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Risk Categorization of Diabetic Foot in Patients with Type-II Diabetes and Relationship of Various Risk Factors with Risk Categories of Diabetic Foot

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Authors' contributions

This work was carried out in collaboration among all authors. Author S. Shaikh designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors AA and S. Saifullah managed the analyses of the study. Author S. Saifullah managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Background: Diabetes is the leading cause of nontraumatic amputation. Foot screening which detects and stratification of diabetics which are at the risk of developing diabetic foot ulcer is the simple and useful part of this model of care.
Aims: Primary Aim: To stratify patients with type II diabetes into different risk categories of diabetic foot as per International Diabetic Federation guidelines.
Secondary Aim: To determine the relationship of various risk factors with risk categories of diabetic foot.
Study Design: Cross sectional study.
Place and Duration of Study: Department of Medicine, Liaquat University Hospital Jamshoro / Hyderabad from February 2019 to August 2020.
Methodology: This study included 117 consecutive patients with confirmed diagnosis of Type-II diabetes of either sex ≥ 18 years of age.

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Patients fulfilling above criteria were included in study. Feet were thoroughly examined for neuropathy, peripheral vascular disease, infections, ulcers and osteoarthropathy. All the data was recorded on proforma. Patients having normal protective sensations were put in low risk (category 0), those having loss of protective sensations in moderate risk (category 1), those having loss of protective sensations with either high pressure or poor circulation or structural foot deformities or onychomycosis in high risk (category 2) and those having past history of ulceration, amputation or neuropathic fracture were put in very high risk (category 3). Data was analyzed by using SPSS version. 20.

Results: Total 117 patients of diabetic foot ulcer were studied, their mean age was 52.28±9.26 years, diabetic duration 10.21±8.10 years and mean HbA1c level was 10.07±1.96 mmol/l. Male were in majority 52.1%. Ulceration history was in 18.8% cases, amputation history was in 7.7% cases, 46 patients (39.3%) had risk category 1. A strong relationship was found between risk categories and age, sex, duration of diabetes, HBA1c.

Conclusion: This study revealed that 33 (28%) patients attending the diabetic clinic were at high risk of developing diabetic ulcer.

Keywords: Type 2 diabetes mellitus; risk categorization; neuropathy; peripheral artery disease.

1. INTRODUCTION

Diabetes Mellitus has been labelled as global epidemic with 463 million people have diabetes in 2019 and this number is projected to reach 700 million by 2045 [1]. Currently Pakistan is at 4th position in the world with 19.4 million people suffering from diabetes which by year 2045 will be 37.1 million reaching at 3rd position worldwide [1,2].

One of the most common reason for hospitalization in patients with diabetes is diabetic foot and diabetes is the leading cause of nontraumatic amputation constituting more than 50% of nontraumatic amputations [3]. The life time risk of developing diabetic foot ranges from 15-25%. The annual risk of developing diabetic foot ulcer in patients with diabetes is estimated to be about 2%, but this risk in patients with previous history of foot ulceration is expected to increase to 17–60% over the next three years. The prevalence of diabetic foot ulcer is reported to be 1.3–12% in different studies [4]. In 2017, IDF estimates the total healthcare expenditure on diabetes will reach USD 727 billion (20-79 years), which represents an 8% increase compared to the 2015 estimate and by year 2045 it would be reached up to 776 billion [5].

The most common contributing factors in the development of diabetic foot include peripheral neuropathy, previous ulcer or amputation, structural deformity, limited joint mobility, peripheral artery disease, poor glycemic control, male gender and advance age.

Diabetic Peripheral neuropathy occurring in 16% to 66% of patients causing the impairment of normal activities of the nerves throughout the body and can alter the sensory, motor and autonomic function [5]. Sensory neuropathy occurring in most distal part of the extremity causes diminished feedback, predisposing the patients to become more prone to foot injuries. More than half of all foot ulcers will become infected, requiring hospitalization and 20% of lower extremity infections will result in amputation [6].

Diabetes is an important risk factor for the peripheral artery disease (PAD). The prevalence of PAD ranges from 10 to 40% in diabetics compare to 5 to 6% in general nondiabetic population. PAD does not cause the diabetic foot alone but it contributes foot ulceration and amputation by impairing the wound healing due to reduced blood flow [7].

In Diabetes, elevated glycemic levels increase the risk of micro-vascular and macro-vascular complications, eventually affecting every part of the body but it frequently involves the feet first. Foot lesions occur as a consequence of diabetic neuropathy and peripheral vascular disease [8].

Foot screening which detects and stratification of diabetics which are at the risk of developing diabetic foot ulcer is the simple and useful part of this model of care. A screening process can only be successful if it is simple, quick and reliable, using validated clinical tools to determine risk factors [9,10]. Over years many risk stratification systems has been used to identify and treat high risk patients. Some of these systems use a simple low and high risk schemes whereas others categorize the patients into four or five risk categories and advised prevention planning for each [11,12,13,14].

The primary aim of this study was to stratify patients with type II diabetes into different risk categories of diabetic foot as per International Diabetic Federation guidelines.

Secondarily to determine the relationship of various risk factors with risk categories of diabetic foot.

2. MATERIALS AND METHODS

2.1 Study Design and Population

This Cross sectional study was conducted at Department of Medicine, Liaquat University Hospital Jamshoro / Hyderabad from February 2019 to August 2020. The data of the patients was collected in a well designed proforma.

2.2 Sample Size Calculation

The sample size calculation was done using the online raosoft software by taking the margin of error 5% at 95% confidence interval, population of diabetic patients in Pakistan 7.5 million with response distribution of 8.3% (In Pakistan total number of people with Diabetes is 7.5 million with prevalence of 8.3%). The total sample size calculated is 117 [15,9].

2.3 Inclusion Criteria

This study comprised 117 consecutive patients of type 2 diabetes mellitus > 18 years of either sex.

The diagnosis of Diabetes mellitus was based on Fasting Plasma Glucose of 126 mg/dl (7.00 mmol/L) or higher, Hb A_{1C} of 6.5% or higher and 2-hour value of Oral Glucose Tolerance test of 200 mg/dl (11.1 mmol/L) or higher is defined as diabetes [16,17].

2.4 Exclusion Criteria

1. Patient who do not agree to participate in study,
2. Patients with Type-I diabetes,
3. Patients with peripheral neuropathy, peripheral vascular disease, foot infection, foot ulcers or osteoneuropathy due to causes other than Type-II diabetes,
4. Renal failure,
5. Liver failure,
6. Vertebral column pathologies e.g. Lumbar stenosis, Disc prolapse

2.5 Data Collection and Measurement

The patients fulfilling the inclusion criteria were further evaluated for Peripheral neuropathy, peripheral artery disease (PAD) by calculating Ankle-brachial index (ABI), age of the patient, Duration of disease, HBa1c levels and risk categorization of diabetic foot.

2.5.1 Neuropathy

Diabetic peripheral neuropathy is simply defined as “the presence of symptoms, and/or signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes” [18].

2.5.2 10-g Semmes-Weinstein monofilament

Nine testing sites were selected i.e. Dorsal surface between base of 1st and 2nd toes, on the planter surface of the 1st, 3rd, 5th toes, 1st ,3rd and the 5th metatarsal heads, the medial and lateral midfoot and the heal. 10 gram nylon monofilament was applied on the skin surface of foot for 2 seconds to a sufficient force till the bending of monofilament and patient was asked if he /she is appreciating the touch. The test is set to be positive if the patient is able to perceive it as touch. The test is said to be negative if the subjects were unable to detect the applied pressure at least three consecutive testing at the same site [13].

2.5.3 Motor Neuropathy

Motor Neuropathy was assessed by ankle reflex test with Achilles tendon stretched until the ankle is in neutral position and the tendon is stroked with reflex hammer. The test is said to be negative if ankle reflex is negative even with reinforcement [14].

2.5.4 Biothesiometry

vibration perception threshold (VPT) test was carried out by biothesiometer which was applied to the distal part of great toe and vibration was increased until the threshold is reached where vibration is recognized. Two repetitive tests on each location is carried out and averaged, and values above 25 Volts are considered positive for neuropathy and has shown strong correlations with foot ulcerations [15].

2.5.5 Age

Subjects were divided based on age less than 50 years, 50 ≤ 65 years and >65 [16].

2.5.6 Duration of DM

Subjects were divided based on the duration of DM in to Less than 10 years and >10 years [16].

2.5.7 HbA1c

Glycosylated hemoglobin (HbA1c) was analyzed by high-performance liquid chromatography (HPLC Liaquat University) Research Center laboratory. Subjects were classified into three groups based on serum glycosylated hemoglobin (HbA1c) levels into <7%, 7% to 9.9% and > 10% [16].

2.5.8 History of previous Ulcer / amputations

Based on the history of previous ulcer/ amputations [16].

2.5.9 Foot deformity

For the presence and absence of foot deformity [16].

2.5.10 ABI

The ratio of ankle to arm systolic blood pressure was calculated by Pulse wave form (PVW) Doppler. Presence of peripheral artery disease (PAD) was confirmed if ankle brachial index was < 0.9 as recommended by American Diabetes Association [19]. The ABI was measured by The Summit Doppler Vantage machine in radiology department of Liaquat University Hospital. PAD severity in each leg is assessed according to the levels of ABI [20]:

- 0.91–1.30: normal;
- 0.70–0.90: mild occlusion;
- 0.40–0.69: moderate occlusion;
- <0.40: severe occlusion
- >1.30: poorly compressible vessels.

2.5.11 Risk stratification

Patients having normal protective sensations were put in low risk (category 0), those having loss of protective sensations in moderate risk (category 1), those having loss of protective sensations with either high pressure or poor circulation or structural foot deformities or onychomycosis in high risk (category 2) and those having past history of ulceration, amputation or neuropathic fracture were put in very high risk (category 3) [21].

2.6 Data Analysis Procedure

Data was analyzed by using SPSS version 20. Frequency and Percentages were calculated for categorical variables like sex, age, duration of diabetes and HBA1c, risk factors (peripheral neuropathy, peripheral artery disease, ulceration, diabetic foot infection, Charcot neuro-osteoarthropathy and categorization of diabetic foot. Chi square test was applied between sex, age, duration of diabetes and HBA1c with Risk Categories value ≤ 0.05 was considered as significant.

3. RESULTS

Among the 117 diabetic patients 77(65.8 %) were male and 40 (34.2%) female.

The age distribution of patients were < 50years 33 (28.2%), 50-65 were 56 (47.9%) years and 28 (23.9%) were > 65 years.

Neuropathy was present in 79 (67.5%) patients and 38 (32.5%) had no neuropathy.

According to the sign and symptoms frequency of numbness and tingling was among 75.2% cases, burning sensation was among 65.0% patients, pain was among 61.5% cases, swelling was in 36.8% cases, hot cold sensation was seen in 5.1% patients, leg foot symptoms was in 48.7% cases and according to skin changes dry and fissures were in 23.9% cases, increased moisture was in 3.4% patients, thick or calluses was in 12.0% patents and 60.7% cases were with normal skin.

Absent Ankle Jerk was present in 99(84.6%), Vibration Perception Threshold (VPT) > 25V in 93 (79.4%) and Monofilament test was positive in 81 (69.2%) patients.

HBA1c <7% was found in 20 (17.1%), 7 - 9.9% in 31(26.5%) and > 10% in 66 (56.4%). Duration of diabetes < 10 years 46 (39.3%) and > 10 years in 71(60.7%) ABI was normal in 86(73.5%), mild in 16 (13.7%), moderate 7(6.1%) and severe in 8 (7%).

In this study 38(32.5%) had risk category 0, followed by 46 patients (39.3%) had risk category 1,19 (16.2%) patients risk category 2 and 14 (12%) patients risk category3. Table 1 shows the baseline characteristics of Patients.

A strong relationship was found between sex, age, duration of diabetes and HBA1c.

As far as sex is concerned there were 7 female and 31 male in category 0, 28 female and 18 male in category 1, 5 female and 14 in category 2 and 0 female and 14 male in category 3 (p= 0.001).

Risk category 0 there were 33 patients < 50 years, 5 patients in 50 to 65 years and 0 in > 65 years. In risk category 1 there were 46 patients.

Patients in 50 to 65 years range whereas and 0 in < 50 and > 65 years. In risk category 2 there were 0 in < 50, 05 patients in 50 to 65 years range and 14 in > 65 years. In risk category 3 there were 0 in < 50 and 50 to 65 years range and 14 in > 65 years p= (0.001).

Among the risk category 0 HbA1c < 7 was present in 20 patients 7 to 9.9% in 18 patents and 0 in > 10%. The risk category 19 patients HbA1c 7 to 9.9% and 37 had HbA1c > 10%. The risk category 2 had Hba1c 7.9.9 and 12 had Hba1c in 14 patients. In risk category 3 2 had 7 to 9.9% and 12 was in >10%Hba1c (p=0.001).

Duration of Diabetes < 10 years was present in 38 risk category 0 and 8 in risk category 1 whereas duration of diabetes > 10 years was present in 38 risk category 1, 19 patients in category 2 and 14 patients in category 3 (p=0.001).

Table 2. Shows relationship between sex, age, duration of diabetes and HBA1c with Risk Categories.

Table 1. Baseline characteristics of patients (117)

Variable	Frequency	Percentage (%)
Sex		
Male	77	65.8
Female	40	34.2
Age		
< 50years	33	28.2
50-65 were	56	47.9
> 65	28	23.9
Duration of Diabetes		
< 10 years	46	39.3
> 10 years	71	60.7
Neuropathy		
present	79	67.5
Absent	38	32.5
Neuropathy symptoms		
1.numbness and tingling sensation		75.2%
2.Burning sensation		65.0%
3.pain was among cases,		61.5%
4. swelling		36.8%
Neuropathy signs		
1.Absent Ankle Jerk	99	84.6
2.Vibration Perception Threshold (VPT) > 25V	93	79.4
3.Monofilament test	81	69.2%
Peripheral Arterial disease		
1. normal	86	73.5
2. Mild	16	13.7
3. moderate	7	6
4. severe	8	7
HBA1c (%)		
1.< 7	20	17.1
2.7 -9.9	31	26.5
3. > 10	66	56.4
Risk category		
0	38	32.5
1	46	39.3
2	19	16.2
3	14	12

Table 2. Relationship between sex, age, duration of diabetes and HBA1c with risk categories

Variables	Risk Category				P value
	0	1	2	3	
Sex					
1.Male	31	18	14	14	0.001
2. Female	7	28	05	00	
Age					
1.<50	33	00	00	00	
2.50-65	5	46	05	00	0.001
3.>65	0	00	14	14	
Duration of Diabetes					
1.< 10 Years	38	08	00	00	0.001
2.>10 Years	00	38	19	14	
HbA1c(%)					
< 7	20	00	00	00	
7- 10	18	09	02	02	0.001
>10	00	37	17	12	

4. DISCUSSION

Diabetic foot ulcer (DFU) is a major source of morbidity and a leading cause of hospitalization in patients with diabetes.

Among the 117 diabetic patients 77(65.8 %) were male and 40 (34.2%) female in this study.

Iqbal S et al. also found similar findings regarding gender as 52 (80%) were male and 13 (20%) female presenting with diabetic foot ulcer out of all 65 study cases [22].

In the study by Ahmad W et al male patients were 157 (80.1%) and female were 39 (19.9%) [23].

The age distribution of patients were < 50 years 33 (28.2%), ≥ 50-65 years were 56 (47.9%) and 28 (23.9%) were > 65 years.

In this study the majority of patients > 50 years of age TG et al reported that out of total number of 154 participants involved in the study the mean age of participants was 49.8 with SD ± 15.6 years [24]. Cardoso HC et al reported that mean age of patients was 59.6 years [25]. Similar findings were also seen in the study of Ahmad W et al as mean age of the patients was 58.09±11 years in their study [19].

In this study neuropathy was present in 79 (67.5%) patients and 38 (32.5%) had no neuropathy.

According to PROMISE (Prospective Metabolism and Islet Cell Evaluation) study in which 50% diabetic patients, 49% subjects with prediabetes and 29 % in control group developed neuropathy after 3 years follow up [26].

In Rochester Neuropathy Study which comprised 380 type 2 diabetic patients. Peripheral neuropathy was found in 59% patients by using neuropathy symptom score, neuropathy disability score and nerve conduction study [27].

In this study according to the symptoms and sign frequency of numbness and tingling was among 75.2% cases, burning sensation in 65.0% patients, pain in 61.5% cases, swelling in 36.8% cases, hot cold sensation was seen in 5.1% patients, leg foot symptoms was in 48.7% cases and according to skin changes dry and fissures were in 23.9% cases, increased moisture was in 3.4% patients, thick or calluses was in 12.0% patents and 60.7% cases were with normal skin.

In a study by Vibha et.al the numbness and tingling sensation was the most prevalent symptom being present in 91% patients [28]. Adgaonkar et al., observed the tingling and numbness in all (100%) patients presented with Diabetic sensory Neuropathy [29].

In this study the most prevalent sign of neuropathy was absent Ankle Jerk in 99 (84.6%), Vibration Perception Threshold (VPT) > 25V in 93 (79.4%) and Monofilament test was positive in 81 (69.2%) patients.

In a study by P Sahana et.al comprising 410 patients 265(64.5%) had impaired monofilament test at one or more sites. The vibration Perception threshold more than or equal to 25 volts was present in 239 (58.3%) cases [30].

Absent ankle jerk was found in 97% patients in study population by Dr. Abhishek et al. [31]. In a study by Jayprakash et al, absent ankle jerk was found in 97.7% patients [32].

According to our study 12 (7%) patients had previous history of foot ulcer or amputation.

In a study in Iran 7% of the study population had previous history of ulceration [19]. In another study done in Portugal past history of ulceration was observed in 16% of patients [33].

In this study the duration of diabetes > 10 years was present in 71(60.7%) and < 10 years in 46 (39.3%).

In a study by Dr. Abhishek et al comprising 45 patients of which 26 (58%) patients had duration of diabetes more than 5 years duration [31]. A positive correlation was observed between the duration of diabetes and polyneuropathy by Kasturi et al. [34].

Oguejiofor et.al also confirms our finding of having high frequency of polyneuropathy in patients with > 15 years of duration of diabetes [35].

In another study in UK showed neuropathy in 36% patients with duration of diabetes > 10years compared to 20% when the duration of diabetes was < 5 years [36].

In this study 38 (32.5%) had risk category 0, followed by 46 patients (39.3%) had risk category 1,19 (16.2%) patients had risk category 2 and 14 (12%) patients had risk category 3.

Shahbazian H et al. reported that out of two hundred and seventy five patients 122 (44,3%) were in group 0, 75(27.2%) in group 1, 47 (17.0 %) in group 2 and 31 (11.1%) in group 3. [19].

In a study by Lawrence A. Lavery and collogues studied in 1666 observed 977 (58.6%) in category 0, 98 (5.9%) patients were in category 1, 412(24.7%) in category 2 and 179 (10.8%) were in category 3. [37]. According to by Edgar J.G. Peters et al in 225 diabetic patients were stratified according to IWGDF classification which is similar to international diabetic foot classification observed 25(11.1%) in category 0, 32 (14.2%) in category 1, 42 (18.6%) in category 2 and 126 (55.8%) in category 3 [38].

In another study which included 100 patients and risk stratification was done on the basis of American Diabetes Association (ADA) task force report for comprehensive foot examination. According to this classification 48 (48%) patients were in category 0, 33(33%) in category 1,19 (19%) in category 2 [39].

In a large prospective study comprising 3526 patients which was stratified according to Scottish risk stratification system. According to this system 2257 (64%) were in low risk, 811(23%) in moderate risk and 458(13%) high risk category [40].

In this study a strong relation was observed between HbA1c and the risk category as the uncontrolled diabetes was present in the risk category 2 and 3 (p=0.001).

In a study by Adgaonkar et al majority of patients suffering from neuropathy has uncontrolled diabetes with fasting blood sugar ranging from 200 to 220 mg/dl and post-prandial blood sugar > 260 mg/dl [29].

Behl et.al in a study of 539 diabetic observed a direct relationship between severity of hyperglycemia and peripheral neuropathy [41].

According to the Jain et.al observed HbA1C > 9% in 60% of patients with diabetic neuropathy [42]. A study by Kamran and colleagues in 333 patients observed that patients with uncontrolled diabetes (HbA1c > 10%) had high risk diabetic foot compared to moderately controlled (< 10% HbA1c) [43].

5. CONCLUSION

This study revealed that 33 (28%) patients attending the diabetic clinic were at high risk of developing diabetic ulcer. A strong relation was found between sex, age, duration of diabetes, HBA1c and the risk of foot ulceration. The foot risk classification in Diabetic Foot predicts ulceration and amputation and can function as a tool to prevent lower-extremity complications of diabetes.

6. LIMITATION OF STUDY

This is a cross sectional study and the result of this study can not be generalized. Prospective cohort studies are needed in local population to determine the risk of ulceration in different categories.

CONSENT AND ETHICAL APPROVAL

The study was performed after the permission of Ethical Review Committee of University. Written informed consent was taken from participants.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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