

Validity and reliability of the Turkish version of brief diabetic foot ulceration risk checklist

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ABSTRACT

OBJECTIVE: This study aims to determine the validity and reliability of the Turkish translation of brief diabetic foot ulceration risk checklist (BDURC).

METHODS: This methodological study was conducted at the diabetes clinic of a state hospital in Istanbul, Turkey. The data were collected with the BDURC developed by Zhou et al. in 2018. A study was conducted with 430 patients with Type 2 diabetes. The scale was retested after 4 weeks by 60 participants. Language equivalence of the scale was provided. Experts' opinions were taken about the content validity of the scale. Reliability of the scale was determined with the test-retest reliability, item-total correlation, and internal consistency analysis.

RESULTS: Confirmatory factor analysis revealed a two-factor structure with good model suitability. Cronbach's alpha coefficient for the scale and its subscales was 0.79. Test-retest scores showed no statistically significant difference between the items ($p > 0.05$). The reliability index was higher than 0.80.

CONCLUSION: The BDURC-TR is a valid and reliable tool that can be used in clinics to identify the risk factors for diabetic foot ulcers in patients with Type 2 diabetes in Turkey.

Keywords: Amputation; diabetic foot ulcer; risk; scale.

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Globally, diabetes is one of the major health problems of this century [1, 2]. With the changes in lifestyle, the prevalence of Type II diabetes is rising rapidly all over the world. According to the International Diabetes Federation data, approximately 463 million people of the age group 20–79 had diabetes worldwide in 2019 [1]. Uncontrolled diabetes leads to many

complications, affecting all systems of the body [1, 2]. Diabetic foot is one of the most serious and the most commonly observed complications in diabetes [2]. Each person with diabetes has 12–15% risk of developing diabetic foot ulcers during the lifetime [3–5]. About 40–60% of non-traumatic foot amputations are due to diabetic foot ulcers [6].



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According to the 2011–2014 Turkish Diabetes Program data, it is reported that there are 400 thousand diabetic foot ulcer developments and 6000 amputations performed in Turkey [4]. Diabetic foot ulcer causes increased morbidity, deterioration of patients' life qualities, and high treatment costs in addition to the risk of amputation.

The main aim of the diabetic foot ulcers approach is to provide primary prevention. For this purpose, it is necessary to identify risky groups, to develop preventive health behaviors, and to perform a foot examination at every control [7–9]. Many risk factors can trigger the development of diabetic foot ulcers. A meta-analysis indicated that insensitivity to a 10 g monofilament, absent pedal pulses, and a history of ulceration or lower extremities amputations were predictors of diabetic foot formation [10]. Another meta-analysis results reported that patients with diabetic foot ulcers were older, had a lower body mass index, had a longer diabetic duration, and had more hypertension, diabetic retinopathy, and smoking history than patients without diabetic foot ulcers [11]. It is essential to provide a multidisciplinary approach to determine these risk factors.

The brief diabetic foot ulceration risk checklist (BDURC) is a scale that provides a multidisciplinary approach to determining the diabetic foot risk of patients with Type 2 diabetes [12]. BDURC was developed in 2018 to determine diabetic foot risk by Zhou et al. [12]. The scale had been stated to have good psychometric properties and good predictive ability according to mixed evidence from classical and modern test theory. There is no scale with a multidisciplinary team approach to assess diabetic foot risk in Turkey. This study aimed to evaluate the reliability and validity of a translated Turkish version of BDURC (BDURC-TR) among Turkish patients with Type 2 diabetes.

MATERIALS AND METHODS

Setting and Samples

In this study, the data methodologically designed was performed at the diabetes outpatient clinic of a University Hospital in Istanbul, Turkey, between May 2018 and December 2019. The proposed study sample consisted of all patients who met the eligibility criteria. Criteria for the inclusion of the patients in research are as follows:

- (a) Being 18 years of age and older and literate,
- (b) Having been diagnosed with diabetes for at least 1 year,
- (c) Having no diabetic foot ulcer,

Highlight key points

- The BDURC-TR is a valid and reliable tool that can be used in clinics to identify the risk factors for diabetic foot ulcers.
- Confirmatory factor analysis revealed a two-factor structure with good model suitability.
- The BDURC-TR may be helpful to the diabet team for deciding who should receive more care and support for diabetic foot ulcer.

(d) Intact hearing, speech, and cognitive functions.

Totally, 438 patients met the research criteria. However, the eight patients refused to participate in the study. Thus, 430 patients completed participating in the study, resulting in 98% response rate.

Instrument

The basic information form, BDURC, was used for the study.

Basic information form

The form prepared by the researchers in accordance with the literature [12–15] includes 12 questions on age, gender, educational status, course of diabetes, treatment type of diabetes, smoking, alcohol use, diabetes control tightness, chronic disease status, and compliance with treatment. In addition, HbA1c level can be used to determine risk in diabetes patients [12, 16].

BDURC (Appendix 1)

BDURC had been developed to determine the risk of foot ulceration in patients with diabetes. The development and validation of the BDURC had been completed by Zhou et al. [12]. The tool consists of 12 items. The responses to all items were scored on a true-or-false scale. Items were categorized into five dimensions:

1. Neuropathy and vasculopathy,
2. Structural deformity and associated changes,
3. The course of disease and comorbidity,
4. Ulcer history and general skin change,
5. Fungal infection of skin and toenail.

Procedures and Data Collection

The study consists of three phases, which include translation, transition, and reliability tests of BDURC-TR. Translation includes a four-step process:

1. Forward translation from English to Turkish,

2. Backward translation from Turkish to English,
3. Examination of original English and Turkish forms with forms translated backward English for the solution of inconsistencies as errors and all differences in the forms,
4. The final development of the Turkish version of BDURC.

Content, structure, and divergent validity of BDURC-TR were evaluated. The expert panel including five diabetes nurses, four dermatologists, two endocrinologists, two physiotherapists, and three internal medicine specialists examined the validity of the content for BDURC-TR. All panel members reviewed the relevance, simplicity, and clarity levels of the items.

They pointed the scale with 4-point Likert scoring system as indicated 1: unacceptable, 2: somewhat acceptable, 3: acceptable, and 4: highly acceptable.

Then, the content validity index (CVI) was calculated for the total BDURC-TR. It was found to be 0.92. This demonstrated that BDURC-TR has clear, concise, readable, and excellent content validity through different elements.

Construct validity was evaluated to prove two-factor structure of the BDURC-TR. Divergent validity was tested to evaluate discriminative power of BDURC-TR. Reliability was assessed to test internal consistency and test-retest stability of the BDURC-TR. Construct and divergent validity and internal consistency were tested in the total sample. The basic information form of the instruments was applied in the hospital training room at the diabetes outpatient clinic, a quiet and well-lit room where patients could focus on filling out questionnaires without being disturbed. In the same room, nurses (academician 3 years experienced on diabetes nursing in 5 years nursing academics section), specialist dermatologist, internal medicine specialist, and physiotherapist of the authors managed diabetic foot examination to fill BDURC-TR.

For test-retest stability, patients who were able to visit the clinic within 4 weeks after the initial assessment were invited. A total of 65 patients agreed to pay a second visit to the clinic. Two days before the scheduled date, a researcher called patients to remind them of their appointments. Sixty of the 65 patients who accepted the second visit to our clinic and BDURC-TR were completed. Patients completed BDURC-TR in 5–11 min. About 90% of them completed their questions within the BDURC-TR in 5 min. The examination took an average of 20.14 ± 5.7 min to complete.

TABLE 1. The sociodemographic characteristics of the participants (n=430)

Features	%
Gender	
Female	64.7
Male	35.3
Marital status	
Married	77.0
Bachelor	23.0
Education	
Primary	40.9
Secondary	17.4
High	19.5
University	15.1
Graduate	7.0
Occupation	
Retired	57.7
Non-working	6.0
Officer-worker	17.9
Freelancer	18.4
Treatment	
Oral antidiabetics	70.46
Insulin	29.53
Age (Mean±SD)	49.54±17.43
Diabetes duration (Mean±SD)	14.29±10.11
HbA1c (Mean±SD)	8.22±2.34

SD: Standard deviation.

Ethical Considerations

The study was approved by the Clinical Studies Ethics Committee of the Istanbul Medeniyet University Goztepe Training and Research Hospital (Approval No: 2018/0094, Date: March 21, 2018), and written permission was obtained from the institution to conduct the study. Written informed consent was obtained from participants before participation as well. The study was carried out according to the guidelines presented in the Declaration of Helsinki.

RESULTS

General Characteristics of Participants

The overall characteristics of the participants are shown in Table 1. The average age of the participants was 49.54 ± 17.43 (min: 20 and max: 81) and the majority of them were female (64.7%), married (77%), retired

TABLE 2. Factor loads obtained as a result of the first-level single-factor confirmatory factor analysis on the scale (n=430)

Factors and substances	Factor load	Error ratio
F1		
DA1: Presence of diabetes for 10 years or more. According to the patient's reply	0.736	0.10
DA2: Presence of nephropathy detected by physician	0.710	0.10
DA3: Presence of retinopathy detected by physician	0.793	0.08
DA4: According to the patient's reply. A previously existing foot wound or amputation	0.693	0.11
DA5: Presence of skin changes (scars, erythema, or edema) detected by the dermatologist	0.681	0.12
DA6: Presence of structural deformity in the foot (including talipes cavus, talipes echinus, talipes calcaneovalgus, talipes calcaneovarus, flat sole, hammer finger, hallux valgus, and Charcot foot) that has been detected by the nurse	0.541	0.15
DA7: Toenail fungus detected by a dermatologist.	0.533	0.14
DA8: Non-normal foot skin temperature measured by infrared thermometer (the temperature measured from the top of the foot or between the fingers is $\geq 26^{\circ}\text{C}$ or the temperature difference between the feet is $\geq 2^{\circ}\text{C}$)	0.676	0.12
DA9: Dorsalis pedis pulse weakening detected by nurse	0.619	0.13
F2		
DA10: Protective sensory loss measured by nurse using Semmes-Weinstein 5.07/10 g monofilament test	0.992	0.00
DA11: Presence of fungus infection in the foot detected by dermatologist	0.997	0.00
DA12: Presence of callus or calluses detected by dermatologist	0.589	0.14

TABLE 3. Model tests and comparisons (n=430)

Tested models	RMSEA	CFI	NFI	IFI	GFI	TLI	AGFI	CMIN	CMIN/df
Model 1 (hypothesized model with five factors)	0.083	0.956	0.941	0.956	0.918	0.945	0.879	207.776	3.920
Model 2 (alternative model with two factors)	0.066	0.972	0.959	0.972	0.943	0.964	0.913	147.298	2.888

AGFI: Adjusted goodness of fit index; CFI: Comparative fit index; GFI: Goodness of fit index; IFI: Incremental fit index; NFI: Normed fit index; RMSEA: Root mean square error of approximation; TLI: Tucker Lewis index.

(57.7%), and educated at primary school level (40.9%). About 52.8% of Type II diabetics with an average diabetes duration of 14.29 ± 10.11 years were using insulin. Mean HbA1c of patients was 8.22 ± 2.34 .

According to the confirmatory factor analysis, it is stated that structural equation modeling result of the scale is significant at the level of $p=0.000$, and the 12 items and the two sub-dimensions that make up the scale are related to the scale structure. Restoration was made in the model (Table 2).

Variables reducing fit were specified during the improvement and new covariances were created for those with high covariance among the residual values (e_6 -

e_7 ; e_4 - e_8). In the calculations of fit indices renewed subsequently, accepted values for the fit indices are shown in Table 3.

In Table 4, the results of the independent group t-test show the distinctiveness power of all substances and total correlations of the substances are included. The minimum value required to be adequate for the item-total test correlation is stated as 0.3 [17]. Items of the scale we evaluated the correlations below 0.3 were not included in the analysis.

The item-total test correlation values of the participants' answers to the scale questions were examined and it was determined that there were no items below 0.3.

TABLE 4. Substance analysis results for participants of the scale (n=430)

Item number	Item-total score correlation	t (bottom 27%*-top 27%*)	P value (bottom 27%*-top 27%*)
S1	0.681	-22.809	<0.001
S2	0.667	-19.470	<0.001
S3	0.714	-21.564	<0.001
S4	0.662	-20.460	<0.001
S5	0.625	-21.564	<0.001
S6	0.543	-16.654	<0.001
S7	0.537	-15.670	<0.001
S8	0.642	-22.167	<0.001
S9	0.568	-17.007	<0.001
S10	0.882	-115.00	0.004
S11	0.883	-116.00	<0.001
S12	0.588	-22.809	<0.001

*: n1=n2=116.

The substance total test correlation values of all substances vary between 0.537 and 0.883. As can be seen in the item-total test correlation table, all substances are found to be related to each other.

The unprocessed scores obtained from the scale were sorted from large to small to determine the distinctiveness of the substances in the scale and the score averages of the groups locating in the bottom 27% and at the top 27% were compared with the independent group t-test. As a result of the comparison, there was no statistically significant difference between the averages of the lower and higher group item scores. Hence, it can be said that the scale is distinctive in the context of measuring the desired quality.

Reliability of the D-FISQ

As shown in Table 5, the scale intended to measure has been achieved in only two dimensions. In this context, explanatory factor analysis results to determine the factor pattern of the BDURC-TR are also shown in Figure 1.

TABLE 5. Explanatory factor analysis of scale and reliability results (n=430)

Factors and substances		Described variance (%)	Eigen value (Λ)	Factor load	Mean	SD
F1: ($\alpha=0.881$)						
• Presence of callus or calluses detected by dermatologist	3	37.432	5.216	0.759	0.70	0.46
• Toenail fungus detected by a dermatologist	4			0.758	0.71	0.45
• Dorsalis pedis pulse weakening detected by nurse	8			0.739	0.70	0.46
• The presence of skin changes (wound, erythema, or edema) detected by the dermatologist	1			0.707	0.70	0.46
• Protective sensory loss measured by nurse using Semmes-Weinstein 5.07/10 g monofilament test	2			0.684	0.67	0.47
• Presence of fungus infection in the foot detected by dermatologist	5			0.680	0.70	0.46
• Non-normal foot skin temperature measured by infrared thermometer (the temperature measured from the top of the foot or between the fingers is $\geq 26^{\circ}\text{C}$ or the temperature difference between the feet is $\geq 2^{\circ}\text{C}$)	9			0.666	0.72	0.45
• Presence of diabetes for 10 years or more, according to the patient's reply	6			0.660	0.67	0.47
• Presence of structural deformity (including talipes cavus, talipes echinus, talipes calcaneovalgus, talipes calcaneovarus, flat sole, hammer finger hallux valgus, and Charcot foot) in the foot that has been detected by the nurse	7			0.645	0.71	0.46
F2: ($\alpha=0.885$)						
• Presence of nephropathy detected by physician	10	22.095	1.927	0.951	0.70	0.46
• According to the patient's reply, a previously existing foot ulcer or amputation	11			0.948	0.70	0.46
• Presence of retinopathy detected by physician	12			0.746	0.68	0.47

Bartlett globality test, total $\alpha=0.879$, KMO=0.855, $\chi^2(66)=3509.796$.

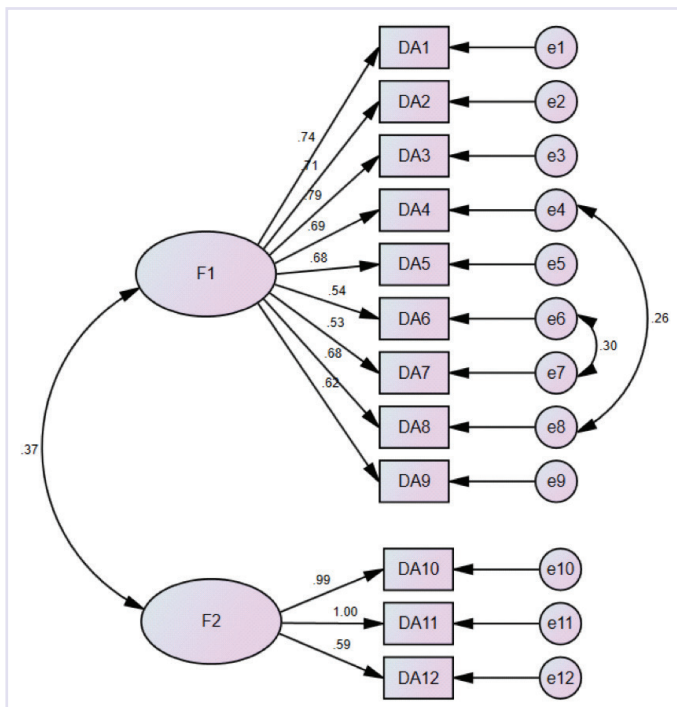


FIGURE 1. Model for first-level single-factor confirmatory factor analysis of the scale.

Before the application of explanatory factor analysis, the Kaiser-Meyer-Olkin (KMO) test was applied to test the fit of the sample size for factorization. As a result of the analysis, the KMO value was 0.855.

After confirming the fit of the data for factor analysis, explanatory factor analysis was performed using principal components analysis method and varimax rotation methods to examine the factor structure of the scale.

As a result of the analysis, it was found that there were only two components with an eigenvalue of over 1 for 12 items as a basis for the analysis. The contribution of this component to the total variance was found to be 59.527%. The first factor describes 37.432% of the total variance and the second factor describes 22.095% of the total variance.

In the explanatory factor analysis to determine the factor pattern of the scale, the acceptance level for factor load values was determined as 0.3.

As shown in Table 5, the Cronbach alpha value was calculated as 0.879 for the entire scale (12 items). Cronbach alpha 0.881 and Cronbach alpha 0.885 were calculated for the first factor.

After applying the same measuring tool to the same group twice at different times, the correlation coefficient is calculated ($r=0.902, p<0.05$). This calculated number is considered to be the reliability coefficient. As the correlation coefficient gets closer to +1, the reliability rises. Therefore, the two scales are consistent according to the correlation coefficient.

Simple linear regression analysis was performed to explain the effect of the scores obtained from the scale on HbA1c level. When we look at the level of significance corresponding to the value of F, it is seen that the established model is statistically significant ($F=70.756; p<0.05$) (Table 6). When we look at the t value and significance levels of the beta coefficient of the independent variable, it is seen that the scores obtained from the scale have a statistically significant effect on HbA1c level ($p<0.05$).

Fifty-four of the variations on the scores obtained from the HbA1c level are explained by the scores obtained from the scale (arranged $R^2=0.538$). There is no problem of autocorrelation in regression analysis ($DW=2.23$). Of the participants with a total score of 4 and over is 86.7% ($n=373$) and under 4 is 13.3% ($n=57$).

DISCUSSION

Preventing the development of diabetic foot ulcers and identifying the high-risk patients are possible with a good foot examination by dermatological, neurological, vascular, and biomechanical evaluation. Ulcer prevention

TABLE 6. Regression analysis results ($n=430$)

Dependent variable	Independent variable	β	t	P	F	Model(P)	Adjusted R2	DW
HbA1c	Constant	4.583	12.288	0.000	70.756	0.000	0.538	2.230
	Scale	0.406	8.412	0.000				

DW: Durbin Watson statistic.

guidelines recommend an interprofessional approach involving physicians and ancillary health care workers and patients. There is no scale for diabetic foot examination and risk detection in our country. Therefore, there was a need to develop a tool to measure the risk. This scale has been adapted to Turkish since there is an existing scale. The risk assessment tool should be simple and clear, because the tool will be used to estimate the risk levels of diabetes patients for diabetic foot ulcers [10]. Early identification of the risks for diabetic foot ulcer is crucial to reducing the number of morbidity and mortality. The BDURC scale developed by Zhou et al. [12] was adapted into Turkish and a study of validity and reliability was conducted. The validity of a research tool is assessed by how successfully it can measure the object it is designed to measure [11].

Bush states that content validity refers to the degree to which the instrument covers content that it should measure [18]. It also refers to the adequacy of sampling of content that needs to be measured [19]. Content validity, therefore, measures the comprehensiveness and representability of a scale's content. The CVI was then calculated for the total BDURC-TR. As a result of the assessment, the CVI value of BDURC-TR was 0.92. This demonstrated that BDURC-TR has clear, concise, readable, and excellent content validity through different elements. In the literature, 0.80 was determined as the validity criterion for the CVI score [20].

Sample quantity is an important factor in validating factor analysis for the estimation method to produce accurate results, but there is no firm consensus on how many samples should be taken [20]. According to Kline [21], the sample should be 10 times the number of substances and this number should not be <200.

The scale developed by Zhou et al. [12] consisted of a total of 12 items and 5 factors. In our study, the Turkish version of the scale was composed of 12 items and 2 factors as a result of explanatory and confirmatory factor analyses. Model fit was tested by confirmatory factor analysis of two-factor structure obtained by explanatory factor analysis.

In cases of the observed variables collected under multiple and separate factors during applications of confirmatory factor analysis, the second-level confirmatory factor models also need to be tested where these factors are combined under a broader and more inclusive factor. It is required to be <0.05 for root mean square error of approximation (RMSEA). The range

0.05–0.08 is an acceptable ratio, but values above 0.08 are undesirable [21]. Factor loads should not be <0.30. The goodness of fit index (GFI) value should be between 0.90 and 0.95 after the measurement and 0.95 and above is considered to be a good fit. Because it is sensitive to the sample size, it gives more suitable values in large samples [22]. The comparative fit index (CFI) value above 0.95 indicates acceptable fit [23]. The higher tucker Lewis index (TLI) value indicated better fit for the model. Although values more than 0.95 are interpreted as acceptable fit, 0.97 is accepted as cutoff value in a great deal of researches [23]. The normed fit index (NFI) value should be above 0.95 [24]. NFI is acceptable up to 0.80. The adjusted goodness of fit index (AGFI) value of 0.90 and above indicates a good fit. Incremental fit index (IFI) value 0.90 and above indicates a good fit [25]. As a result of the first level confirmatory factor analysis conducted to test the model fit of the BDURC-TR scale, it was found that the model fit of the scale was good and the two-factor structure was confirmed (RMSEA=0.066, CFI=0.972, NFI=0.959, IFI=0.972, GFI=0.943, TLI=0.964, AGFI=0.913). By looking at these results, it can be said that the scale has acceptable fit indices.

Reliability tests measure the consistency, precision, repeatability, and righteousness of a research [26]. Reliability is used to assess the stability of measurements applied to the same individuals at different times and the equivalence of sets of items from the same test [27].

In our study, internal consistency and time invariance were used to determine reliability. Substance total score analysis and Cronbach alpha coefficient were used to evaluate internal consistency. The use of Cronbach alpha in research with multiple substance measurements is considered routine. It is expressed with values between 0 and 1. Values between 0.7 and 0.8 are acceptable, 0.8–0.9 are good, and 0.9–1 show excellent internal consistency [28]. In the study of Zhou et al. [12], the Cronbach alpha coefficient was found to be 0.56. In our study, the Cronbach alpha coefficient of the adapted scale was 0.79.

Generally speaking, a correlation coefficient of <0.3 indicates a weak correlation, while the coefficients of 0.3–0.5 medium and >0.5 indicate a strong correlation [29]. A small element correlation provides empirical evidence that the element does not measure the same structure as measured by other elements included. A correlation value of <0.2 or 0.3 indicates that the rel-

evant substance is not very well related to the scale in general, and may, therefore, fall [30]. The correlation coefficients between each item on a scale and the total values are expected to be high. The higher the correlation coefficient, the higher the relationship of that substance with the desired quality to be measured. The BDURC-TR provides these characteristics when looking at item-total score correlations.

The test-retest method was used to test the stability of the quality measured by the Turkish form of the scale statistically in terms of time. If the two sets of points are highly correlated, then random error resulting from temporal factors may be minimal. In general, reliability coefficients around 0.90 are considered “excellent,” values around 0.80 are considered “very good,” and values around 0.70 are considered “adequate” [30]. The fact that the BDURC-TR scale’s test-retest correlation has been seen statistically significant as a finding that supports reliability in terms of time consistency of the scores obtained from the scale.

Limitations

This study was conducted in a single center and may not be representative of the sample; it is not clear whether the findings can be generalized to Turkey. With a larger and representative sample, it should provide stronger evidence. Literate patients diagnosed with diabetes in the past 6 months were included in the study. Different studies may be conducted involving newly diagnosed and illiterate patients. The scale can be used in all diabetes patients, and it is strongly recommended that the scale to be applied to large groups.

Conclusion

The Turkish translation of the brief diabetic foot ulceration risk scale was tested for validity and reliability in Turkish diabetes patients and found useful for Turkish populations. The factor structures of the original scale and the Turkish version are compatible. As a result, BDURC-TR can be used for patients with Type 2 diabetes to detect the risk of diabetic foot in Turkey. This scale was developed especially for patients with Type 2 diabetes. The entire scale and subscales evaluate the risk of diabetic foot formation. The scale is easy to understand and patients can easily use it. The results of this study aim to guide the diabetes team with determining the risk for both foot wound formation and better patient outcomes in diabetes patients.

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APPENDIX 1. Brief diabetic foot ulceration risk checklist

Items	Yes	No
1. Course of diabetes equal to or more than 10 years, patient reported		
2. Having nephropathy, determined by physician		
3. Having retinopathy, determined by physician		
4. Previous foot ulceration or amputation, patient reported		
5. Presence of skin changes (damage, redness, or edema), determined by dermatologist		
6. Fungal infection of foot skin, determined by dermatologist		
7. Presence of callus or corn, determined by dermatologist		
8. Structural deformity of foot (including talipes cavus, talipes equinus, talipes calcaneovalgus, talipes calcaneovarus, flat foot, hammer toe, hallux valgus, and Charcot's foot), determined by nurse		
9. Fungal toenail, determined by dermatologist		
10. Abnormal foot skin temperature, measured using infrared thermometers (dorsal pedal or interdigitalis temperature $\leq 26^{\circ}\text{C}$, or temperature difference between feet $\geq 2^{\circ}\text{C}$)		
11. Dorsalis pedis pulse diminution, determined by nurse		
12. Loss of protective sensation, measured by nurse, using the Semmes-Weinstein 5.07/10 g monofilament		
Scoring: Each positive item endorses 1 point.		