



High Risk Foot Among Type-2 Diabetes Mellitus Patients in a Tertiary Care Hospital

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Abstract

Background: Feet of diabetic persons are at a high risk of developing complications and their prevalence is very high. Uncontrolled diabetes i.e. hyperglycemia particularly chronic hyperglycemia plays the most critical role in developing all forms of macro and microvascular complications in foot. The “high risk foot” can be identified by simple clinical examination. A structured screening program for “High Risk Foot” integrated with all diabetic care units is essential. **Objectives:** The study was initiated to determine the frequency of “high-risk foot” among Type 2 diabetic patients. **Methods:** It was a cross-sectional observational study, conducted among 324 Type 2 diabetic patients attending BIRDEM General Hospital, Dhaka, Bangladesh. All participants were interviewed by an administered questionnaire, underwent clinical examination and review of medical records from the diabetic guide book of the patients and hospital records. **Results:** Among a total of 324 patients, 198(61%) patients were having high-risk feet. Of the diabetics with high risk foot- loss of protective sensation 73.2%; absent pedal pulse 23.2%; history foot ulcer 25.3%; limited joint mobility 15.2%; foot deformity 11.1% and previous foot amputation 3.5%. The study population had poor glycemic status (HbA1c 10.81±5.23%). Other variables age 55.43 (± 11.062) years; BMI: 25.33±5.7 kg/m²; duration of diabetes 14.24±7.25 years; sex ratio (M: F) 1.3:1; family history of DM 71.9%; hypertensive 53.1%; smoker 73.5%; dislipidemia 52.8%, albuminuria 58.6%, and retinopathy 53.7%. Males are significantly higher in the high-risk foot. **Conclusion:** This study documented a very high frequency of high risks foot in our diabetic population. Peripheral Neuropathy (PN) and PVD are two common forms of high risk foot and these are influenced by a longer duration of diabetes, the presence of albuminuria for PN, and retinopathy. Male sex, longer duration of diabetes, presence of hypertension and smoking for PVD. Regular foot examination and treatment to target patients will modify the modifiable risk factors and thereby prevent foot ulcers and amputation.

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INTRODUCTION

Diabetes mellitus (DM) is defined as a group of metabolic diseases characterized by

hyperglycemia resulting from defects in insulin secretion, insulin action, or both.^[1] Diabetes mellitus is classified on the basis of etiology and clinical presentation of the disorder into four



types: type1diabetes, type 2 diabetes, other specific types, and gestational diabetes.[2] In 2019, global estimates of people with diabetes is 463 million , projected to reach 700 million by 2045 and the prevalence of diabetes would rise from 8.3% to 9.6% by 2045.[3] Diabetes is the fifth leading cause of death in the world which accounts for about 4.2 million deaths annually.[3,4] Prevalence of diabetes is increasing at an alarming rate all over the world.[5] The low and middle-income countries, in particular are the major contributors (about three quarters) to the global burden of diabetes.[3,6] China and India hold the 1st and 2nd position respectively having 116.4 and 77.0 millions of total cases of diabetes in adult population in 2019.[3] It is anticipated that more than 80% of the world's population with diabetes will come from developing countries and by the year 2030 more than 60% of the world's population with diabetes is expected to be living in Asia.[2] In 2019, it was estimated that 8.4 million of the Bangladeshi population were diabetic.[3] Compared with the previous reports of Bangladesh and other Asian studies, the prevalence of diabetes and IFG in the rural population was found to be on the increase. Older age, higher obesity, higher income, family history of diabetes, and reduced physical activity were proved significant risk factors for diabetes and IFG.[8] Foot ulcerations are one of the most common complications in patients with diabetes. It has been estimated that the lifetime risk of a patient with diabetes developing a foot ulcer may be as high as 25% and at any one time in western countries, 2%-3% of diabetic patients are likely to have active foot ulceration.[9,10] Diabetic Foot Ulcer (DFU) affects 15% of people with diabetes.[11] DFUs typically result from peripheral neuropathy

and/or large vessel disease. But most commonly DFUs are caused by peripheral neuropathy complicated by deformity, callus and trauma.[12] Vascular insufficiencies, infections, and failure to implement effective treatment of DFUs are linked to secondary medical complications, such as osteomyelitis and amputation.[13] The factors predispose to tissue damage in the diabetic foot are neuropathy, peripheral vascular disease, and infection. From the practical point of view, the diabetic foot can generally be considered as one of two entities: the neuropathic foot and ischaemic foot. In a neuropathic foot, somatic and autonomic nerve fibers have been damaged but the circulation is intact and pulses palpable, resulting in a warm, numb, and dry foot. Neuropathy develops in both type-1 and type-2 patients with longstanding diabetes. The most common manifestation is peripheral neuropathy of the foot and ulcers can occur on the weight-bearing surface. The incidence of peripheral neuropathy (PN) in T2DM is 30%. [14] A study conducted in BIRDEM Hospital in Bangladesh showed the overall prevalence of diabetic peripheral neuropathy (DPN) as 19.7%. [15] A study conducted in Sweden showed the prevalence of DPN was 57%. [16] General healing rates for neuropathic DFUs have been reported in the literature. [17] The ischaemic foot has reduced blood supply, but usually also shows a variable degree of neuropathy and so should strictly be termed as the neuroischaemic foot is usually cold and pulseless and may be complicated by rest-pain, ulceration due to localized pressure necrosis and ultimately gangrene formation. Peripheral arterial disease (PAD) is a chronic atherosclerotic process that causes narrowing of peripheral arterial vasculature, mainly of the lower limbs which



has an estimated worldwide prevalence of up to 10%, increasing to about 30% in patients more than 50 years of age.^[18] Patients with diabetes have a 4-fold increased risk of developing PAD which presents at an earlier stage and progresses more rapidly than in people without diabetes.^[19] The larger arteries are affected in the same way as for non-diabetics, but those of the calf are involved to a greater extent.^[20] Hyperglycemia appears to be directly related to the susceptibility to infection. When glucose concentrations exceed 240 mg/dl, neutrophilic chemotaxis is impaired.^[21] It has also been shown that elevated plasma glucose levels in the postoperative period increases the risk of infection.^[22] Chronic hyperglycemias have also been shown to diminish a patient's capacity to heal wounds after surgery. Although the precise mechanism remains unknown, hyperglycemia increases the presence of microvascular and macrovascular diseases, decrease phagocytosis, chemotaxis, and polymorphonuclear leukocyte mobilization.^[23] Growth factors such as VEGF, PDGF, and KGF may also be produced at lower levels or in less effective forms.^[24] Skin fibroblast proliferation has also been shown to decrease in the presence of hyperglycemia.^[25] Diabetic foot ulcers and infections are usually initiated by minor trauma and can become extensive, deep, and spreading. These infections require surgical drainage and debridement, which frequently involves amputation at the toes, the trans metatarsal level, or even the foot or leg. In patients with major foot infections and signs of spreading sepsis, antibiotics active over a wide spectrum of organisms including anaerobes, are indicated. Diabetic foot problems are a global burden and the consequences are major. There is an increase in amputation rates globally

despite increased foot care education, research, and prevention. This has been attributed mainly to diabetes and the failure of early detection of the risk group. As it is a complication that is preventable by simple measures that can largely be taken by the patient himself. Frequent clinical examination of the feet and related systems forms the mainstay of detecting diabetic foot; investigations are only an adjunct to clinical examination. The treatment is usually conservative and a limb sparing approach is used, along with proper diabetes control. Early detection and management of aetiological factors like vasculopathy, neuropathy and infection is essential to get good outcomes. Amputation is usually used as a last resort in non-salvageable limbs. Above all, this is one condition which proves the maxim that "prevention is better than cure".^[26]

Objectives

To detect high risk foot among type 2 diabetic patients and to determine its frequency.

MATERIAL AND METHODS

It was a cross-sectional observational study, conducted at Bangladesh Institute of Research & Rehabilitation in Diabetes, Endocrine and Metabolic Disorders (BIRDEM), Dhaka from July 2013 to June 2014. The adult patient of more than 18 years type 2 diabetic who fulfilled the inclusion criteria attending both out-patient & in-patient departments were enrolled in the study as the study population. Patients suffering from severe co-morbid conditions (ESRD, severe heart failure, liver failure, respiratory failure), type 1 diabetes, GDM, other specific type of diabetes and patients with impaired glucose tolerance or impaired fasting

glucose were excluded in this study. The information regarding demographics, socioeconomic, and lifestyle characteristics were collected by interviewing the participant. Complete history and physical examinations were done. Weight and height were measured with minimal clothes without shoes and BMI (kg/m²) was calculated. Both feet were examined for signs of vasculopathy (assessment of pedal pulses) and neuropathy (using 10-gm monofilament, 128-Hz tuning fork, percussion hammer) including the presence of deformities, callus, limited joint mobility. History of ulceration, gangrene, and amputation were also noted. From the patient's guidebook and hospital records, diagnosis and diseases related recent biochemical data (within the last 6 months) were collected. Ethical approval from the ethical approval committee of the Diabetes Association of Bangladesh was obtained prior to the commencement of the study. From the participants informed written consent was taken. SPSS version 19.0. used for data analysis. Individual risk factors were identified through Multivariate analysis and the possible confounders were adjusted. Odds Ratio with 95% CI was generated through binary logistic regression to assess individual refractors adjusting for all possible confounders. A value of $p < 0.05$ was considered statistically significant.

RESULTS

In 324 type 2 diabetic patients, mean age was 55.43 (± 11.062) years & median was 56.0. SD 11.064, SE 0.615, range (30-80); CI (54.22-56.64), male female ratio was 1.3:1. Most of the patients were ≥ 60 years old. Most of the patients were educated up to various levels. More than half of the patients were either current or ex-smokers.

Considerable percentages of the patients (44%) were overweight or obese. High risk foot was diagnosed on the basis of the presence of one or more of the following factors: loss of protective sensation, absent pedal pulse, foot deformity, limited joint mobility, history of foot ulcer and previous amputation. Among them 61% (198) were having high risk foot. Risk factors were loss of protective sensation 44.7% (145), H/O foot ulcer 15.43% (50), absent pedal pulse 14.20% (46), limited joint mobility 9.26% (30), foot deformity 6.79% (22) and H/O previous amputation 2.16% (7).

Among total 324 patients, 44% were diagnosed through screenings and 35% by symptoms. Incidental diagnosis was less. More than 34% of the patients had the disease for ≥ 10 years. Of the total population 53% had hypertension. Importantly, 72% had family history of DM. Peripheral neuropathy was present in more than half of the patients (54%) while the frequency of peripheral vascular disease was less (14.2%) [Table 2].

High total cholesterol was present in 31.5%, high triglycerides in 43%, high LDL in 18.8% while low HDL was present in 52.5% of the study population. The analysis of glycaemic control using HbA1C showed that 28% had good control [Table 3].

The parameters on which high risk foot was diagnosed are given in the table 4. Among the 198 Diabetic patients with High risk foot - Loss of protective sensation was reported in 145 patients (73.2%); Fifty patients (25.3%) had history of foot ulceration; Pedal pulse was absent in 46 patients (23.2%) while 30 patients (15.2%) had limited joint mobility and 22

patients (11.1%) had foot deformity and 7 patients (3.5%) had history of foot amputation.

The number of current smokers and ex-smokers were significantly higher in high risk group. Non-smokers were almost equal in both groups [Table 5].

In controlled diabetes group the frequency of high risk foot was less but in uncontrolled diabetes group this was significantly higher [Table 6].

Old patients suffered from the condition significantly more than relatively younger ones. Longer duration of DM, presence of albuminuria, poor control of DM and presence of retinopathy were significantly related to PN [Table 7].

Cross tabulation between peripheral vascular diseases (PVD) and different variables are showed in [Table 8]. No difference was observed for gender or age while presence of retinopathy and hypertension were significantly related to PVD.

The multivariate stepwise logistic regression analysis of PN on variables including sex, level of education, age group, duration of disease, presence of retinopathy, albuminuria, and HbA1c, showed that PN was only significantly associated with increased duration of disease ($p=0.002$), presence of albuminuria ($p=0.012$) and presence of retinopathy ($p<0.001$) [Table 9].

The multivariate stepwise logistic regression analysis of PVD on variables including sex, age group, level of education, duration of disease, presence of hypertension, HbA1C and presence of albuminuria revealed that only male, (adjusted OR: 0.254; 95% CI: 0.132-0.631), increased DM duration (adjusted OR: 0.452; 95% CI: 0.278-0.682), low level of education (adjusted OR: 2.371; 95% CI: 1.03-3.720), presence of hypertension (adjusted OR: 1.352; 95% CI: 0.83-2.20) and H/O smoking (adjusted OR: 1.321; 95% CI: 0.81-2.17) were significantly associated with PVD [Table 10].

Table 1: Socio-demographic characteristics of the patients (N=324).

Variables	Frequency (n)	Percent (%)
Gender		
Male	183	56.5
Female	141	43.5
Age group (yrs.)		
≤ 40	35	10.8
41-49	64	19.7
50-59	88	27.2
≥ 60	137	42.3
Smoking & tobacco use		
Current smoker	59	18.21
Ex-smoker	91	28.09

Non smoker	150	46.30
Tobacco user	24	7.41
BMI group		
Under weight	18	5.6
Normal weight	163	50.3
Over weight	96	29.6
Obese	47	14.5

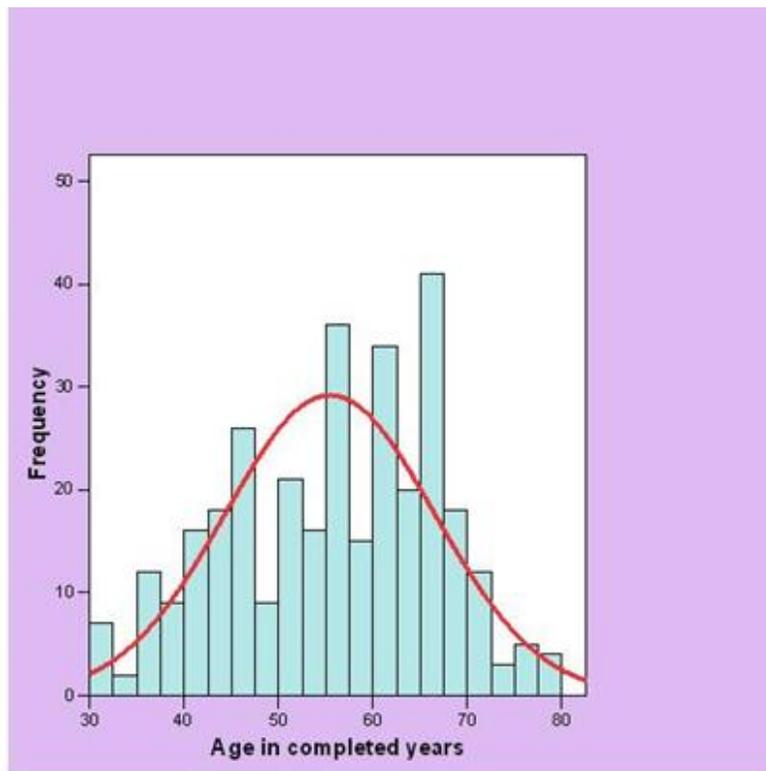


Figure 1: Age distribution of the patients

Table 2: Clinical characteristics of Type 2 diabetes patients (N=324).

Variables	Frequency (n)	Percent (%)
Mode of diagnosis		
Incidental	68	21.0
Screening	142	43.8
Symptomatic	114	35.2
F/H of diseases		
Diabetes	233	71.91
Hypertension	128	39.51
Ischemic Heart Disease	29	8.95



Duration of Diabetes		
<1 year	29	9.0
1-5 years	119	36.7
6-10 years	58	17.9
11-20 years	90	27.8
>21 years	28	8.6
Hypertension		
Present	172	53.1
Absent	152	46.9
Peripheral neuropathy		
Present	175	54.0
Absent	149	46.0
Peripheral vascular disease		
Present	46	14.2
Absent	278	85.8

Table 3: Lipid profile and some other investigations of patients (N=324)

Variables	Frequency (n)	Percent (%)
Total cholesterol		
High (> 200 mg/dL)	102	31.5
Normal (≤ 200 mg/dL)	222	68.5
Triglyceride		
High (> 150 mg/dL)	140	43.21
Normal (≤ 150 mg/dL)	184	56.79
HDL		
High (> 40 mg/dL)	154	47.53
Low (≤ 40 mg/dL)	170	52.47
LDL		
High (> 100 mg/dL)	61	18.83
Normal (≤ 100 mg/dL)	263	81.17
Albuminuria		
Present	190	58.64
Absent	134	41.36
HbA1C		
Good control (< 7%)	91	28.09
Poor control (≥7%)	233	71.91

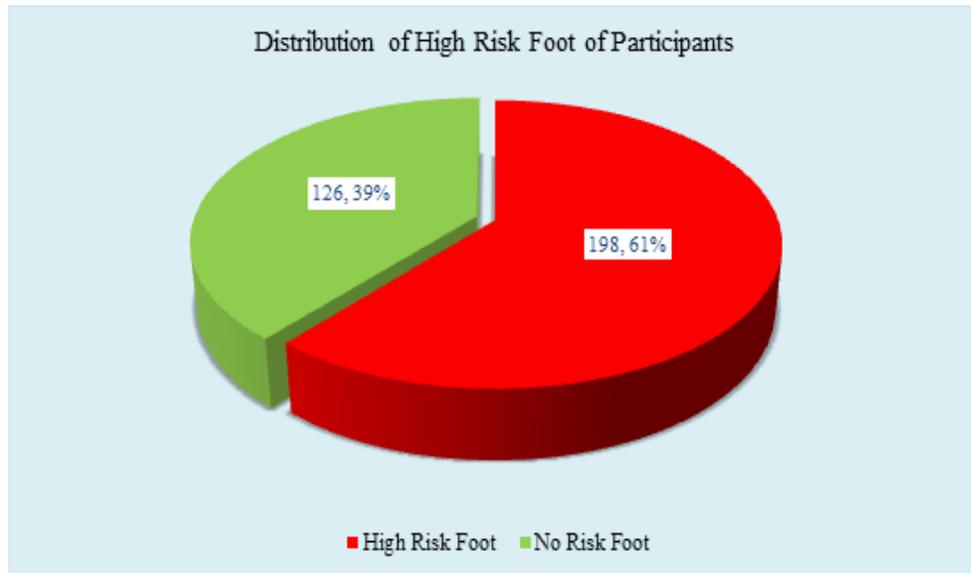


Figure 2: Pie diagram showing high risk foot among type 2 diabetic subjects (N=324)

Table 4: Conditions lead to high risk foot(N=198)

Variables	Frequency (n)	Percent (%)
Loss of protective sensation	145	73.2
H/O foot ulcer	50	25.3
Absent pedal pulse	46	23.2
Limited joint mobility	30	15.2
Foot deformity	22	11.1
H/O previous amputation	7	3.5

Table 5: Cross tabulation between smoking habits and high risk foot (N=324)

Habits of smoking	High risk foot		p-Value
	Yes n (%)	No n (%)	
Current smoker	65 (32.8)	38 (30.2)	<0.001 ^s
Ex- smoker	76 (38.4)	21 (16.7)	
Non- smoker	44 (22.2)	42 (33.3)	
Tobacco user	13 (6.6)	25 (19.7)	

Table 6: Cross tabulation between status of diabetes and high risk foot (N=324)

Diabetes Status	High risk foot		p-Value
	Yes n (%)	No n (%)	
Controlled	24 (12.1)	67 (53.2)	<0.001 ^s
uncontrolled	174 (87.9)	59 (46.8)	

Table 7: Peripheral Neuropathy in relation to baseline characteristics of the study population

Variables	Peripheral Neuropathy		p-Value
	Present n (%)	Absent n (%)	
Gender			
Male	104 (59.4)	79 (53.0)	0.246
Female	71 (40.6)	70 (47.0)	
Age group			
Up to 40 years	19 (10.9)	16 (10.7)	0.007 ^s
41-49 years	31 (17.7)	33 (22.1)	
50-59 years	61 (34.9)	27 (18.1)	
≥ 60 years	64 (36.6)	73 (49.0)	
Duration of the disease			
<1 year	7 (4.1)	14 (9.6)	<0.001 ^s
1-5 years	40 (23.5)	79 (54.1)	
6-10 years	38 (22.4)	20 (13.7)	
11-20 years	67 (39.4)	23 (15.8)	
>21 years	18 (10.6)	10 (6.8)	
Albuminuria			
Present	109 (62.3)	21 (14.1)	<0.001 ^s
Absent	66 (37.7)	128 (85.9)	
HbA1C			
Good control (< 7%)	44 (25.1)	102 (68.5)	<0.001 ^s
Poor control (> 7%)	131(74.9)	47 (31.5)	
Retinopathy			
Present	141 (80.6)	33 (22.1)	0.002 ^s
Absent	34 (19.4)	116 (77.9)	

Table 8: Peripheral Vascular Disease in relation to baseline characteristics of the study population

Variables	Peripheral Vascular Disease		p-Value
	Present n (%)	Absent n (%)	
Gender			
Male	28 (60.9)	155 (55.8)	0.517
Female	18 (39.1)	123 (44.2)	
Age group			
Up to 40 years	1 (2.2)	34 (12.2)	0.074
41-49 years	14 (30.4)	50 (18.0)	
50-59 years	13 (28.3)	75 (27.0)	
≥ 60 years	18 (39.1)	119 (42.8)	

Retinopathy			
Present	34 (73.9)	140 (50.4)	0.003 ^s
Absent	12 (26.1)	138 (49.6)	
Coronary artery disease			
Present	10 (21.7)	33 (11.9)	0.068
Absent	36 (78.3)	245 (88.1)	
Hypertension			
Present	33 (71.7)	139 (50.0)	0.006 ^s
Absent	13 (28.3)	139 (50.0)	

Table 9: Multivariate analysis of risk factors for PN among DM patients using stepwise Logistic Regression

Variable	Regression coefficient	p-Value	Adjusted OR	95% CI
Increase DM duration	-0.491	0.002	0.67	0.056-0.96
Presence of albuminuria	-0.547	0.012	0.59	0.38-0.78
Presence of retinopathy	2.590	<0.001	1.37	0.52-3.620

Table 10: Multivariate analysis of risk factors for PVD among DM patients using stepwise Logistic Regression

Variable	Regression coefficient	p-Value	Adjusted OR	95% CI
Male	-1.435	0.013	0.254	0.132-0.631
Increased DM duration	-0.765	0.012	0.452	0.278-0.682
Low level of education	0.876	0.002	2.371	1.03-3.720
Presence of hypertension	0.786	0.003	1.352	0.83-2.20
H/O smoking	-1.287	<0.001	1.321	0.81-2.17

DISCUSSION

The mean age of the patients was 55.43 (±11.062) years. Among total 324 patients, most of the patients were ≥60 years and literate. Male-female ratio was 1.3:1. More than half of the patients were either current or ex-smokers. 44% patients were diagnosed through screenings and 35% by symptoms. More than 34% of the patients had the disease for ≥10 years. Of the total population, 53% had hypertension. 72% had a family history of DM which is consistent

with other studies.[27, 28] High total cholesterol was present in 31.5%, high triglycerides in 43%, high LDL in 18.8% while low HDL was present in 52.5% of the study population. Other study reported high total cholesterol in 34.4%, high triglycerides in 25.2%, high LDL in 53.4% while low HDL in 25.7% study population.[27] The analysis of glycaemic control using HbA1C showed that 28% had good control in contrast to 38%.[27] The majority of patients who attended 100 diabetic patient care centers all

over Bangladesh, had HbA1C and FPG levels above the recommended levels, and around 80% diabetic patients failed to achieve target glycaemic control.^[29] The parameters on which high-risk foot was diagnosed were loss of protective sensation (44.7%), history of foot ulceration (15.43%), absent pedal pulse (14.2%), limited joint mobility (9.3%), and foot deformity (6.8%) and 7 patients (2.16%) had a history of foot amputation. On the basis of the presence of one or more parameters, 198 (61%) patients were stratified as having high risk foot. This rate is high as some other studies reported lower rates.^[28] Older patients significantly suffered more from the condition than relatively younger ones. As proved elsewhere, the current study results demonstrate that DM eventually leads to chronic complications, including PVD and PN which are known potential risk factors for foot complications. So, it is vital to observe PN and PVD among patients for diabetes foot complications. The results of this study showed that the overall frequency of PN was 54%, which is almost similar to rates reported in other studies and higher than the equivalent rates reported in other study.^[30,31] The risk factors for neuropathy, predicted using univariate analysis were: age ($p=0.007$), disease duration ($p<0.001$), poor level of education ($p=0.001$), and poor glycaemic control ($p<0.001$). The complication was also highly significantly associated with other microangiopathic complications such as the presence of albuminuria ($p<0.001$) and diabetic retinopathy ($p=0.002$). These findings are quite comparable to another study findings except that in their study male gender was also significantly associated with PN which was not the case in the present study.^[27] Small sample size could be the cause for such a difference.

Comparatively, the rate revealed for PVD (14.2%) in the study population was lower than that reported in other study populations,^[32] but almost similar to UAE population which showed 12% prevalence of PVD.^[27] However, the fact that 54% of the sample population have signs of neuropathy, is a clear indication that they are at increased risk of developing foot complications in the future. The high prevalence of PN compared with the relatively low prevalence of PVD in the study population can be due to methodological biases for diagnosing neuropathy and PVD. On univariate analysis predicted risk factors for PVD were: the presence of retinopathy ($p=0.003$) and hypertension ($p=0.006$). The multivariate stepwise logistic regression analysis of PN and PVD on variables including sex, level of education, age group, duration of disease, presence of hypertension, retinopathy, albuminuria, and HbA1c, showed that PN was only significantly associated with increased duration of disease ($p=0.002$), presence of albuminuria ($p=0.012$) and presence of retinopathy ($p<0.001$). On the other hand, only males, (adjusted OR: 0.254; 95% CI: 0.132-0.631), increased DM duration (adjusted OR: 0.452; 95% CI: 0.278-0.682), low level of education (adjusted OR: 2.371; 95% CI: 1.03-3.720), presence of hypertension (adjusted OR: 1.352; 95% CI: 0.83-2.20) and H/O smoking (adjusted OR: 1.321; 95% CI: 0.81-2.17) were significantly associated with PVD. The results are consistent with findings elsewhere.^[33] It is interesting to note that albuminuria was the modifiable risk factor for PN, revealed in the study and the result is consistent with similar studies elsewhere.^[34] However, some studies suggest that increased urinary albumin might be a marker for endothelial damage, the function of



which may be the common cause of both microvascular and macrovascular diseases.^[35,36,37] Similarly, the analysis revealed that hypertension is the modifiable risk factor for PVD in the study population, and the result is consistent with findings elsewhere.^[38]

Limitations of the study

Assessment of inter-observer variability was not possible due to the single observer study design. For neuropathy, the study was unable to correlate the clinical findings with electrophysiological and morphologic findings such as nerve conduction studies. For diagnosis of PVD only presence or absence of peripheral pulse was used, measurement of Ankle Brachial Index (ABI) & duplex ultrasound was not done.

CONCLUSIONS

It was observed that high-risk foot was related to a) loss of protective sensation like loss of vibration sense and ankle jerk; b) history of foot ulceration; c) absent pedal pulse that represented peripheral vascular disease and d)

limited joint mobility. Of these, the most frequent findings were loss of sensation especially vibration sense, and loss of ankle jerk. More study is needed to confirm the study findings so that early detection may help to prevent foot ulcer and eventual amputation and disabilities.

Recommendations

It is essential to encourage physicians to pay more attention and care to foot examination, regular screening for foot complications to all diabetic patients especially among the elderly and illiterate patients, in view of the high reported rates of high-risk foot and to maintain glycaemia at a satisfactory level to reduce the risk of diabetes-associated complications. Emphasize the importance of regular screening for albuminuria and hypertension in diabetic patients as it is a modifiable risk factor for both microvascular and macrovascular complications. To improve patient's knowledge on risks of developing foot ulcers and on foot self-care.

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