

Investigation of the Risk of Diabetic Foot Ulcers and Affecting Factors in Patients with Type 2 Diabetes

✉ Müzeyyen Şalva, ✉ Sibel Tunç Karaman, ✉ Okcan Basat

University of Health Sciences Turkey, Gaziosmanpaşa Training and Research Hospital, Clinic of Family Medicine, İstanbul, Turkey

ABSTRACT

Introduction: patients with diabetes are at risk of developing diabetic foot ulcers (DFUs), which can lead to serious consequences such as the loss of a limb. This study investigated the DFU risk of patients with type 2 diabetes (T2D) and to examine the factors affecting it.

Methods: This cross-sectional study was conducted using patients aged 18 and over who had T2D for at least one year and without DFU. The Patient Information Form and the Turkish Version of the Brief Diabetic Foot Ulceration Risk Checklist (BDURC-TR) were used to obtain data. Anthropometric measurements, levels of glycosylated hemoglobin A1c, and fasting plasma glucose were recorded.

Results: The total BDURC-TR score of the 150 participants was 1.81 ± 1.42 and 11.3% (n=17) had a score of ≥ 4 . The BDURC-TR score was statistically significantly ≥ 4 in those with known diabetes-related complications, those using combined diabetes treatment, those with long diabetes duration, and those with greater height ($p < 0.001$; $p = 0.033$; $p = 0.004$; $p = 0.013$, respectively). Although not significant according to the cut-off values, there was a statistically significant correlation between the BDURC-TR total score and age, weight, and waist circumference values ($r = 0.246$, $p = 0.002$; $r = 0.0163$, $p = 0.046$; $r = 0.182$, $p = 0.026$, respectively). The BDURC-TR total score was also higher in men and in those using additional drugs ($p = 0.037$ and $p = 0.024$).

Conclusion: Our study showed that 11.3% of the patients with T2D had a high DFU risk. The presence of diabetes-related complications, combined diabetes treatment, a long duration of diabetes, and having greater height was high-risk factors for DFU.

Keywords: Complications, diabetic foot ulcers, diabetic foot ulcer risk checklist, type 2 diabetes

Introduction

Diabetic foot ulcer (DFU) is characterized by ulceration, infection, and/or gangrene associated with diabetic neuropathy (DNP) and peripheral vascular disease in the foot (1). The risk of DFU occurrence in patients with diabetes is approximately 15-25% (2).

The DFU is the most common complication of diabetes that is difficult to treat and causes hospitalizations (3). It results in disability, loss of workforce, decreased the quality of life, and increased health care costs. Prolonged life expectancy and years with diabetes increase the risk of developing DFU (4).

The lifetime risk of DFU is also rising with increased medical complexity in people with diabetes. Therefore, the development of DFU can be prevented by keeping diabetes under control and providing foot care education to patients. High-risk patients should be identified and followed more frequently with both routine examination and risk assessment for DFU (5).

This study investigated the DFU risk of patients with type 2 diabetes (T2D) and examine the factors affecting it.

Methods

Study Design and Ethical Approval

This study was designed as a single-centered and cross-sectional study. Ethical permission to conduct this study was obtained from the University of Health Sciences Turkey, Gaziosmanpaşa Training and Research Hospital Local Ethics Committee (approval number: 379, date: 24.11.2021). The study was conducted under the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants.

The selection and Description of Participants

Study Population

All participants were selected from patients with T2D and were referred to the family medicine outpatient clinic of a tertiary hospital from from



Address for Correspondence: Sibel Tunç Karaman MD, University of Health Sciences Turkey, Gaziosmanpaşa Training and Research Hospital, Clinic of Family Medicine, İstanbul, Turkey
Phone: +90 505 715 46 99 E-mail: drsibeltunc@hotmail.com ORCID ID: orcid.org/0000-0003-1833-8758

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December 2021 to April 2022 for any reason. The study included 150 patients aged 18 and over who had a known diagnosis of T2D for at least one year, did not have been diagnosed with DFU, could understand, answered the questions asked, was literate, and agreed to participate in the study.

The sample size was calculated with the simple random sampling method from the study population, and when the incidence of DFU was considered 0.15 at the α effect level of 0.05, the minimum number of participants required for the study was 110 with a 95% confidence interval.

Exclusion Criteria

Patients under the age of 18, those with a disability to communicate (hearing and speech disorders, cognitive dysfunction, uncooperative), gestational diabetes, type 1 diabetes (T1D), T2D diagnosis less than 1 year ago, and illiterates were excluded.

Data Collection Tools

Patient Information Form

A patient information form was formulated that questioned the participants' sociodemographic characteristics (age, gender), diabetes characteristics (duration, treatment type, presence of known (physician-diagnosed) diabetes-related complications, hospitalization in the last year, treatment compliance), presence of comorbidities, and smoking history. Compliance with treatment was determined according to the patient's statement. Arterial blood pressure (mmHg), waist circumference (WC) (cm), height (m), weight (kg), and body mass index (BMI, kg/m²) were measured and recorded. The levels of glycosylated hemoglobin A1c (HbA1c) and fasting plasma glucose (FPG) obtained from venous blood were recorded.

The Turkish Version of Brief Diabetic Foot Ulceration Risk Checklist

The Brief Diabetic Foot Ulceration Risk Checklist (BDURC) was developed by Zhou et al. (6) in 2018 to determine the risk of DFU in diabetic patients. The Turkish validity and reliability study of the scale was performed by Dincer et al. (7) in 2021. BDURC-TR was composed of 12 items and 2 factors. The questions in the scale can be answered as "Yes" or "No." The "Yes" answer is scored as 1 point and the "No" answer as 0 points. A total of 0-12 points can be obtained from the scale. An increase in scores indicates an increased risk of DFU. The Cronbach's alpha coefficient of the Turkish version was determined to be 0.79 (7). The cut-off point for DFU risk was determined as 4 in the original study (6).

Statistical Analysis

The IBM SPSS Statistics 25.0 program was used for statistical analysis. Descriptive data on the sociodemographic information of the participants were presented as number (%) and mean \pm standard deviation tables. When the study data were analyzed in terms of normality assumptions, Kolmogorov-Smirnov values were determined as $p < 0.05$. Spearman correlation analysis, one of the non-parametric tests, was performed to investigate the relationship between BDURC scores and various numerical variables. The Mann-Whitney U test was applied to determine whether there was a significant difference between BDURC scores and various numerical variables of the participants. Chi-square test was

used for comparison of categorical variables. $p < 0.05$ was considered statistically significant.

Results

The ages of 150 participants in the study ranged from 33 to 88 years, with a mean value of 60.37 ± 10.56 . The total score from BDURC-TR was 1.81 ± 1.42 (0.00-6.00). 11.3% of the participants ($n=17$) had a BDURC-TR total score of ≥ 4 . The distribution of baseline characteristics of the participants is presented in Table 1.

The BDURC-TR score was statistically significantly ≥ 4 in patients with a long diabetes duration and those with greater height ($p=0.004$ and $p=0.013$). The data of the participants on laboratory examinations and anthropometric measurements and the distribution of data according to BDURC-TR risk groups are summarized in Table 2.

As seen in Table 3, in patients with known diabetes-related complications and in those using combined therapy, the BDURC-TR score was statistically significantly ≥ 4 ($p < 0.001$ and $p=0.033$). All participants who had a BDURC-TR total score of ≥ 4 , were determined to have a chronic disease other than diabetes. But it was not found statistically significant ($p > 0.05$). The distribution of the participants' medical characteristics according to the BDURC total score and risk groups are analyzed in Table 3.

Although not significant according to the cut-off values, there was a statistically significant difference between the BDURC-TR total score and age, weight, and WC of the participants ($r=0.246$, $p=0.002$; $r=0.0163$, $p=0.046$; $r=0.182$, $p=0.026$, respectively). The BDURC-TR total score was higher in men and in those using additional drugs ($p=0.037$ and $p=0.024$).

Discussion

Main Findings

In this study, which aimed to examine the DFU risk and affecting factors in patients with T2D, 11.3% of the patients with T2D were found to have a high risk of DFU. The presence of diabetes-related complications, combined therapy, long duration of the diabetes, and greater height were determined to be DFU risk factors regarding BDURC-TR cut-off levels. Gender, age, weight, and WC were also influential factors on the BDURC-TR total score.

Comparison with Existing Literature

The reported incidence and prevalence of DFU vary widely depending on the study design, population, and era. They are also affected by differences in DFU definitions. As is known, DFU may develop in 15-25% of patients with diabetes (2). Although the global prevalence of DFU varies between countries, it has been reported to be between 1.5 and 16.6% (8). In the BDURC development study, the one-year incidence of DFU was found to be 3.6% in T2D patients followed for 1 year, and the scale total score was 4.2 ± 2.3 (6). In a multicenter study investigating the incidence of DFU in patients with T2D and a new foot ulcer, the annual incidence of a new DFU was 0.42% (9). In the study in which BDURC was adapted into Turkish, it was reported that 86.7% of the patients had a total scale score of 4 and above, which is different from the literature (7).

In our study, 17 patients (11.33%) were determined to be at high risk (scored 4 or more on the BDURC-TR) for DFU. Studies measuring DFU risk using BDURC are limited in the literature. Since it is a scale that evaluates the risk of diabetic foot in Turkish people and has a multidisciplinary team approach, BDURC-TR was used in this study. Although there is a small number of people with DFU risk according to the cut-off level of the BDURC-TR, it can be said that it is compatible with the literature when compared to the number of all participants. This result also shows

the importance of risk screening for DFU, which can lead to important results such as loss of a limb. It should be noted that DFU-specific instruments to be used in risk assessment may include more clinical aspects of DFU and will be more sensitive to disease-related changes than generic tools.

In the literature, many factors have been shown to be associated with the risk of DFU. Demographic, socioeconomic, and metabolic factors are also strongly related to DFU. There are many studies indicating that the

Table 1. Baseline characteristics of the study participants (n=150)

		Min.-Max.	Mean \pm SD
Age (years)		33-88	60.37 \pm 10.56
Diabetes duration (years)		1.00-35.00	10.19 \pm 6.78
BDURC-TR total score		0.00-6.00	1.81 \pm 1.42
Total score <4 (n=133)		0.00-3.00	1.46 \pm 1.06
Total score \geq 4 (n=17)		4.00-6.00	4.52 \pm 0.71
		n	%
Gender			
	Female	94	62.7
	Male	56	37.3
Smoking status			
	Active smoker	27	18.0
	Ex-smoker	33	22.0
	Non-smoker	90	60.0
Presence of comorbidities			
	No	13	8.7
	Yes	137	91.3
Additional drug use			
	Yes	134	89.3
	No	16	10.7
Presence of complication due to diabetes			
	No	93	62.0
	Yes	57	38.0
Complication due to diabetes (n=57)*			
	Retinopathy	23	27.4
	Nephropathy	56	66.7
	Neuropathy	5	6.0
History of hospitalization due to diabetes in last year			
	No	144	96.0
	Yes	6	4.0
Diabetes treatment type*			
	OAD	61	40.7
	Insulin	17	11.3
	Combined therapy	72	48.0
Compliance with treatment			
	Yes	106	70.7
	Partially	28	18.7
	No	16	10.7

Data presented as min.-max., mean (SD), n and %. BDURC-TR: The Turkish version of Brief Diabetic Foot Ulceration Risk Checklist, OAD: Oral anti-diabetic drug, SD: Standard deviation.

*As the questions can contain multiple answers, the number of (n) exceeds the sample size

risk of DFU increases with age and years of living with diabetes (10,11). In addition, a statistically significant relationship has been revealed between being 60 years of age and older and DFU (12).

Similar to the literature, the present study determined that the risk of DFU increased with age and disease duration. The incidence of

complications increases with the prolongation of life expectancy and therefore the time spent with diabetes. Adequate metabolic control is required to reduce the cumulative effects of hyperglycemia and micro- and macrovascular complications as age and duration of diabetes increase.

Major comorbidities increase the risk of DFU and other diabetes-related complications (13,14). It has been shown that coronary artery disease has a significantly higher prevalence in patients with DFU because of a combination of cardiovascular risk factors (15). Studies have also revealed a positive relationship between hypertension and DFU (16). In addition, some studies have reported that dyslipidemia is a risk factor for DFU development (17).

In our study, the majority of the participants had any chronic disease and all the participants who had a BDURC-TR total score of ≥ 4 , were determined to have a chronic disease other than diabetes. However, it was not statistically significant. It is thought that the cut-off value of the scale we used effects obtaining different results from the literature in this context.

Diabetes-related complications are the most important basic risk factors for DFU. Since their symptoms are not obvious in the first stage, the risk of DFU may increase further as patients may be overlooked (18). The combination of neuropathy and peripheral arterial disease has been associated with an increased risk of ulcers in most previous studies (5). In a multicenter study, patients with diabetes-related complications were determined to have a higher risk of DFU (19).

Similar to the literature, the present study demonstrated that having DM complications other than DFU increased the risk of DFU. Since DFU

Table 2. Data on participants' laboratory findings and anthropometric measurements according to risk groups

	Findings according to BDURC-TR total scores		
	Total score <4, (n=133)	Total score ≥ 4 , (n=17)	
	Mean \pm SD	Mean \pm SD	p
Age (years)	59.86 \pm 10.41	64.35 \pm 11.18	0.120
DM duration (years)	9.62 \pm 6.47	14.64 \pm 7.68	0.004
FPG (mg/dL)	202.14 \pm 91.98	204.24 \pm 91.56	0.760
HbA1c (%)	8.92 \pm 2.23	9.35 \pm 2.92	0.727
Height (m)	1.61 \pm 0.08	1.68 \pm 0.09	0.013
Weight (kg)	80.68 \pm 15.24	86.00 \pm 14.42	0.142
WC (cm)	107.19 \pm 12.07	111.59 \pm 12.74	0.251
BMI (kg/m ²)	30.92 \pm 5.95	30.49 \pm 4.88	0.769
HR (rate/min)	75.41 \pm 7.53	79.53 \pm 8.74	0.071
SBP (mmHg)	126.58 \pm 17.70	124.12 \pm 15.12	0.523
DBP (mmHg)	77.17 \pm 8.48	75.59 \pm 7.04	0.476

Mann-Whitney U test, Data presented as min.-max. and mean (SD). BDURC-TR: The Turkish Version of Brief Diabetic Foot Ulceration Risk Checklist, DBP: Diastolic blood pressure, FPG: Fasting plasma glucose, HbA1c: Hemoglobin A1c, HR: Heart rate, SBP: Systolic blood pressure, SD: Standard deviation, WC: Waist circumference

Table 3. Comparison of BDURC risk groups according to clinical variables of the participants

		BDURC-TR		p
		Total score <4, (n=133)	Total score ≥ 4 , (n=17)	
		n (%)	n (%)	
Gender	Female	86 (64.7%)	8 (47.1%)	0.158 ^a
	Male	47 (35.3%)	9 (52.9%)	
Smoking status	Active smoker	24 (18.0%)	3 (17.6%)	1.000 ^b
	Ex-smoker	29 (21.8%)	4 (23.5%)	
	Non-smoker	80 (60.2%)	10 (58.8%)	
Groups according to BMI	Normal	17 (12.8%)	3 (17.6%)	0.787 ^a
	Overweight	43 (32.3%)	6 (35.3%)	
	Obese	73 (54.9%)	8 (47.1%)	
Presence of comorbidities	No	13 (9.8%)	0 (0.0%)	0.363 ^b
	Yes	120 (90.2%)	17 (100.0%)	
Presence of diabetes-related complications	No	90 (67.7%)	3 (17.6%)	<0.001 ^a
	Yes	43 (32.3%)	14 (82.4%)	
Diabetes treatment*	OAD	57 (42.9%)	4 (23.5%)	0.033^a
	Insulin	17 (12.8%)	0 (0.0%)	
	Combined therapy	59 (44.4%)	13 (76.5%)	
Compliance with treatment	Yes	96 (72.2%)	10 (58.8%)	0.421 ^b
	Partially	24 (18.0%)	4 (23.5%)	
	No	13 (9.8%)	3 (17.6%)	

Data presented as n (%). *Pearson chi-square, ^bFisher's exact test, p<0.05. BMI: Body mass index, BDURC-TR: The Turkish Version of Brief Diabetic Foot Ulceration Risk Checklist, OAD: Oral antidiabetic drug, SD: Standard deviation. *As the questions can contain multiple answers, the number of "n" exceeds the sample size

and other DM-related complications act synergistically in contributing to clinical outcomes and morbidity, their development should be prevented with multidisciplinary DM care and risk assessments.

Generally, the male gender is a crucial risk factor for DFU (13,15). However, there are also studies indicating no significant relationship between gender and DFU (20,21).

As in many previous studies, the risk of DFU was also higher in men (regarding BDURC total score) in our study. Sex differences could be explained by underlying risk factors, attitudes about footwear and footcare, and adherence to the treatment.

Glycemic control is one of the most critical factors in DFU development and glycemic disorders increase the risk of DFU. Dekker et al. (16) revealed that diabetic patients with foot ulcers had higher averages of HbA1c than those without foot ulcers, as well as a higher cumulative glycemic load. Similarly, mean HbA1c values were found to be statistically significantly higher in diabetic patients with DFU. On the other hand, the DFU risk of those with HbA1c values above 9% was significantly higher than those with HbA1c values lower than 6.5%. There was no significant increase in DFU risk in those with HbA1c values between 6.5 and 9% compared to those with HbA1c values lower than 6.5% (22). Also, studies showed that patients with high plasma glucose levels have a higher risk of developing DFU in the future (23,24).

Contrary to previous studies, in our study, there was no statistically significant difference between FPG and HbA1c from DFU risk. This suggests that glycemic control alone may not be a responsible factor in the development of DFU and may be due to differences in other variables (patient-and foot-specific factors) of the participants.

In many studies, a significant relationship was reported between insulin use and DFU. Yazdanpanah et al. (25) determined in their two-year follow-up study that patients treated with insulin were more likely to develop DFU than patients treated with oral anti-diabetic drug (OAD) or lifestyle changes alone. In a cohort study, insulin and combined therapy (insulin and OAD) were found to be associated with DFU risk, but there was no significant relationship between OAD and DFU (26).

In our study, those using combined therapy had a higher risk of DFU. Considering that patients with poor glycemic control cannot be achieved with OAD, they are switched to combined therapy. It should be kept in mind that these patients have poor glycemic control, which increases the risk of DFU.

Although obesity is one of the main risk factors for developing T2D, its contribution to DFU development risk is still controversial. There are studies in the literature revealing that obesity increases DFU risk (15). In fact, obesity increases the likelihood of developing DFU by 2.1 times (27). In contrast, according to recent systematic reviews, obesity is not associated with incident or recurrence of DFU, amputation, or mortality (28). Furthermore, increased WC was indicated to be a risk factor for DFU (29).

Similar to the literature, there was no significant relationship between BMI and DFU risk in our study. However, a significant correlation was

found between weight and WC, which are critical components of obesity, and the risk of DFU.

It is thought that the length of the nerve roots is an important factor in the development of neuropathy due to DNP, that the long nerve roots are affected early by degeneration, and therefore the risk of neuropathy increases as the height of the patients increases (30).

In support of this, our study observed a significant correlation between height and DFU risk. In fact, the correlation of the total score with weight, height, and WC could also be due to different gender compositions in subjects with high versus low DFU risk.

Study Limitations

This study has some limitations. First, due to the single-center and cross-sectional design and relatively small sample size of the study, the findings may not be generalized to the population. Second, we only included T2D patients because we predicted that we would not be able to reach sufficient T1D patients. Lastly, the participants were not followed-up. Contributions to the literature should continue with a larger sample, more comprehensive, and multicenter studies, including patients with T1D and newly diagnosed T2D.

Conclusion

Our study showed that 11.3% of the patients with T2D had a high DFU risk. The presence of diabetes-related complications, combined diabetes treatment, long duration of diabetes, and having greater height were high-risk factors for DFU. Gender, age, weight, and WC were also influential factors on the DFU risk. These factors should be considered to prevent the formation of DFU. In addition to routine evaluations, patients with T2D should be examined periodically in terms of DFU risk with DFU-specific risk assessment methods, and high-risk patients should be followed more frequently. Modifiable risk factors should be eliminated by providing metabolic control. In-need referral to a higher level of healthcare can save both the leg and the life of the patient.

Ethics Committee Approval: Ethical permission to conduct this study was obtained from the University of Health Sciences Turkey, Gaziosmanpaşa Training and Research Hospital Local Ethics Committee (approval number: 379, date: 24.11.2021). The study was conducted under the principles of the Declaration of Helsinki.

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