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Original Article

Risk of Diabetic Foot Ulcer in Patients of Diabetes Mellitus Visiting a Private Setting of South Punjab, Pakistan

Qazi Masroor Ali,[1] Saba Anjum,[2] Sadaf Shafique,[3] Hareem Hamza,[4] Ali Imran,[5] Raheel Khan,[3] Muhammad Sohail Tariq,[3] Maria Masroor,[6] Hafiz Muhammad Kaleem Ullah,[3] Ghulam Muhy-u-Din Chaudhary[7]

[1]Aleena Hospital, Bahawalpur, [2]Shahida Islam Teaching Hospital, Lodhran, [3]Bahawal Victoria Hospital, Bahawalpur, [4]Royal Alex Hospital, Canada. [5]Quaid-e-Azam Medical College, Bahawalpur, [6]Shaikh Zayed Hospital, Rahim Yar Khan, [7]Nishtar Medical University, Multan,

Abstract

Objective: To evaluate the risk of diabetic foot ulcer (DFU) among diabetes mellitus (DM) patients visiting outpatient department of a private healthcare setting.

Methods: A cross-sectional study performed at the outpatient department of medicine, Aleena Hospital, Bahawalpur, Pakistan from 1st July 2021 to 30th June 2022. We included patients of both genders aged above 18 years and known cases of DM with disease duration of ≥ 6 months. Medical record was checked while clinical history was taken and foot examination was performed.

Results: In a total of 781 patients, 394 (50.4%) were female. The mean age, weight, height and BMI were 50.19±12.21 years, 74.08±16.41 kg, 5.52±0.31 feet and 30.80±7.07 kg/m2 respectively. Residential status of 498 (63.8%) patients was rural. There were 778 (99.6%) cases that had type-2 DM (T2DM). There were 443 (56.7%) patients who had no risk for DFU while neuropathy, PAD/foot deformity and neuropathy + PAD/foot deformity were identified among 205 (26.2%0, 97 (12.4%) and 36 (4.6%) patients respectively. Increasing age ($p<0.001$), residential status as rural ($p=0.025$), higher BMI ($p=0.006$), increased disease duration of DM ($p=0.002$), hypertension ($p=0.050$) and smoking ($p=0.006$) were found to have significant association with risk of DFU.

Conclusion: High proportion of DM patients were at risk of DFU. Increasing age, rural residential status, higher BMI, increased disease duration of DM, hypertension and smoking had significant association with the risk of DFU.

Keywords: Diabetic foot ulcer, glycemic control, hypertension, smoking.

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Corresponding Author: Prof. Qazi Masroor Ali **Email:** masroorqazi@outlook.com

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Introduction

In the recent decades, diabetes mellitus (DM) has become a global health issues affecting both developing and developed countries. Global estimates have shown that more than 422 million adult population is accompanying DM while these figures are estimated to escalate around 642 million by year 2040.[1,2] As the burden of DM is increasing, the prevalence of both short term and long term DM related complications are expected rise.[3,4]

Diabetic foot ulcer (DFU) is considered to be a frequent and important complication of DM and represents a serious healthcare issue impacting significant amount of morbidity and mortality.[5,6] The DFU is described as the "presence of infection, ulceration and/or destruction of deep tissues associated with neurological abnormalities and various degrees of peripheral arterial disease (PAD) in the lower limb in patients with diabetes".[6] The DFU is calculated to be the cause of around 20% of all DM related hospitalization.[7] Not only DFU causes significant morbidity and mortality, it also influences major economic burden on healthcare systems.[8,9] The DFU also imparts substantial depression as well as physical issues which impacts the "quality of life (QoL)" in the affected patients.[10]

Literature highlights loss of protective sensation because of diabetic peripheral neuropathy (DPN), PAD and trauma to be major factors contributing to DFU.[11] Male gender, past history of diabetic foot ulcer or amputation, foot deformity, callus, Charcot arthopathy and higher plantar pressure are described to be few of the notable factors associated with higher risk of DFU.[12] Duration of DM, poor glycemic control and poor compliance to medical advice are also linked with raised risk of DFU.[6,12] A prospective evaluation from Iran estimated the cumulative incidence of DFU to be 5.6%.[13] Some others have found that calculated life-time risk of DFU is between 19-34%.[6]

In Pakistan, little much is known about the risk of DFU in patients visiting diabetes clinics while it seems important to estimate the risk and possible factors associated with DFU. We aimed this research to evaluate the risk of DFU among DM patients visiting outpatient department of a private healthcare setting.

Methods

A cross-sectional study performed at the outpatient department of medicine, Aleena Hospital, Bahawalpur, Pakistan from 1st July 2021 to 30th June 2022. We included patients of both genders aged above 18 years and known cases of DM (both type-1 DM or type-2 DM) with disease duration of ≥6 months. Exclusion criteria were patients having DFU at the time of presentation, acute ailment, mental instability or those patients who were unwilling to be part of this research. Individuals having past history of foot ulcers or those who had amputations were also not included. Approval from Institution's "Ethical Review Board" was acquired (letter number: HRC/02-2022, dated: 28-04-2022). Informed and written consents were sought from study participants.

A total of 1249 patients were initially considered for this research but 781 fulfilled the inclusion /exclusion criteria so they were enrolled. At the time of enrollment, medical record was checked while clinical history was taken and foot examination was performed. Socio-demographic characteristics, behavioral factors and disease history were noted. Necessary laboratory investigations including HbA1c levels were ordered. HbA1c ≤7% was labeled as "good glycemic control" while HbA1c > 7% was designated as "poor glycemic control".[14] Body mass indexed was classified as per WHO classification for Asian Population.[15] Detailed foot examination was carried out by a trained physician. The DPN was assessed through detection of monofilament, tuning fork and cotton wool on both feet and absence of sensations by any of these was termed as presence of neuropathy. Foot pulses and deformity were assessed by evaluating tibial posterior arter, dorsal pedal artery, or presence of any foot deformities like Charcot foot, claw toes, hammer toes, bunion or prominent metatarsal head. Risk categories were allocated as "No Risk" if none of the abnormalities were observed. Other groups were labeled as neuropathy, PAD/Foot deformity or neuropathy+PAD/foot deformity. Standard protocols were adopted for foot examinations while assessment of peripheral neuropathy and foot deformities/pulses were done as per methods described by Lavery et al.[16,17]

Data analysis was performed employing "Statistical Package for Social Sciences (SPSS)" version 26.0. Frequency and percentages were shown for categorical data whereas mean and standard deviation (SD) were calculated for numeric data. Association of various characteristics/factors with DFU risk were determined using chi-square test considering $p<0.05$ as statistically significant.

Results

In a total of 781 patients, 394 (50.4%) were female. The mean age, weight, height and BMI were 50.19±12.21 years, 74.08±16.41kg, 5.52±0.31 feet and 30.80±7.07 kg/m^2 respectively. Residential status of 498 (63.8%) patients was rural. The mean duration of DM was 6.03± 6.2 years. There were 778 (99.6%) cases that had type-2

Table 1: *Demographic and Clinical Characteristics (n=781)*

Characteristics		n (%)
Gender	Male	387 (49.6)
	Female	394 (50.4)
Age groups (years)	18-30	46 (5.9)
	31-60	605 (77.5)
	>60	130 (16.6)
Residential Status	Urban	283 (36.2)
	Rural	498 (63.8)
BMI (kg/m^2)	Underweight (<18.5)	17 (2.2)
	Normal (18.5-22.9)	76 (9.7)
	Overweight (23-24.9)	66 (8.5)
	Obese (>24.9)	622 (79.6)
Diabetes Type	1	3 (0.4)
	2	778 (99.6)
Duration of diabetes (years)	<1	86 (11.0)
	1-5	380 (48.7)
	>5	315 (40.3)
Glycemic Control	Good (HbA1c ⩽ 7)	103 (13.2)
	Poor (HbA1c>7)	678 (86.8)
History of Smoking		74 (9.5)
Hypertension		416 (53.3)

DM (T2DM) while remaining 3 (0.4%) cases had type-1 DM(T1DM). The mean HbA1c level was 9.76%±2.34%. Glycemic control was poor (>7%) in 678 (86.8%) patients. Table-1 is highlighting details about the demographic and clinical characteristics of patients.

There were 443 (56.7%) patients who had no risk for DFU while neuropathy, PAD/foot deformity and neuropathy + PAD/foot deformity were identified among 205 (26.2% 0, 97 (12.4%) and 36 (4.6%) patients respectively as shown in figure-1.

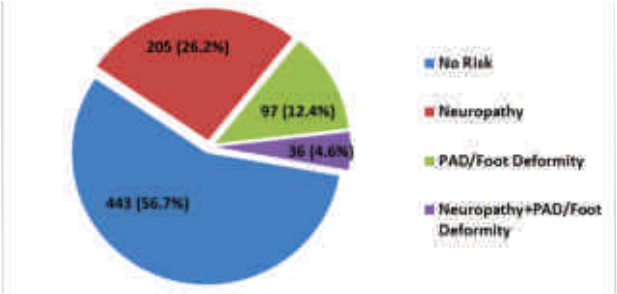

Figure-1: *Risk Categories of Diabetic Foot Ulcer (n=781)*

Increasing age (p<0.001), residential status as rural (p=0.025), higher BMI (p=0.006), increased disease duration of DM (p=0.002), hypertension (p=0.050) and smoking (p=0.006) were found to have significant association with risk of DFU as shown in table-2.

Discussion

Literature describes DM to be the most significant cause behind non-traumatic lower limb amputations worldwide as it is calculated that every 30 seconds, a lower limb gets amputed due to DM.[18,19] In the present study, 43.3% DM patients had risk of DFU. Mutli-central regional data from Bangladesh revealed 44.5% subjects with T2DM to have risk of DFU which is very close to what had noticed.20 The proportion of patients on risk for DFU found in present study is higher than what was found by Shahbazian H et al as 35%.[21] A prospective study from Portugal observed that during a median follow up period of 12 months among diabetic patients having DFU risk, 9.1% developed DFU.[22] Researchers have estimated the annual risk for the development of DFU to be around 2% but among patients with previous

Table 2: *Association of Various Demographic and Disease Characteristics with Risk of Diabetic Foot Ulcer (N=781)*

Characteristics		Diabetic Foot Ulcer Risk Categories				P-Value
		No Risk (n=443)	Neuropathy (n=205)	PAD/Foot Deformity (n=97)	Neuropthy+ PAD/Foot Deformity (n=36)	
Gender	Male	216 (48.8)	97 (47.3)	59 (60.8)	15 (41.7)	0.096
	Female	227 (51.2)	108 (52.7)	38 (39.20	21 (58.3)	
Age groups (years)	18-30	31 (7.0)	7 (3.4)	7 (7.2)	1 (2.8)	<0.001
	31-60	367 (82.8)	141 (68.8)	72 (74.2)	25 (69.4)	
	>60	45 (10.2)	57 (27.8)	18 (18.6)	10 (27.8)	
Residential Status	Urban	165 (37.2)	81 (39.5)	22 (22.7)	15 (41.7)	0.025
	Rural	278 (62.8)	124 (60.5)	75 (77.3)	21 (58.3)	
BMI (kg/m^2)	Underweight	4 (0.9)	6 (2.9)	5 (5.2)	2 (5.6)	0.006
	Normal	37 (8.4)	26 (12.7)	8 (8.20	5 (13.9)	
	Overweight	33 (7.4)	15 (7.3)	11 (11.3)	7 (19.4)	
	Obese	369 (83.3)	158 (77.1)	73 (75.3)	22 (61.1)	
Diabetes Type	1	2 (0.5)	-	1 (1.0)	-	0.564
	2	441 (99.5)	205 (1000	96 (99.0)	36 (100)	
Duration of diabetes (years)	<1	63 (14.2)	11 (5.4)	9 (9.3)	3 (8.3)	0.002
	1-5	224 (50.6)	98 (47.8)	46 (47.4)	12 (33.3)	
	>5	156 (35.20	96 (46.8)	42 (43.30	21 (58.3)	
Glycemic Control	Good	56 (12.6)	28 (13.7)	13 (13.4)	6 (16.7)	0.910
	Poor	387 (87.4)	177 (86.30	84 (86.6)	30 (83.3)	
History of Smoking		41 (9.30	12 (5.9)	18 (18.6)	3 (8.30	0.006
Hypertension		223 (50.3)	123 (60.00	47 (48.5)	23 (63.9)	0.050

history of foot ulcers, this proportion is estimated to escalate somewhere between 17-60% in next 3-years.[23] A research form UK by Abbott et al analyzing different ethnicities involving South-Asian, African-Caribbean and European populations revealed that risk of peripheral neuropathy and PAD were relatively less among South-Asians in comparison to others ethnic populations. The possible reasons behind this could be variations in diagnostic and well as DFU risk classifications adopted by different countries.

We did not find any gender related association with the risk of DFU which is somewhat contrary to the findings of some previous studies. Some studies have shown male gender to be significantly linked with the risk of DFU[25,26] while some others have highlighted female gender[27] to be more likely to have DFU risk. The present study showed increasing age ($p<0.001$), rural residential status ($p=0.025$), higher BMI ($p=0.006$), increased disease duration of DM ($p=0.002$), hypertension ($p=0.050$) and smoking ($p=0.006$) to have significant association with risk of DFU. Many other researchers have pointed out rural populations to have higher risk for the development of DFU so our findings are consistent in this regards.[25,28] High proportion of diabetes patients living in the rural areas have lower literacy rates, lack of diabetes related education while many walk barefoot for their routine activities especially at homes which leaves them to higher risk for the development of DFU.[29,30] A local study done by Younis BB et al from a specialist diabetes clinic situated in Lahore shared that higher age, increased BMI, higher HbA1c and duration of diabetes had significant linkage with DFU.[31] Some other researchers have also pointed out poor glycemic control to be an important risk factor for DFU.[32,33] The possible reasons for not finding any significant association of poor glycemic control with DFU could be that mean baseline HbA1c level among study cases was 9.76%±2.34% and 86.8% patients had poor glycemic control at the time of foot examination. This could have influenced that as vast majority of the patients already had poor glycemic at the time of enrollment.

As number of patients living with diabetes are increasing at pace in Pakistan, the burden of DFU is expected to rise as well. Researcher have shown that almost all the currently accessible risk stratification scoring models for the risk evaluation of DFU have high rates of accuracy[22] so there is a need to devise universal strategies for the screening and examination of feet of all patients of diabetes at regular intervals. There is also a need for specialist foot care physicians and healthcare facilities especially in a country like Pakistan where the prevalence of DM is very high. Education about the foot care, its related complications and proper compliance to medical advice can help reducing the overall burden of DFU and its risk.

Moderately large sample size was one of the major strengths of this study. Being a single center study performed at a private healthcare setting, our findings cannot be generalized. Cross-sectional design of this study had its own limitations. We were unable to analyze diabetes related complications like diabetic retinopathy and nephropathy among current set of patients. There is a need for further prospective trials that track patients on risk for the development of DFU so that the impact of possible interventions employed could be compared to reduce the overall burden of DFU.

Conclusion

High proportion of DM patients were at risk of DFU. Increasing age, rural residential status, higher BMI, increased disease duration of DM, hypertension and smoking had significant association with the risk of DFU.

Conflict of Interest *None*

Funding Source *None*

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