FREQUENCY OF RISK FACTORS AMONG PATIENTS WITH DIABETIC FOOT ULCER (DFU): AN INSTITUTIONAL-BASED CROSS-SECTIONAL STUDY

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Abstract

Objective: To determine the frequency of risk factors involved in development of DFU among adults with diabetes Mellitus.

Study Design: Cross-sectional study

Place and Duration of study: People's University of Medical & Health Sciences for women 1st February 2018 to 31st January 2019.

Materials & Methods: A total of 163 consecutive patients with diabetic foot ulcer were recruited. The risk factors e.g. age, gender etc. were identified by detailed history, physical and local examination of foot and necessary investigations. The appropriate treatment was given to all patients with DFU. Data were collected on a special proforma for analysis.

Results: Out of 163 patients 68.7% were male. Majority (39.9%) of patients was in the range of 61–70 years and 84% of participants had poorly controlled diabetes. Ninety-eight (60.1%) were smokers. Neuropathy was present in 47.22% patients, 28.2% were with neuroischemic and 24.5 patients have vasculopathy. Foot deformities were also common risk factor and present in 63.2%. The trauma was major external factor noted in 65% patients with DFU. Previous history of ulcer and amputation was noted as 8.6% and 6.7% respectively.

Direct relation was found between the neuropathy and trauma.

Conclusion: this study supports that etiology of DFU is multifactorial. The peripheral neuropathy, vasculopathy, uncontrolled diabetes and trauma are most significant risk factors involved in development of DFU. Therefore, education and awareness program for awareness of these risk factors may decrease the prevalence of DFU.

Key Words: Diabetic Foot Ulcer, Risk Factors, Neuropathy, Vasculopathy

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Introduction

Diabetes mellitus (DM) is main health issue in world and its increasing prevalence is major threat in future. International Diabetes Federation (IDF) estimated that in 2045 the population of peoples with diabetes will be around 628.6 million[1].In Pakistan the prevalence of diabetes is 16.98%, estimated by recently published survey[2]. DM related complications poses major mortality and morbidity among diabetics by causing micro and macrovascular complications[3].

Diabetic Foot ulcer (DFU) is one of major and dreadful complications of DM, and it is presenting as component in diabetic foot diseases. About 15% of all people with DM will have an ulcer at some stage of their life. One out of every six people with DM develops DFU during their lifetime in developed countries. The risk is much higher in developing countries [4]. DFU and its related complications results mortality and morbidity leading economic burden [5] and 84% cause of all lower leg amputations [6,7].

Pathophysiology of DFU is multifactorial, three dimensions could be describing the risk factors: physio-pathological, anatomical/structural alterations and environmental influences [8]. When physio-pathological and structural conditions are favorable for DFU, it is the environmental factor that may trigger a breach in the skin to cause an ulcer. Abnormal foot structure and trauma are

common environmental factor in development of DFU [8].

The most common risk factors involved in DFU are; peripheral neuropathy, peripheral vascular disease, deformities of foot and decreased immunity against infections[9]. Other common risk factors are; increasing age, male gender, poor glycemic control, duration of diabetes, smoking [10,11], trauma, previous ulcer, previous amputation and decreased vision. [12-19]. The DFU may ultimately results lower limb amputation that has worse effects on quality of life and decreases the survival rate in patients with affected with ulcer [20,21].

However, these risk factors of DFU can vary different populations with different socioeconomic and demographic status. Therefore, identification of these factors involved in DFU in different areas is very essential to prevent the DFU and its overwhelming effects among diabetic population. This study may help us to put greater effort to improve our health conditions for patients with DFU and it may provide important source of information for policy makers. Therefore, it will reduce DFU associated morbidity and mortality in the community. Therefore, our purpose of this study is to identify risk factors involved in pathogenesis of DFU among adults with DM presented in Peoples University of Medical & Health Sciences for Women (PUMHSW) hospital Nawabshah.

Material and Methods

This cross-sectional study was conducted on patients with DFU who either attends the medical OPD or admitted with DFU in PUMHSW Hospital Nawabshah, district Shaheed Benazirabad during 1st February 2018 to 31st December 2018. PMCHW hospital is tertiary care hospital located in Sindh province of Pakistan. All adults male and female more than 18 years of age and have type 2 Diabetes mellitus (T2DM) complicated with DFU were included in the study. Individuals with other causes of foot ulcer like road traffic accidents were excluded from the study. The study acquired ethical approval from ethical committee of PUMHSW Nawabshah. After verbal consent the data of demographic details, medical history and physical examination and risk factors involved in DFU was obtained in form of questionnaire. Ulceration defined as partial or full thickness loss of foot skin in a patient with diabetes excluding road traffic accidents [17]. The variables included in our study were; age of patient, sex, marital status, occupation, educational status duration of diabetes, previous foot ulcer and amputation, peripheral neuropathy, ischemic, neuroischemic, decreased vision, Wagner grading, smoking status, HbA1c, random blood sugar and total cholesterol. Marital status was expressed as married, unmarried and widow. Educational level was recorded as illiterate and literate. Smoking recorded as smoker or non-smoker. The smoker means; currently smoker or ex-smokers or ex-smokers with nicotine chewing or nicotine chewed patients. For neuropathy the foot sensation was examined by 10 g monofilament and examined four areas in each foot (first, third and fifth metatarsal head and plantar side of great toe). Neuropathy was considered if patient unable to perceived even one site [22]. Vasculopathy was established on history and examination. Patient either with symptoms of isvheamia, intermittent claudication, rest pain or night pain, or absence of any one pulse, dorsalis pedis or tibialis posterior, were labeled as ischemic. Decreased vision assessed by either history of decreased vision from patient or from his/her family member. We defined DFU as neuropathic, ischemic and neuroischemic. The traumatic ulcer was recorded as bare foot walking, tight fitting shows, nail cutting, spontaneous and insect bite. Wagner grading system was used to describe DFU and graded as: “Grade 0: pre-ulcer condition; Grade 1: superficial ulcer; Grade 2: deep ulcer with tendon or capsule involvement; Grade 3: bone involvement (osteomyelitis); Grade 4: forefoot gangrene; Grade 5: generalized gangrene” [17].

Random blood sugar was checked with glucometer (Accu-Chek Performa by Roche) in every patient during their first visit or at the time of admission. After proper techniques blood sample was taken to measure HbA1c and for total cholesterol. The lab tests were done in research and diagnostic laboratory of PUMHSW Nawabshah. For status of diabetes the HbA1c was used. Patient considered as good glycemic if his/her HbA1c was less than 7% relatively good control if HbA1c was under 7–8% and if more than 8% we labeled as poor glycemic control [23].

The statistical data was obtained and recorded on IBM SPSS statistics version 25. For continuous data mean $\pm$ SD was used, and for categorical data, frequency and percentage were used. The variables were first evaluated by Chi square test (or Fischer's exact test). P value < 0.05 was considered as significant.

RESULTS:

Out of 163 subjects, 69.9% (n=114) recruited through OPD and 26% (n=49) were included from indoor department. Males were 68.7% (n=112) and Females were 31.3% (n=51).

More males were involved with frequency of as compared to females. (Table 1.) The mean (±SD) age of the patients was 59.68 (± 9.87) years. Most of the patients were found in the age group of 61-70 years (39.9%) followed by 51-60 years (31.3%) and only 8.6%. were more than 70 years of age. Majority of patients were belonging to rural areas 88.3%, and 56.4% were uneducated. Among all patients 96.3% were married and 56.4% were Illiterate.

The frequency of smokers was 60.1% (n=98), out of which, 27.6% were current smokers, 6.6% were ex-smokers, 9.2% were tobacco chewers and 6.1% were ex-smokers taking chewable tobacco (Naas, Naswar). Right foot was involved in 35.6% (n= 58) patients, left foot in 55.8% (n= 91) patients and both feet were involved in 8.6% (n= 14) patients (Table 1).

Most of patients with DFU (84%) had poor glycemic control. The mean (±SD) random blood glucose level was 281 (± 70.13) mg/dL, mean (±SD) HbA1c was 9.06 (± 1.3) %. Out of 163 patients, 52% (n=100) patients were had diabetes for more than 10 years, 39% (n=75) patients were of duration between 5 and 10 years, and only 9% (n=17) patients were of duration less than 5 years. Mean (±SD) duration of diabetes was 11.4 (±3.47) years. The mean (±SD) total cholesterol was 201 (± 73.3) mg/dL. One hundred (61.3%) patients with DFU had other co-morbid conditions, among these, 20.9% (n= 34) participants were hypertensive. Wagner Grade 3 founded in 52. %1 and Grade 1- and 2-foot ulcers comprised 12.3% and 21.5% respectively.

Neuropathy was detected in 47.22% (n= 77) patients with DFU, 28.2% (n=46) were with neuro-ischemic and 24.5% (n= 40) had vasculopathy.

The trauma was major external factor in DFU and seen in 65% (n=106) patients, 8.6% (14) have past history of ulcer, 63.2% (n=103) have foot deformities, 2.5% (n=4) have decreased vision and 6.7% (n=11) patients have past history of amputation.

The risk factors also cross tabulated with gender to check any association but we didn't any significant association. (Table2

TABLE: 1: BASELINE CHARACTERISTICS AND LABORATORY FINDINGS

Demographics	n (%)	Mean (+SD)
Age		59.68 (+ 9.87)
Age scale		
Gender Male Female	 112 (68.7) 51 (31.3)	
Marital status Married Unmarried Widow	 157 (96.3) 00(00) 06(3.7)	
Education Literate Illiterate	 92 (56.4) 71 (43.6)	
Residence Urban Rural	144 (88.3) 19 (11.7)	.
Duration of diabetes		9.71 (+ 3.56)
Foot examination Right foot Left foot Forefoot hindfoot	 58 (35.6) 91(55.8) 87 (53.4) 76 (46.6)	
Labs		
RBS		281.91 (+ 70.13)
HbA1c		9.06 (+ 1.36)
Total cholesterol		201.60 (+ 73.33)

TABLE: 2 FREQUENCIES OF RISK FACTORS ACCORDING TO DEMOGRAPHIC CHARACTERISTICS

Variable	Male (%)	Female (%)	p-value
Age (years) 31-40 41-50 51-60 61-70 >70	 5 (3.1) 18 (11.0) 32 (19.6) 50 (30.7) 7 (4.3)	 00(00) 10 (6.1) 19 (11.7) 15 (9.2) 7 (4.3)	0.103
Diabetes duration (years) 1-5 6-10 11-15 16-20 >20	 2 (1.2) 17 (10.4) 85 (52.1) 7 (4.3) 1 (0.9)	 1 (0.6) 8 (4.9) 38 (23.3) 3 (1.8) 1 (0.6)	0.986
Education level Literate Illiterate	 50 (30.7) 62 (38.0)	 221 (12.9) 30 (18.4)	0.735*
Glycemic control Uncontrolled Controlled	 99 (60.7) 13 (11.6)	 38 (23.3) 13 (8.0)	0.037*
Type of ulcer Neuropathic Neuroischemic Ischemic	 62 (38.0) 25 (15.3) 25 (15.3)	 15 (9.2) 21 (12.9) 15 (12.9)	0.006
Smoking Yes No	 67 (41.1) 45 (40.2)	 31 (19.0) 20 (12.3)	0.524
Foot Trauma No Yes Bare foot Spontaneous Tightfitting shows Nail cutting	 61 (37.4) 51 (31.3) 21 (12.9) 16 (9.8) 8 (4.9) 6 (3.7)	 30 (18.4) 21 (12.9) 12 (7.4) 3 (1.8) 4 (2.5) 2 (1.2)	0.364
Neuropathy	Foot trauma		0.000
Foot deformities Present Absent	 76 (46.6) 36 (22.1)	 26 (16.0) 25 (15.3)	0.39
Previous Ulcer	04 (2.5)	04 (2.5)	0.242
Previous Amputation	07 (4.3)	02 (1.2)	0.546
Decreased Vision	09 (5.5)	02 (1.2)	0.332

Discussion

This study determines the frequency of risk factors involves in development of DFU in type 2 diabetes mellitus in tertiary care hospital of Sindh, Pakistan. DFU is multifactorial disease and hyperglycemia is basic factor in pathophysiology of diabetic complications, and its molecular effects ultimately results vascular dysfunction and neuropathy. Therefore, there is interplay of various intrinsic e.g. poor glycemic control, neuropathy, vasculopathy and foot deformities and extrinsic factors e.g. trauma, smoking, that lead to development of DFU [8].

Age is one of the important causative risk factors in development of DFU [22,23]. In our study the mean age was 59.68 years, that is very close to other studies. Study by Ahmed W et al, [14] reported mean age 58.09 years. Study in Iran noted 55.9 (± 13.47) (17). Our results showed that DFU was more common 51-60 years (39.9%) very close to study by Bhaktavatsalam M et al, [19] and Ahmed W, [14]. Study conducted in Iran 50–59 years age group (37.9%) was most common age group [18]. Data of our study demonstrate that DFU was common in males (68.7%) as compared to females (31.3%). Other studies also almost same results [14, 17,19]. Males are more engaged in outside activities and have more foot exposure to different risks that could be possible explanation [9,17,24.] Uncontrolled diabetes or poor glycemic control is basic mechanism in DFU and considered as prerequisite in development of ulceration and we found that 84% patients with DFU have uncontrolled diabetes their mean HbA1c was 9.06% and mean random blood sugar was 281.91 mg/dL noted. Other studies also noted poor glycemic. Study in Iran (18) noted 8.7% mean HbA1c and 64.2% had poor glycemic control [14,17,19,24.]

Duration of diabetes is also major and important risk factor in DFU, and our study demonstrated 78.5% patients were belongs to diabetes duration of 11– 20. Many other studies [9, 14,17,18, 24] also recorded almost same results. Bortoletto et al. [25], reported diabetes duration of more than 10 years as a risk factor of DFU. Two studies recoded different data. Abbott et al. [26] results against these findings and suggested that increasing age was associated with a decreases risk of new ulceration. Almobarak et al, [27] data supports the same findings but they observed the decreased risk of DFU in patients with diabetes duration of more than 20 years.

In our study 47.2% patients with DFU have neuropathy, 28.2% have neuroischemia and 24.55% have ischemic type of DFU. The data is conflicting regarding this finding. Study by Nyamu et al. [28] noted, 47.5% had neuropathic, 30.5% had neuro-ischemic and 30.5% had ischemic ulcers. Yazdanpanah L et al, [17] also showed more cases with neuropathy and neuroischemic, but no single patient had ischemic type of ulcer, the small sample size may be reason. Studies in Thailand [29] and China [30], were contrary to our results, these studies noted more neuroischemic type ulcer (53.1%). Studies in Pakistan noted neuropathy in 20–40% [14], another study noted 44% of their patients have sensory loss [31.]

According to Wagner grading of ulcers, the common grade in our study was Wagner grade 3 (52.1%), which is different to some other studies that noted grade 1 as common [17, 32]. Sarinnapakorn et al. [29] noted Wagner grade 2 was predominant. The late consultation or late referral is common reason that most patients in our study presented with Wagner grade 3.

Neuropathy (sensory, motor and autonomic) alter the structure of the foot and that result the foot deformities. [4]. Excessive pressure results in the formation of calluses which are prone to ulceration. We noted 62.6 percent patients having various foot deformities. Many other studies also observed foot deformity as a major risk factor of DFU [16,17, 27].

When the intrinsic and structural/anatomical conditions are favorable for foot ulceration, it is usually an environmental factor breach the skin and trigger the foot ulcer [8]. We observed that 20.2% patients got injury secondary to

barefoot walking, 11.7% got injury spontaneously and was second common factor, 8 % due to tight fitting shows, 4.95% due to nail cutting. We found significant association of trauma with illiteracy (p value .000). We attributed that other factors like inflammation, dryness and foot calluses would be major mechanism in spontaneous ulcers that are missed by patients due to illiteracy or decreased vison.

A cohort study by Abbott et al, [33] noted pressure from footwear (55%) major factor in DFU, we did not assess this factor in over study. The triad of neuropathy, minor trauma, and foot deformity was observed in our study to be present in the majority of cases of ulceration. study in Sri Lanka [34] noted bare foot walking as major risk factor in DFU.

Smoking is another common risk factor in development of DFU in diabetic patients and our results showed that 60.1% patients with DFU were smoker. Yazdanpanah L et al, [17] noted 9.1% but their sample size was small (39 cases). Another study by Yazdanpanah L et al, (18) ne noted 4.9 % as current smokers and 8% as ex-smokers. This difference may be due to different smoking habits in Iran. Study in Egypt [15] noted 50% patients with DFU were smokers. But data by Zhong et al [24] showed a highest DFU risk in the nonsmoking patients with smoking histories and this difference attributed to use of different definitions of current smoker and nonsmoking with smoking history.

Previous ulcer significantly increases the risk of successive ulceration, this risk may be 18 times higher than in the absence of a former ulcer [35]. We found only 4.9 percent of patients with DFU have history of previous ulcer. Study by Yazdanpanah L et al, [17] noted 6.1% had history of previous foot ulcer. In our study 5.5% patients were already had amputation, but study by Yazdanpanah L et al, [17] noted only 1% patients have history of amputation. It may be due to better health environment and facilities in these countries.

Limitations ours studies were; First, we did not consider some potential confounders in the occurrence of new foot ulceration such as health care provision level and patient behavioral factors. Second, differences in methods of neuropathy and vasculopathy assessment may affect the results to be compared with those of other studies. Finally, we didn't study the BMI because most of patients with DFU didn't stand on feet properly, so data was somehow faulty therefore it was omitted from study.

In conclusion, our data reported that independent risk factors of DFU development were age, gender, neuropathy, vasculopathy, poor glycemic control, duration of diabetes, trauma, history of previous DFU or amputation and foot deformity. This finding provides support for a multifactorial etiology of DFU. The peripheral neuropathy, vasculopathy, uncontrolled diabetes and trauma are most significant risk factors for diabetic foot ulcer observed in our study. Therefore, the primary and secondary prevention programs are urgently needed to minimize both morbidity and cost from this dangerous complication.

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