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Factors Associated with Diabetic Foot Ulceration among Diabetes Mellitus Type 2 Patients at Dow University Hospital, Karachi

Syed Muhammad Adnan[1*], Samreen Fatima[2] and Syed Muhammad Hasan[3]

[1]Department of Community Medicine, Dow International Medical College, Dow University of Health Sciences, Karachi, Pakistan
[2]Department of Statistics, University of Karachi, Karachi, Pakistan
[3]Department of National Institute of Diabetes and Endocrinology, Dow International Medical College, Dow University of Health Sciences, Karachi, Pakistan

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***Corresponding Author:**
Syed Muhammad Adnan
Department of Community Medicine, Dow International Medical College, Dow University of Health Sciences, Karachi, Pakistan
syed.adnan@duhs.edu.pk

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ABSTRACT

Diabetic foot ulcer is one of the important problems related to diabetes which affects the quality of life of the diabetic patients. **Objective:** To determine the factors (demographic characteristics, glycemic control, CVD or CKD) associated with diabetic foot ulceration among diabetic patients. **Methods:** A registered patient's data taken from Dow University Hospital (DUH), Karachi.The multiple risk factors which includedphysical activity, smoking status, dietary intakes, duration of diabetes and co-morbidities. Multiple logistic regression and STATA version 15 was used to analyze the overall results and p value < 0.05 was considered to statistically significant.**Results:** In DM Type 2 patients, 664(71.4%) were male and 266 (28.6%) were female and the median age was 53.23 years.The hypertensive patients were 4.33 times higher risk of developing DFU (OR=4.33, 95% CI: 2.11-8.89, p<0.001) and the CVD patients was 2.67 times higher risk of developing DFU (OR=2.67, 95% CI: 1.25-5.68, p=0.011). The diabetic patients who did regularly exercises were 68% less chances of risk of developing DFU (OR=1.68, 95% CI: 0.16-0.74 p=0.006). On the other hand, the diabetic patients for regular foot checkup were 2.02 times less chances of developing DFU (OR=2.04, 95% CI: 0.02-0.11 p<0.001).According to evaluation of HADS, the anxiety (p=0.023) and depression (p<0.01) score were more increased in DFU patients as compare to without DFU patients. **Conclusions:** Risk factors (age, BMI, duration of diabetes, physical activity, co- morbidities and anxiety and depression) were highly connected with DM type 2 diabetic foot ulcers patients.

INTRODUCTION

Diabetes Mellitus is a chronic lifelong metabolic disorder characterized by increase level of blood sugar and there are abnormalities in carbohydrate, protein and fat metabolism. Worldwide diabetes is one of the prime causes of death and disability and based on etiology it is divided into four categories, type I diabetes, type II diabetes, gestational diabetes and other specific type [1]. Certain macro vascular and micro vascular complications are associated to diabetes, macro vascular complication involves large blood vessels consist of cardiovascular disease, and peripheral vascular disease, on the other hand small blood vessel involve in micro vascular complication which comprise nephropathy, retinopathy and neuropathy [2]. Worldwide prevalence of adult diabetes is 537 million between the age group of 20 to 79, which is by 2030 a number of 643 million people or one adult in 10, this means in every 10 second approximately 3 new cases of diabetes will appear.Prediction of worldwide increasing of diabetes cases is about 783 million by 2045 [3]. According to international diabetic foundation in Pakistan, diabetic inhabitants were estimated 6.9 million people of age group 20 to 79 years in 2003, and it is predictable to reach 11.5 million by 2025, this produces the diabetic population of Pakistan on 1st position, in next ten years in Pakistan, deaths by diabetes alone estimated to rise by 51% [4]. It is predictable that just about 15% of the more than 150 million people with diabetes worldwide will at some stage build up diabetic foot ulceration [5]. Foot ulceration is disabling and

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common diabetic complication and life time threat to develop this complication may be as high as 25% in patient having diabetes [6].In diabetic people lower extremity disease, including, foot ulceration, peripheral neuropathy and lower extremity amputation are twofold common as compared to non-diabetic people and if the diabetic person is older than 40 years its affect 30% [7]. The risk of new diabetic foot ulceration increases if there is history of previous foot ulceration. Diabetic foot ulceration precedes 85% of lower limb amputation and after limb amputation mortality rate is high [8].In Pakistan the burden of DFU is varies from 10 to 22% and the cases of amputation in DFU patients is ranges from 8-21%, based on used of methodology and treatment of the disease [9].

DFU is an important issue and few researches conducted in this issue especiallyinourcommunity,thereforein thecurrentstudydeterminedthedifferent factors associated with DFU in order to recover their quality of life and minimize the heavy cost of treatment.

METHODS

An institional based retrospective case control study was conducted and the hospital recorded patients data were taken during the period of january 2010 to May 2017 from the permission of institutional head of National Institute of Diabetes and Endocrinology, DUH, Karachi with Reference No: DUHS/NIDE/2017-07-129. Detailed history from each patients regarding demographic profile (age, gender, marital status, income, education, occupation), physical activity, smoking status, dietary intakes, co-morbidities (HTN, dyslipidemia, CVD), foot hygiene's, Haemoglobin A1c (HBA1C), Fasting Blood Sugar (FBS), Random Blood Sugar (RBS), cholesterol levels, duration of diabetes, duration of hypertension and duration of diabetes foot ulcer were included after taken informed consent. A non-probability consecutive sampling technique was used for including the all diabetic type 2 foot and withoutfoot ulcer patients. All T2DM patients either gender andage were included in this study. At the time of history taken from patients with unilateral or bilateral amputations were excluded from the study. Data were entered in Microsoft Excel and analyzed in STATA version 15. Descriptive statistics were calculated for numerical data like age, duration of diabetes etc., and frequencies (percentages) in case of categorical data like classification of diabetic foot ulcer, co-morbidities or smoking status. Chi-square test of association was applied on data to analyses the direction of association of categories of foot ulcer with age, gender, Body Mass Index (BMI)(underweight, normal, overweigh and, obese) and co-morbidities, i.e. Hypertension (HTN), dyslipidemia, Choronic Kidney Diseases (CKD) and Cardio Vascular Diseases (CVD). Multivariate logistic regression analysis was applied among study variables with Adjusted Odds Rations (AOR) and 95% CI for determining the strength of association.Mann Whitney U test was used after applying Shapiro Wallis test of normality to compare the two independent variables. P-value < 0.05 was considered for statistical significant result.

RESULTS

A total n=930 DMType 2 patients (without foot ulcer n=465 and with footulcer n=465) were included in the study. In DM Type 2 patients, 664(71.4%) were male and 266 (28.6%) were female. The median age was 53.23, BMI, 28.44, duration of diabetes, 9.14, duration of hypertension, 3.12,HBA1c,8.08, low-density lipoproteins (LDL), 117.51, High-density lipoprotein (HDL), 29.18 and total cholesterol was 196.17(Table 1).

Table 1: Characteristics of Study Population

Variables	Median	IQR
Age	53.23	12.82
Income	35028.99	14.32
BMI	28.44	13.62
Waist to Hip Ratio (WHR)	0.92	1.02
Duration of Diabetes	9.14	3.31
Duration of Hypertension	3.12	2.13
HBA1C	8.08	3.43
Low-Density Lipoproteins (LDL)	117.51	10.99
High-Density Lipoprotein (HDL)	29.18	5.02
Total Cholesterol	196.17	5.30
Triglyceride	95.76	7.25

Patients with DFU were mean age (58.44 ± 15.12 years) higher than patients without foot ulcer mean age (49.13 ± 7.82 years, p<0.001). The average period of diabetes was rise in foot ulcer patients (9.03 ± 3.38 years) than patients having no sign of diabetic foot ulcer (3.14± 2.31 years, p<0.001). The average BMI of diabetic foot ulcer cases was higher (26.50 ± 5.39) than the without diabetic foot ulcer (24.44 ± 4.62, p= 0.039). The average HBA1c was higher in diabetic foot ulcer (9.91 ± 2.71) than the without diabetic foot ulcer(6.08 ± 1.32, p<0.001)(Table 2).

Table 2: Distribution of Descriptive and Demographics of Continuous Variables among the Classification of DFU

Variables	DFU		
	Yes (Mean ± SD)	No (Mean ± SD)	p-Value*
Age	58.44 ± 15.12	49.13 ± 7.82	<0.001
Income	14579.71 ± 4486.6	19028.99 ± 7553.67	0.034
BMI	26.50 ± 5.39	24.44 ± 4.62	0.039
WHR	0.92 ± 0.04	0.88 ± 0.05	<0.001
Duration of Diabetes	9.03 ± 3.38	3.14 ± 2.31	<0.001
Duration of Hypertension	4.78 ± 3.30	0.87 ± 1.13	<0.001
HBA1c	9.91 ± 2.71	6.08 ± 1.32	<0.001
LDL	128.83 ± 16.01	117.51 ± 13.99	<0.001
HDL	31.97.83 ± 5.09	29.18 ± 8.02	0.013
Total Cholesterol	201.87 ± 12.32	196.17 ± 3.30	0.025
Triglyceride	127.43 ± 18.62	95.76 ± 11.25	<0.001

*P-value calculated by Mann Whitney U Test

There was a statistically positive association between co-

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morbidity (HTN, Dyslipidemia and CVD) and diabetic foot ulcer. The hypertensive patients were 4.33 times higher risk of DFU as compared to non -hypertensive patients (OR=4.33, 95% CI: 2.11-8.89, p<0.001). Similarly, the CVD patients was 2.67 times higher risk of foot ulcer (OR=2.67, 95% CI: 1.25-5.68, p=0.011). The physical activity, diabetic diet and proper medications were also significantly associated with DFU. The diabetic patients who did regularly exercises were 34% less chances of risk of DU (OR=0.34, 95% CI: 0.16-0.74 p=0.006). On the other hand, the diabetic patients who visit regular for foot checkup were4%less chances of risk of diabetic foot ulcer(OR=0.04, 95%CI: 0.02-0.11 p<0.001),(Table3).

Table 3: Association between Dichotomous Variables among the Classification of Foot Ulcer

Variables	DFU			
	Yes N (%)	No N (%)	OR(95% CI)	p-Value*
Gender				
Male	50 (71.4%)	47 (67.1%)	1.22 (0.60-2.51)	0.583
Female	20 (28.6%)	23 (32.9%)		
HTN				
Yes	42 (60.0%)	18 (25.7%)	4.33 (2.11-8.89)	<0.001
No	28 (40.0%)	52 (74.3%)		
Dyslipidemia				
Yes	40 (57.1%)	27 (38.6%)	2.12 (1.08-4.17)	0.029
No	30 (42.9%)	43 (61.4%)		
CVD				
Yes	28 (40.0%)	14 (20.0%)	2.67 (1.25-5.68)	0.011
No	42 (60.0%)	56 (80.0%)		
Exercise				
Yes	42 (60.0%)	57 (81.4%)	0.34 (0.16-0.74)	0.006
No	28 (40.0%)	13 (18.6%)		
Diabetic Diet				
Yes	21 (30.0%)	52 (74.3%)	0.15 (0.07-0.31)	<0.001
No	49 (70.0%)	18 (27.7%)		
Regular Foot Checkup				
Yes	16 (22.9%)	61 (87.1%)	0.04 (0.02-0.11)	<0.001
No	54 (77.1%)	09 (12.9%)		
Regular Diabetic Medication				
Yes	23 (32.9%)	48 (68.6%)	0.22 (0.11-0.46)	<0.001
No	47 (67.1%)	22 (31.4%)		
Regular Cholesterol				
Medication				
Yes	26 (37.1%)	46 (65.7%)	0.31 (0.15-0.62)	0.001
No	44 (62.9%)	24 (34.3%)		
Cigarette Smoking				
No	14 (20.0%)	48 (68.6%)	-	<0.001
Ex-Smoker	10 (14.3%)	6 (8.6%)		
< 1 packet per day	20 (28.6%)	11 (15.7%)		
> 1 pack per day	26 (37.1%)	5 (7.1%)		

Author Computations; *p-value calculated by logisticre gression analysis

The multiple regression analysis showed that, there was a statistically significant relationship between gender, age and co-morbidity (HTN, Dyslipidemia, CVD) with diabetic foot ulcer patients. The hypertensive patients was 3.23 times higher risk of developing DFU as compared to non-hypertensive patients (OR=2.33, 95% CI: 2.11-3.89, p<0.001). Similarly, the CVD patients was 2.69 times higher risk of developed foot ulcer (OR=2.69, 95% CI: 1.25-5.68, p=0.011). The physical activity, obesity history and smokers were also significantly associated with developed diabetic foot ulcer. The diabetic patients who did regularly exercises were 68% less chances ofrisk of developing DFU (OR=1.68, 95% CI: 0.16-0.74 p=0.006). On the other hand, the diabetic patients who visit regular for foot checkup were 2.02 times were less chances of developing DFU (OR=2.04, 95% CI: 0.02-0.11 p<0.001)(Table4).

Table 4: Association between Factors of DFU with DM Type 2 Patients

Variables	Diabetic Foot Ulcer		Logistic Regression Analysis	
	Yes N (%)	No N (%)	AOR (95%CI)	p-Value
Gender				
Male	312 (67.09%)	332 (71.40%)	1.00	0.023
Female	153 (32.90%)	133 (28.60%)	1.22 (0.60-2.51)	
Age				
<30	9 (1.93%)	12 (2.58%)	1	0.019
30-39	189 (40.64%)	186 (40.00%)	1.43 (0.92-1.23)	
40-49	169 (36.34%)	158 (33.98%)	1.22 (1.2-1.98)	
50-59	67 (14.41%)	59 (12.69%)	1.49 (0.69-1.86)	
>60	33 (7.10%)	47 (10.11%)	1.23 (0.92-1.12)	
Marital Status				
Married	356 (76.56%)	292 (62.80%)	1.92 (1.23-1.89)	0.129
Unmarried	109 (23.44%)	173 (37.20%)	1	
HTN				
Yes	42 (60.0%)	112 (24.09%)	2.33 (2.11-3.89)	<0.001
No	28 (40.0%)	353 (75.91%)	1	
Dyslipidemia				
Yes	298 (64.09%)	127 (27.31%)	2.12 (1.08-2.56)	0.029
No	167 (35.91%)	338 (72.69%)	1	
CVD				
Yes	197 (42.36%)	49 (10.54%)	2.67 (1.25-5.68)	0.011
No	268 (57.64%)	416 (89.46%)	1	
CKD				
Yes	223 (47.96%)	36 (7.74%)	1.67 (1.25-3.68)	0.928
No	242 (52.04%)	429 (92.26%)	1	
Exercise				
Yes	42 (9.03%)	298 (64.09%)	1.68 (0.16-2.74)	<0.001
No	423 (90.97%)	167 (35.91%)	1	
Obesity History				
Yes	321 (69.03%)	86 (18.49%)	2.15(0.07-3.31)	<0.001
No	144 (30.97%)	379 (81.51%)	1	
Delay for Follow-Up				
Yes	389 (83.66%)	61 (13.12%)	2.04 (1.02-2.11)	<0.001
No	76 (16.34%)	404 (86.88%)	1	

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Infection History				
Yes	344 (73.98%)	51 (10.97%)	3.59 (1.02-3.11)	0.029
No	121 (26.02%)	414 (89.03%)	1	
Baseline Medication				
Insulin	166 (35.70%)	267 (57.42%)	1.22 (0.11-1.46)	0.980
Oral	299 (64.3%)	198 (42.58%)		

Author Computations; *p-value calculated by logistic regression analysis

DISCUSSION

The aim of the studywas to elaborate the risk factors related to DFUs in DM Type 2 patients. The data analysis shows that there was a multiple micro and macro vascular complications associated with DFUs. In the current study the prevalence of DFU was 50.0% and it is much higher than the global prevalence of diabetic foot ulcer, i.e., 6.3%. The diabetic foot ulcer was higher in males (71.4%) as compare to female (28.6%) and it is also much higher in global prevalence of males (4.5%) and females (3.5%) population of diabetic foot ulcer [10]. In the current study it was found that about 77.1% higher rate of having DFU who did not regular checkup of diabetic foot as compare to who did regular checkup (22.9%) and it is similar to another study results the proportion of usual care of DFU 13.3% much lower than the unusual care 25.4% (RR = 0.49, 95% CI, 0.28-0.84) [11]. These differences might be different study design, sampling techniques, sample size, different socio economic status, health related behaviors and quality of health system. T2DM patients had higher probability of developing DFUs as compare to other type of diabetes [12].Study have been reported that the burden of DFUs mostly in above 30 years of aged group and it is similar to current study the average age of diabetes patients was 58.44 years [13]. Results pertaining to diabetic foot ulcers with habits of smoking seem very interesting. The proportion of DFUs is higher in subjects with habitual of smoking as compared to those with non-smokers [14]. It is difficult to clarify the incidence of foot ulcers in view of the report that smoking does not seem to be risk factor for DFU. Study have been reported that multiple risk factors involved in the development of DFUs.Usually, long duration and uncontrolled diabetes are supposed to rise the chances of chronic complications [15]. Our results expose that over age, old diabetic patients, uneducated patients, habitual smoking and uncontrolled diabetes are separately associated risk factors for the growth of DFUs.Moreover, many patients had diabetes and foot ulcer for longer periods but ignored treatment or were not appropriately treated. They visited the clinic for the first time. A similar trend has been described from another country [15]. The previous studies reported that age, gender (male), co-morbidities like heart diseases, hypertension, and HbA1c are the main risk factors for DFUs [16]. It was identified that positive relationships for duration of diabetes, age and smoking habit with diabeticfootulcers. It has been advisedthat with avalue-added health education platformoffering guidanceon safety in the work and at home, physical examination (using special mirrorfor foot to examine feet may help), good hygiene and patients and healthcare providers may help to improve this infection.The primary prevention of diabetes related complications such as DFUs is to improve blood- glucose level [16-18]. Moreover, continuous monitoring of blood-glucose level is also essential for managing the DFUs. In present study showed, self-monitoring blood glucose was beneficial in managingfoot ulcer in all the diabeticpatients .Continuous foot checkupwasalso given to preventfoot infection. Other factors which can be causes of increased level of mood disorder like increase level of BMI, high level ofHbA1c, lowlevel of education, low level ofincome, gender, duration ofDM,marital status, other diabetic complications [19, 20].

CONCLUSIONS

Our study confirmed the there was a positive association between DFU with different factors and co-morbidity. In current study it was also found that the strong risk factors of DFU like over age, active smokers, long and uncontrolled duration of diabetes and low literacy rate. It is important that management of DFUs based on knowledge of the risk factors of DFUs. Moreover, it is most important to create awareness and education about diabetes and diabetes related complications, particularly amongst uneducated patients.

Authors Contribution

Conceptualization: SMA
Methodology: SMA, SMH
Formal analysis: SF
Writing, review and editing: SMA

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

The authors declare no conflict of interest.

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