

Diabetic Foot Risk Factors & level in Diabetes People: A Cross-Sectional Study

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Abstract

Objective: Determining diabetic foot risk levels and risk factors and treating foot problems is one of the main components of the prevention of diabetic foot ulcers (DFU). This study aimed to determine diabetic foot risk levels and risk factors in diabetic people.

Materials and Methods: This descriptive cross-sectional study included 278 participants during September 2020 to March 2021. The patients' general characteristics, peripheral sensory loss (10 g-Semmes-Weinstein monofilament), foot skin temperature (palpation method) and vascular evaluation (pedal pulses) were examined.

Results: Among 278 patients, 83 cases had DFU. Of those without DFU, 33.3% had risk level "0", 35.4% had risk level "1", 23.6% had risk level "2" and 7.7% had risk level "3". In the regression analysis, male gender [OR= 0.74, 95% CI (0.014-0.338), *P*= 0.002], education (literate) [OR= 0.38, 95% CI (0.002-0.630), *P*= 0.022], foot examination by health professional [OR= 0.013, 95% CI (0.001-0.183), *P*= 0.001], foot deformity [OR= 0.170, 95% CI (0.042-0.679), *P*< 0.001], foot skin temperature (cold) [OR= 0.003, 95% CI (0.000–0.026), *P*< 0.001], and pedal pulse [OR= 8.146, 95% CI (1.505-44.081), *P*< 0.015] were found to have a high effect on diabetic foot development.

Conclusion: The annual DFU rate is 29.8%. Independent risk factors of DFU were gender, education, previous history foot examination, foot skin temperature, pedal pulse and foot deformity. These findings provide support for a multifactorial etiology for DFU.


Keywords: Diabetes, Foot, Risk factor, Risk assessment

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Introduction

Lower extremity complications of diabetes are common, difficult to manage and costly. Foot ulcers are the most common lower extremity complications in diabetics (1). Additionally, foot ulcers have become an important health problem due to psychological impacts and decreased quality of life in individuals who are unable to perform their daily activities due to foot ulcers or amputation (2). Around 1.0 to 3.5 million people in the United States have a history of foot ulcers (3). According to the literature the global prevalence of diabetic foot ulcer (DFU) is 6.3%. Developing countries have a higher prevalence of DFUs than developed countries (4-8). Turkey is ranked number one among the European countries with its population suffering from diabetes (9). Although there are not enough studies on the prevalence of DFUs, more than one million DFUs and approximately half a million diabetic foot infections have been registered in Turkey (10).

DFU is one of the most serious and costly complications of diabetes, as well as a social and public health problem. Ten percent (\$760 billion) of health expenditures worldwide are caused by diabetes (9).

In Turkey, diabetic foot complications accounted for 16% of the 7.350.16 billion in the overall health cost for diabetes complications in 2012 (11).

Two main factors, including peripheral sensory neuropathy and peripheral artery disease (PAD), play a fundamental role in the formation of DFUs (12). In addition, smoking (13,14) diabetes diagnosis period (14-16), nephropathy (17,18), foot deformities (18), amputation/history of foot ulcers (13,18), male gender (15), systolic hypertension (14), older than 50 Y/O (16) were among the other risk factors determined.

Early detection and treatment of foot problems in people at risk of DFU and amputation can delay or prevent unintended consequences. A cornerstone of preventing diabetic foot is the determination of

individuals with at-risk foot (12). According to previous studies, the risk levels of patients with diabetes vary according to the type of study, the population and the number of samples (19-21).

Diabetes mellitus is prevalent in Turkey (22). This study aimed to determine diabetic foot risk levels and risk factors in the diabetes education clinic of a training research hospital in Gaziantep, located in the southeast of Turkey, between September 2020 and March 2021.

Material and methods

This descriptive, cross-sectional study was conducted in the diabetes education clinic of a training research hospital in Gaziantep, located in the southeast of Turkey, between September 2020 and March 2021.

The population of the study consisted of 997 diabetic patients (type 1 and 2) who came to the diabetes education clinic during the data collection dates. The literature has reported that approximately 50% of patients with diabetes are at risk of diabetic foot throughout their entire lives (10,23). According to the sample size calculation, the sample size was 278 patients with diabetes. The study sample was selected using a systematic random sampling method. One in every four patients with diabetes was included in the sample. In the post hoc power analysis performed after the study, the power of the study was found to be 0.99.

Individuals older than 18 y/o who suffer more than 5 years from diabetes (24) were included. Also, type 1 and type 2 diabetes mellitus, speaking and understanding Turkish were considered as inclusion criteria. Patients with diabetes who had communication problems and did not agree to participate in the study were excluded.

The form consisted of three parts. First part included age, gender, educational status, type of diabetes, smoking status (18). In the second part; duration of diabetes, chronic

complications of diabetes, history of ulcers and amputation, previous foot examination and foot care training, health care professional and foot care training in diabetes, glycated hemoglobin A1c (HbA1c) (%), blood pressure and body mass index (kg/m^2) includes evaluations (4). In the third part, there were two sections of both for both feet that included foot temperature (dorsal area of the foot), pedal pulse (dorsalis pedis, tibialis posterior), callus, nail pathologies (nail thickening, nail fungus, ingrown nail), deformities (hallux valgus, hammer/claw toe, pes cavus, charcot), evaluation of shoe suitability (suitable, unsuitable) and diabetic foot risk classification (12,25,26). Foot care behaviors were evaluated with the Turkish valid and reliable Foot Self Care Behaviors Scale (27).

The Loss of Protective Sensation (LOPS) test (yes/no protective sensation) was performed using 10-g (5.07 Semmes-Weinstein) monofilament. Apply the monofilament perpendicular to the skin surface with sufficient force to cause the filament to bend or buckle (C shape). The total duration should be approximately two seconds (12).

The data was collected by the researcher through face-to-face interview the participant with an individual with diabetes. The researcher who collected the data had 10 years of experience in diabetes education. She was certified as a diabetes education nurse at the Turkish Ministry of Health. The data collection process for each participant took an average of 30 minutes. The data on HbA1c for the last three months was derived from the hospital database. Patients with diabetes after resting for at least five minutes systolic and diastolic blood pressure were measured from the brachial artery with the previously calibrated manual sphygmomanometer. During foot examination after the shoes were removed, the area from below the knee to the toe tip was observed. The "dorsalis pedis" and "tibialis posterior" pulses were evaluated using the palpation method and categorized as "present" and "absent". Foot skin temperature

was also evaluated using the palpation method and categorized as "normal", "warm" and "cold". In the footwear assessment, slippers, high heels, pointed toes and shoes that did not take the shape of the foot were defined as unsuitable shoes (26).

Diabetic peripheral neuropathy (DPN) was diagnosed through LOPS evaluation. The evaluation conducted during the foot examination was carried out according to the relevant guidelines (12,28).

After completing the foot examination, diabetic foot risk levels were classified according to the International Diabetic Foot Working Group (IWGDF) as mentioned below (12)

0: Very low risk (No LOPS and No PAD)

1: Low risk (LOPS or PAD)

2: Moderate risk (LOPS+ PAD or LOPS+ foot deformity or PAD+ foot deformity)

3: High risk (LOPS or PAD and one or more of the following below:

-A history of foot ulcers

-Lower extremity amputation (minor or major)

-End-stage kidney disease)

Statistical analysis

As descriptive statistics; arithmetic mean and standard deviations were given for quantitative data, frequencies and percentages were given for qualitative data. Normality tests were used to assess the distribution of quantitative data. For group comparisons, independent sample T-test for quantitative data, chi-square test and Fisher's exact test for qualitative data was used. Potential risk factors for DFU were assessed by using binary logistic regression. The variables that were determined to have a significant relationship and difference according to the chi-square and T-test were included in the binary logistic regression model. The method used in the study is the backward stepwise method and the α significance level used to remove the variables is 0.1. The α significance level to be used to test the model in general is 0.05. In this way, variables that do not contribute to the

model are removed and the best model is tried to be created. Adjusted odds ratios and 95% confidence intervals were obtained. $P < 0.05$ was considered statistically significant. Analyses was performed using IBM SPSS Statistics for Windows, Version 25.0.

Ethical considerations

Research permission was obtained from the University's Non-invasive Research Ethics Committee with the approval date of 07.02.2020 and the ethics code 2020/09, No: 01. Written and verbal consent was obtained by explaining the purpose and process of the study to patients with diabetes. The study was conducted in accordance with the principles of Helsinki Declaration.

Results

In this study, 83 diabetic individuals had DFUs. A total of 195 diabetic individuals without ulcers were evaluated based on the International working Group on the Diabetic Foot (IWGDF) risk classification system. Accordingly, 33.3% of patients with diabetes had a risk level of "0", 35.4% had a risk level of "1", 23.6% had a risk level of "2" and 7.7% had a risk level of "3" (Figure 1).

Table 1 shows demographic and clinical characteristics of patients with diabetes and the comparison of these data between the DFU and non-DFU group.

The mean (\pm SD) age of diabetic individuals was 55.14 (\pm 12.47) of them, 51.8% were male 48.2% were primary school graduates, 71.9% lived in urban areas, 33.1.8% use smoke, 90.6% of diabetic individuals had type 2 diabetes, 39.2% of those with complications had diabetic retinopathy, 7.6% had PAD, 43.9% had DPN, 21.2% had no ulcer history, 73.4% did not did not foot examination by health professional and 69.8% did not receive training on foot care (Table 1).

According to chi square analysis; a significant relationship was found between DFU and gender, education level, duration of diabetes, foot care training, foot examination by a healthcare professional, body mass index, foot care behaviors, chronic complications (PAD, retinopathy, DPN), ulcer/amputation history, systolic/diastolic blood pressure ($P < 0.001$, $P = 0.001$, $P = 0.009$, $P = 0.015$, $P = 0.008$) (Table 1).

Tables 2 show descriptive data on the foot examination findings of diabetic individuals and the comparison of these data between the DFU and non-DFU group. The results showed that 60.1% of the patients with diabetes had nail pathology, 14% had callus, 43.9% had LOPS, 40.3% had foot deformity and 41.7% had inappropriate shoes. According to chi square analysis; A significant relationship was found between DFU and LOPS, pedal pulse, nail pathology, shoe suitability, foot skin temperature, and foot deformity ($P < 0.001$, $P = 0.003$).

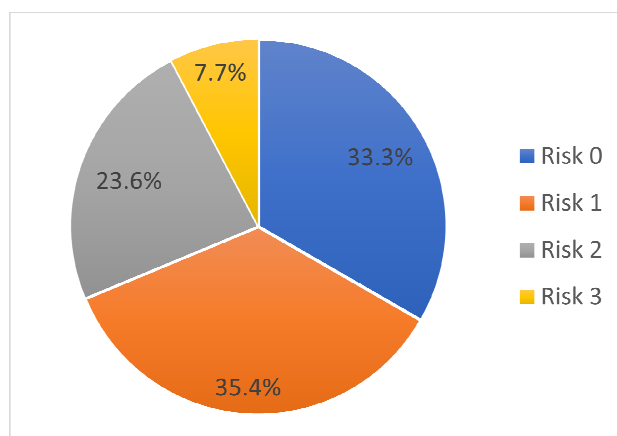


Figure 1. Diabetic foot risk levels in patients with diabetes

Table 1. Comparison of demographic and clinical characteristics between DFU and non-DFU groups

Variable		DFU n (%)	Non DFU n (%)	Total n (%)	<i>P</i>
Gender	Male	60 (72.3)	84 (43.1)	144 (51.8)	<0.001
	Female	23 (27.7)	111 (56.9)	134 (48.2)	
Education status	Illiterate	18 (21.7)	37 (19.7)	55 (19.8)	0.001
	Literate	13 (15.7)	14 (7.2)	27 (9.7)	
	Primary	45 (54.2)	89 (45.6)	134 (48.2)	
Type of living area	High school and above	7 (8.4)	55 (28.2)	62 (22.3)	0.450
	Rural	29 (34.9)	49 (25.1)	78 (%28.1)	
	Urban	54 (65.1)	146 (74.9)	200(%71.9)	
Smoking status	Uses	24 (28.9)	68 (34.9)	92 (33.1)	0.210
	Not using	37 (44.6)	93 (47.7)	130 (46.8)	
Type of diabetes	Disposes	22 (26.5)	34 (17.4)	56 (20.1)	0.009
	Type 1	2(2.4)	24(12.3)	26(9.4)	
	Type 2	81(97.6)	171(87.7)	252(90.6)	
Training on foot care	Yes	39 (47.0)	45 (23.1)	84 (30.2)	<0.001
	No	44 (53.0)	150 (76.9)	194 (69.8)	
Foot examination by health professional	Yes	46 (55.4)	28 (14.4)	74 (26.6)	<0.001
	No	37 (44.6)	167 (85.6)	204 (73.4)	
Diabetic retinopathy	Yes	45 (54.2)	64 (32.8)	109 (39.2)	0.001
	No	38 (45.8)	131 (67.2)	169 (60.8)	
Diabetic nephropathy	Yes	15 (18.1)	19 (9.7)	34 (12.2)	0.082
	No	68 (81.9)	176 (90.3)	244 (87.8)	
PAD	Yes	17 (20.5)	4 (2.5)	21 (7.6)	<0.001
	No	66 (79.5)	191 (97.5)	257 (92.4)	
DPN	Yes	14(16.9)	108(55.4)	122(43.9)	<0.001
	No	69 (83.1)	87(44.6)	156(56.1)	
Ulcer history	Yes	43 (51.8)	16 (8.2)	59 (21.2)	<0.001
	No	40 (48.2)	179 (91.8)	219 (78.8)	
Amputation history	Yes	18 (21.7)	4 (2.1)	22 (7.9)	<0.001
	No	65 (78.3)	191 (97.9)	256 (92.1)	
		Mean±SD	Mean±SD	Total mean ±SD	<i>P</i>
Age		57.71±10.50	54.05±13.09	55.14±12.47	0.015
Diabetes duration (year)		14.79 ± 6.33	12.61 ± 6.23	13.26±6.33	0.008
Systolic blood pressure (mmHg)		147.89±21.62	136.33±20.86	139.78±21.71	<0.001
Diastolic blood pressure (mmHg)		85.24±10.64	79.07±11.91	80.91±11.87	<0.001
HbA1c (%)		10.17 ± 1.89	10.23 ±2.14	10.21±2.07	0.826
Body Mass index (BMI) (kg/m²)		30.71 ±6.17	32.27 ±7.38	31.81 ±7.07	0.070
Foot care behavior		40.61 ± 13.69	47.20 ±12.28	45.23±13.04	<0.001

PAD: peripheral artery disease; DPN: diabetic peripheral neuropathy

In the established logistical regression model, DFU status was considered as a dependent variable. The factors affecting DFU status were examined and the effect levels of these factors were determined. Table 3 shows the parameter estimation results of the coefficients for the independent variables. According to the results obtained, male gender ($P= 0.002$), education (literate) ($P= 0.022$), pedal pulse ($P= 0.015$), foot deformity ($P= 0.012$), foot examination by health professional ($P= 0.001$), and foot skin temperature (cold) ($P< 0.001$) had a significant effect on DFU (Table 3).

Discussion

Foot ulcers are an important cause of morbidity and hospitalization in patients with diabetes. The economic burden associated with DFU is enormous. Although there are not enough data on DFU rates in Turkey in recent years, Saltoğlu et al. report that the rates are high (10). Determining the DFU risk level and patient risk factors is the cornerstone of the prevention of DFUs. To determine the DFU risk level and risk factors, foot examination should be performed and preventive treatments should be planned for the identified foot problems (12,25). There are almost no studies on the definition of DFU risk level and risk factors in Turkey.

Table 2. Comparison of Foot Examination Findings of Patients with diabetes in DFU and non-DFU groups

Variable	DFU n (%)	Non DFU n (%)	Total n (%)	P
LOPS				
Present	69 (83.1)	87(44.6)	156(56.1)	<0.001
Absent	14(16.9)	108(55.4)	122(43.9)	
Pedal pulse				
Present	32(15.7)	172(84.3)	204(73.4)	<0.001
Absent	51(61.4)	23(11.8)	74(26.6)	
Nail pathology				
Present	66 (79.5)	101 (52.7)	167 (60.1)	<0.001
None	17 (20.5)	94 (48.2)	111 (39.9)	
Foot skin temperature				
Normal	7(8.4)	158(81.0)	165(59.4)	<0.001
Warm	18(21.7)	32(16.4)	50(18.0)	
Cold	58(69.9)	5(2.6)	22.7(278)	
Callus				
Present	14 (16.9)	25 (12.8)	39 (14.0)	0.374
None	69 (83.1)	170 (87.2)	239 (86.0)	
Shoe suitability				
Appropriate	37 (44.6)	125 (64.1)	162 (58.3)	0.003
Inappropriate	46 (55.4)	70 (35.9)	116 (41.7)	
Deformity				
Present	75 (90.4)	37 (19.0)	112 (40,3)	<0.001
None	8 (9.6)	158 (81.0)	166 (59,7)	

LOPS: Loss of Protective Sensation

Table 3. Predicted parameter values and significance levels of the logistic regression model

Variable	OR (95% CI)	P
Gender (male)	0.074 (0.014 -0.388)	0.002
Education (literate)	0.038 (0.002 - 0.630)	0.022
Amputation history (yes)	0.443 (0.026 – 7.552)	0.574
PAD (yes)	2.132 (0.551 – 8.250)	0.273
Training on foot care (no)	7.029 (0.662 – 74.618)	0.106
Foot examination by health professional (yes)	0.013 (0.001 - 0.183)	0.001
Foot care behavior	1.036 (0.990 – 1.085)	0.130
Foot deformity (present)	0.170 (0. 042 - 0.679)	0.012
Pedal pulse (absent)	8.146 (1.505 – 44.081)	0.015
Foot skin temperature (cold)	0.003 (0.000 - 0.026)	0.000
LOPS (present)	0.255 (0.047 – 1.376)	0.112

LOPS: Loss of Protective Sensation; PAD: Peripheral arterial disease

Therefore, the present study evaluated DFU risk levels and risk factors for patients with diabetes in a province with a high prevalence of diabetes in Turkey.

This current study determined that approximately one-third of patients with diabetes were in the "high-risk" and "moderate-risk" groups according to the IWGDF classification system. Vibha et al. evaluated diabetic foot risk levels and risk factors in 620 people in India and found that one fifth of the participants were at moderate-risk to high-risk (8). The percent of patients in the moderate-risk and high-risk groups was lower than that in this study. Patients with diabetes in the middle- and high-risk groups

are more important, especially in terms of diabetic foot risk level and the frequency of follow-up of this group of diabetics should be increased (29). Doaa O et al. in their study in Egypt, determined that 68% of patients with diabetes had a high-risk level of DFU (21). According to Kishore et al. in their study conducted in India (n=100), approximately 50% of patients with diabetes had a low-moderate DFU risk level, which is similar to the present study (20).

Some characteristic data such as age, gender and educational level may be a risk factor for the development of DFUs. In this study, male gender was found to be associated with DFU. Similar to this study, many studies have

identified male gender as a risk factor for DFU (2,13,15,21). The increase in foot ulcers among diabetic male patients may be of concern for families as men are often the only earning members of the family.

In this study, it was determined that there was a relationship between low education level (literate) and DFU among demographic variables. Kishore et al. In a study conducted in New Delhi, India, it was determined that the education levels of patients at high risk level were significantly lower (28). Al-Maskari and Mohammed El-Sadig's study conducted in the United Arab Emirates also found that low education level increases the likelihood of DFU (30). Education level may not be a direct risk factor for DFU. However, high level of education is thought to be important in terms of developing positive health behaviors and awareness in individuals. It is stated that the development of diabetic foot can be reduced by 85% with good foot care, education and a multidisciplinary team approach (31). Some studies have also found that foot care behaviors are one of the risk factors predicting DFU (18,32,33). In this study, the effect of foot care behaviors in predicting DFU was not determined. However, in pairwise analysis, it was determined that individuals with DFU had lower foot care behavior scores.

In the current study, the rate of not having foot examination by a healthcare professional was high in diabetic individuals with DFU. In addition, there was a significant difference between individuals with and without DFU in terms of not having foot examination. Not having foot examination was a predicting factor for diabetic foot. Patients followed up with regular foot examinations are less likely to have DFU. To provide the necessary care and treatment for the health problem detected during foot examination, it is recommended to perform the foot examination in the periods determined according to the risk level (12).

While foot temperature elevated shows infection, temperature decrease shows vascular circulation (34). In this study, it was determined that 69.9% of individuals with

DFU had low foot temperature and there was a significant relationship between individuals with and without DFU in terms of foot temperature. In recent years, there have been evidence-level studies on self-examination of foot temperature at home in the early diagnosis of DFU, especially in high-risk patients (12,25,35). Therefore, foot temperature evaluation is thought to be important for both the healthcare professional and the patient.

Low foot temperature is one of the important findings of PAD (34). Peripheral artery disease (PAD) is usually due to atherosclerosis and is encountered in more than 50% of diabetic foot patients. PAD impairs wound healing and lower extremity. It is an important risk factor for DFU, which leads to amputations (12,30). In this study, 7.6% (21) of patients with diabetes had PAD and 17 of them had DFU. On further analysis, no relationship was found between the presence of PAD and DFU. However, there was an association between pedal pulses (absence), one of the important findings of PAD, and DFU (35), in this study, data from the patient registry system were used for PAD. In addition, pedal pulses were assessed using manual palpation. Ankle brachial index (ABI) assessment is a more reliable method than manual pulse assessment (34). The fact that PAD was not diagnosed with the ABI method in this study may be a limitation of this study. However, palpation is a simple and rapid physical examination method for both pulse and temperature assessment. It is also one of the important evaluation parameters of foot examination and can be applied in all conditions. Therefore, we believe that the evaluation of these two parameters is extremely important for the detection of conditions that may pose a risk for DFU and the referral of patients for further examination.

At present, numerous stratification systems using different methods have been proposed to identify the degree of risk for foot ulceration among patients with diabetes. Deformity is one of the variables used in diabetic foot risk stratification. In this study, it was determined

that 90% of the patients with foot ulcers had a deformity in their feet and that the presence of deformity was associated with DFU. This result was compatible with the literature (36,37). According to the IWGDF Risk Level System; In case of a deformity accompanying LOPS or PAD, it is recommended that patients be followed up every 3-6 months (12,25). Although the results of this study can only be generalized to the specific study group, the results are important because the study was conducted in a province with a dense population with diabetes in Turkey. Although the manual performance of heat and pulse assessments may seem a limitation, the results obtained are guiding and important in clinical decision-making processes of one-to-one patient examination. Especially in developing countries with a high prevalence of diabetes and limited health personnel, it is potentially simpler than other examination methods.

Conclusions

As a result of the study, DFU was detected in 29.8% of diabetic individuals. 7.7% (15) of 195 diabetic individuals without DFU had a high risk of diabetic foot (risk level 3). Male gender, low education level, foot deformity, absence of pedal pulse and having a foot examination by a healthcare professional were risk factors associated with DFU.

In addition, regarding the two important parameters of foot examination, pulse and foot temperature, weak/absent foot pedal pulse and low foot temperature were risk factors that increased the possibility of DFU.

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The results obtained in this study suggest that patients with diabetes should have their feet examined regularly by diabetes or wound care nurses from the first moment of diagnosis, the risk level should be determined according to the results of the foot examination and the treatment of risk factors should be planned. In this way, early diagnosis may prevent DFUs and possible amputations.

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Conflict of Interest

The original research has not been previously published or intended to be published elsewhere. We declare that there is no conflict of interest between the authors or any institution.

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