Clinical characteristics of patients with high risk for foot ulceration

Variable	No	Mean (SD)	Range
No (M:F)	474 (241:233)	-	-
Age (years)	474	60.2±8.2	33-72
BMI (Kgm^2)	466	26.9±12	17.6-36.9
Weight (Kg)	466	69.6±10.7	44-119
DM duration (yrs)	474	834±534	0-30

Of this number, 474 had the risk for foot ulceration out of which 9(1.9%) had type 1 DM and 465 (98.1%) had type 2 DM. The overall period prevalence of patients with "foot at risk" was 415 per 1000 patients with diabetes mellitus. The proportion of type 2 DM patients with foot at "foot at risk" was much higher than in those with type 1 DM ($\chi 2 = 4.48$, $p < 0.03$).

Distribution of Type 1 and Type 2 DM subjects with the foot at risk.

There was a statistically significant difference in the ages and the age distribution between patients with Type 1 and Type 2 DM. Those with Type 2 DM were older, 262 (62.3%) being over 60 years of age.

Type 2 DM patients were generally heavier than type 1 DM (27.0 vs 24.1 kg/m2, p >0.05,). While only about 10% of the Type 1 DM subjects were either overweight or obese, about 50% of the Type 2 DM patients were either overweight or obese (p=0.004) (Table 2).

Diabetic features of subjects at risk of foot ulceration

Table 3 shows that the duration of diabetes and the mean fasting plasma glucose were higher in patients with type 2 DM but these differences were not statistically significant. In both types of diabetes, more than 50% of the subjects had poor glucose control. Of the Type 2 DM patients, 353 (76%) were on oral hypoglycaemic agents, 54(11.6%) were on insulin, 56(12%) were on dietary management only while 2 (0.4%) were on a combination of a Biguanide and insulin.

Table 2. Distribution of study subjects by demographic and anthropometric indices and according to type of diabetes.

Variable	Type 1 DM subjects	Type 2 DM subjects	P
No (F:M)	9 (3:6)	465 (230:235)	NS
Age Group classes			
Young	4 (44.4%)	9 (0.9%)	0.001
Middle aged	5 (55.6%)	194 (41.7%)	
Elderly	0	262 (65.3%)	
BMI	24.1±4.37	27.0±12.5	
Underweight	1 (11.1%)	3 (0.7%)	
Normal weight	6 (66.7%)	225 (49.3%)	
Overweight	1 (11.1%)	147 (32.2%)	0.004
Obese	1 (11.1%)	81 (17.8%)	

*F-Females, M-males, BMI- Body mass index. *Young/middle aged refers to those patients between 21-60 years while elderly are those aged greater than 60 years. Underweight refers to a BMI of less than 19kg/m^2, overweight refers to a BMI of >25-29.9kg/m^2. While obesity refers to a BMI of >30 kg/m^2.

Table 3. Diabetic features of participants with foot at risk

Vatiable	Type 2 DM	Type 1 DM
Duration of DM		
Mean (SD) range (years)	10.8 (6.2) 3-15	8.4 (5.4) 0-25
DM duration (classes)*		
Short term	2 (22.2%)	118 (25.4%)
Medium term	3 (33.3%)	189 (40.6%)
Long term	4 (44.4%)	158 (34.0%)
Mean FPG (mg/dL)	195±58.4	150±48.8

*Short-term<5yrs, medium-5-9.9yrs, long-term->10yrs

Table 4. Prevalence of risk factors of foot ulceration/microvasular complications of DM in subjects with the foot at risk

Variable	All patients	Type 1 DM	Type 2 DM	P
PVD*	30 (6.3%)	0	30 (6.5%)	NS†
Tinea Pedis	65 (16%)	1 (14.3%)	64 (16.8%)	NS
Foot deformities	126 (26%)	5 (55.6%)	121 (26.4%)	NS
Neuropathy	362 (76.3%)	7 (77.8%)	355 (76.5%)	NS
Retinopathy	56 (22.7%)	1 (20 %)	55 (22.3%)	NS
Nephtopathy	59 (12.4%)	3 (5.1%)	56 (14%)	0.04
Previous amputation	11 (2.5%)	3 (33.3%)	8 (1.8%)	0.001
Walking unshod	403 (85.0%)	5 (55.6%)	398 (85.6%)	0.01
Previous foot ulceration	30 (6.3%)	3 (33.3%)	27 (5.8%)	0.02

*PVD-Peripheral vascular disease; † NS= Not significant

Distribution of subjects by Social and Educational status

Majority of the with type 2 DM were illiterates while for type 1 DM, majority them had some basic form of education. There was no statistically significant difference in the social class and educational status distribution between patients with type 1 and type 2 DM.

Risk factors for foot ulceration.

The prevalence of known risk factors for foot ulceration is 41.5% in this study. Statistically significant differences in the prevalence of risk factors for foot ulceration in patients with Type 1 and Type 2 DM were documented in walking unshod, previous ulceration and amputation. The microvascular complications of DM viz- retinopathy, nephropathy, neuropathy were present in varying proportions with neuropathy (present in 76%of the subjects) being the commonest of these complications. These are shown in Table 4.

Peripheral vascular disease

Symptoms of peripheral vascular disease (PVD) viz. intermittent claudication and rest pain were present in 51(10.7%) of the patients with the foot-at-risk. Of these, 11(2.3%) had cool feet while 52(10.7%) had impalpable pedal pulses in one or both feet. Of the 30 patients that had PVD the mean (SD) ankle brachial pressure index was 0.8 ± 0.1mmHg while the range was 0.4-0.8 mmHg.

Types of foot deformity

As shown in Table 5, prominent metatarsal was the commonest observed foot deformity in patients with the foot-at-risk while the least observed deformity was the presence of bunions. Limited joint mobility in the hands was found in 96(20.3%) of these subjects.

Table 5. Patterns of foot deformity seen in patients with the "foot at risk"

Deformity	Frequency
Prominent metatarsals	61(12.8%)
Callus	40 (8.4%)
Claw toes	35(7.4%)
Hallux valgus	30(6.3%)
Hammer toes	26 (5.5%)
High arched feet	20 (4.2%)
Bunions	13 (2.7%)

Differential clinical features of subjects with the foot at risk and those with non risk feet

A comparison of the patients with foot-at-risk and those without foot-at-risk is shown in Table 6. The patients with the "foot at risk" were older than those with non risk feet and the difference in age was statistically significant.

Table 6. Comparison of the clinical and socioeconomic factors in subjects with foot at risk and those without risk

Factors variable	Foot at risk	Non-risk foot	P
Sex F: M	233:241	150:129	>0.05
Age (years) (mean±SD)	60.4±7.75	58.9±9.36	0.03
Age Group classes			
Young/middle age n (%)*	212 944.7%)	144 (51.7%)	> 0.05
Elderly (%)	262 (55.3%)	135 (48.4%)	
Weight (In kg) (mean±SD)	70.7±29.2	71.8±36.9	> 0.05
BMI (kg/m2) (mean±SD)	26.9±12.1	27.4±15	> 0.05
BMI classes			
Normal weight n (%)	162 (37.1%)	90 (32.8%)	
Overweight/obese n (%)	275 (62.9%)	184 (67.2%)	> 0.05
Educational status†			
High n (%)	172 (36.5%)	164 (54.7%)	< 0.001
Low n (%)	300 (63.5%)	114 (45.3%)	
Social classes‡			
High n (%)	88 (19.9%)	50 (18.1%)	> 0.05
Low n (%)	377 (81.1%)	227 (81.9%)	
Smoking history n (%)	44 (9.3%)	18 (6.6%)	> 0.05
Inadequate shoes n (%)	403 (85%)	252 (90.3%)	> 0.05
Walking unshod			

*Young/middle aged refers to those patients between 21-60 years while elderly are those aged greater than 60 years. †Educ refers to high educational class which comprises those subjects that had university, polytechnic or secondary school education while non Educ refers to those that had primary school education or were illiterates. ‡High social class refers to those that belonged to the professional class or an intermediate professional class while low social class refers to skilled, partially skilled or unskilled workers.

Table 7. Characteristic features of diabetes in patients with "foot at risk" and non "foot at risk"

Variable	Foot at risk	Non risk feet	P
Duration of DM (yrs)	8.4±5.4	5.8±4.8	< 0.001
DM duration (classes)*			
Short term	120 (25.3%)	132 (47.3%)	
Medium/long term	354 (74.7%)	147 (52.7%)	< 0.001
Mean FPG (mg/dL)	150.8±49.3	113.6±31.1	< 0.0001
Glycaemic control			
Good/fair	223 (47.0%)	252 (90.3%)	
Poor	51 (53.0%)	27 (9.7%)	< 0.001

*Short term-<5 yrs, medium-5-9.9yrs, long-term->10yrs

There were however no statistically significant differences observed in the mean weight and mean body mass indices in the two groups. The majority of patients with the "foot at risk" were illiterate while those without the foot at risk had secondary school education.

Comparison of characteristics of diabetes mellitus in patients with and without foot at risk

The mean duration of diabetes mellitus and the mean fasting plasma glucose were sig-

nificantly higher in patients with the "foot at risk" than in those without the "foot at risk". Table 7 shows that more than half of the patients with the foot at risk (261, 53%) had poor glycaemic control while this was found in only 27(9.7%) of those without the foot at risk ($p<0.001$).

Discussion

More than 120 million people in the world suffer from diabetes mellitus and very many of these subjects have diabetic foot ulcers which may eventually lead to an amputation.[11] Given the high costs associated with diabetic foot ulceration, this disorder is not only a major burden to the patient but also the health care system. Identification of the risk factors for foot ulceration is of paramount significance in the prevention of these enormous complications of diabetes mellitus. Diabetic foot lesions are an important cause of morbidity and mortality in Nigerians with diabetes mellitus[2,11,6-10] and therefore deserve an in-depth study. The results are also hoped to influence policy makers to make and implement people oriented policies especially with reference to treatment of diabetes mellitus foot syndrome.

The prevalence of 41.5% of DM patients with the foot at risk in this study was high. This high prevalence may have been due to the fact that over 50% of them had poor glycaemic control and medium/long duration of diabetes mellitus. The majority of the DM subjects with the foot at risk were of a low socio-educational status, overweight or obese, elderly and often walked unshod. There was a slight male preponderance. Generally, there was a predominance of patients with Type 2 DM (>85%). For those with the foot at risk, the commonly used form of treatment was that intake of oral hypoglycaemic agents while the least used treatment modality was the combination of oral hypoglycaemic agents and insulin.

Common potential risk factors for foot ulceration identified in this study were mainly those that have been documented previously[8,10] and included DM neuropathy, poor glycaemic control, structural foot deformity and peripheral vascular disease. These lend support for a multi factorial etiology for diabetic foot ulceration. Long duration of DM has been inconsistently reported as a risk factor for foot ulceration.[8,15-16] Not significantly related to foot ulcer incidence in this study was diabetes duration. Though subjects with the foot at risk had a significantly higher duration of DM than their controls, this difference was not statistically significant.

One universal observation, supported by this study is the presence of neuropathy as being one of the commonest long-term complications of DM[8,10,12,17] and this was documented in 76% of the subjects with the foot at risk in this study.

Mechanical factors play an important role in the initiation of foot ulcers with injury typically occurring in the setting of a foot deformity.[10] The role of mechanical factors in diabetic foot ulceration has not been widely reported in the Nigerian population.[8,11] Studies in the United States of America have reported that foot deformities contribute as much as 78%[10] to DFU. In this study, foot deformity was however, present in 26% of the subjects with the foot at risk. The mechanical abnormalities found in this study included prominent metatarsals-which was the commonest (12.6%), callus formation, claw toes, hallux valgus, hammer toes, high arching of the feet and bunions. Among patients who have lost protective sensation, the most common mechanism of injury appears to be unperceived, excessive, and repetitive pressure on sites of foot deformities. This lead to elevated focal pressure making ulceration even more likely .[10,18]

Twenty percent of the subjects with the foot at risk for ulceration, had limited joint mobility of the hands-an indicator of microvascular complications of DM. The role of the microvascular complications of DM with regards to foot lesions cannot be overempha-

sized as these are well documented risk factors for foot ulceration in diabetes.

Peripheral vascular disease which is said to be less common among Africans with diabetes mellitus[8,10] than their Western counterparts was found in 12% of the patients with the foot at risk. This figure may be an underestimation since people with diabetes mellitus may have medial sclerosis (Monckeberg sclerosis) thus giving rise to falsely elevated ankle systolic pressure.[10] Going beyond ABI measurement and actually visualizing the arterial waveforms gives a more accurate assessment of the vascular status but unfortunately, this could not be done in this study. Previous local studies[8,11,20] did not show strict objective evidence of PVD. This might partly account for the relatively high prevalence of PVD-54% noted in one of these studies.[8]

Inherent factors such as previous ulceration and amputation often lead to reccurrence of ulceration and re-amputation.[10] Previous ulceration was noted in 6.3% while previous amputation was noted in 2.5% of the patients with the foot at risk. These figures are similar to those reported by Bailey et al.[10] Nigerian reports about re-amputation rates in diabetic subjects are scant.

Of paramount importance in the genesis of diabetic complications is poor glycaemic control. The mean fasting plasma glucose was noted to be considerably higher in patients with the foot at risk than the control groups. Various studies have shown similar findings.[8,10,22-23] The proper method of assessing long term glucose control which is by the determination of HbA1c could not be carried out on this study because of financial constraints.

Tinea Pedis, an often overlooked risk factor for foot ulceration may provide a portal entry for more serious infections in the diabetic foot. Tinea pedis presents as numerous small itchy vesicles (the pruritus may be absent in diabetic subjects with neuropathy), or as macerated hyperkeratosis associated with digital fissuring.[10] Tinea pedis though not widely reported in the literature was found in 16 % of the patients with the foot at risk and there was no difference in its distribution between subjects with type1 and type 2 DM.

Conclusion

There is a high prevalence of foot-at-risk among Nigerian patients with diabetes mellitus.

The foot at risk was found more in patients with type 2 DM than in those with type 1 DM (465:9) and the prevalence of risk factors for foot ulceration was 41.5%

Diabetic patients that were particularly at risk for foot ulceration were elderly patients with type 2 DM.

Factors often overlooked such as the presence of mechanical factors and Tinea pedis should be sought out for in people with diabetes mellitus.

As part of a foot care program, education on foot care should also be directed at health care providers. Education about diabetic foot care is not only important for the person with diabetes with an increased foot risk but also for their family members and health-care providers.[24]

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