

Ten Rules of Foot Care—The Development of a Short Questionnaire for Patients with Diabetes

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Abstract

Objective: The aim of this study was to develop and validate a questionnaire for patients with diabetes to assess the foot self-care. **Methods:** A validation study was carried out in a sample of 200 patients with diabetes. Item analyses included the assessment of difficulty index, discrimination capacity and the correlation of items with the total score of the questionnaire. Factor analysis was used to test construct validity. Test-retest reliability was assessed with a sample of 31 patients. Criterion validity was determined by comparing the scores of patients with a history of foot ulcers with the scores of patients without this complication. **Results:** The internal consistency assessed by the Cronbach’s alpha (0.731) and test-retest reliability ($r = 0.714$, $p = 0.001$) for all sections were acceptable. Factor analysis revealed three factors: foot care, footwear and foot-damaging behavior, which explained 54.34% of the variance. All items had factor loading of greater than 0.4. Patients with diabetic neuropathy had a lower score after completing the foot care education questionnaire (Mann-Whitney U, $p < 0.001$). **Conclusion:** This questionnaire meets the reliability and validity conditions necessary for its application in our patients with diabetes.

Keywords

Diabetes Mellitus, Foot Care, Validation Study, Diabetic Foot Ulcers

1. Introduction

Diabetic foot disease is caused by specific complications (neuropathy, peripheral arterial disease) and/or infection. It often leads to foot ulcers and limb amputation. Consequently, diabetic foot disease is considered one of the most expensive diabetic complications. Foot ulcers have an incidence of 1% in Europe and North America and 11% in some African countries [1].

A study on the number of foot ulcers in Romania that included 21,174 patients found that 14.85% had a history of foot ulcers, and 3.60% had an amputation [2]. The risk of ulcers or amputation is increased in the presence of certain risk factors. The most important are poor glycemic control, peripheral neuropathy with loss of protective sensation, cigarette smoking, foot deformities, peripheral arterial disease, visual impairment and history of amputation or previous foot ulcers [3]. The development of a diabetic foot ulcer is associated with a high mortality rate, which has been estimated to be 5% in the first year. The 5-year mortality rate was estimated at 42% [4]. The incidence rates for recurrence are high; in the first year, approximately 40% of patients experienced a new lesion after a previous ulcer had healed. It has been estimated that almost 65% of patients experienced ulcer recurrence within 5 years. Thus, it was [5] proposed that it would be useful to think of patients who have achieved wound closure as being in remission.

Education of patients with diabetes to prevent foot ulcers consists of oral and written information on the importance of foot care and advice on basic foot care for people with diabetes or their caregivers. Specific education alone is associated with better knowledge and improved foot care behavior, but it cannot prevent foot ulcers. Despite these findings, the International Working Group on the Diabetic Foot recommends education to improve patients' knowledge and behavior [6].

There are many instruments available for evaluating care and self-care in diabetic patients, but very few have the primary purpose of assessing foot self-care. Therefore, the creation of a form that is easy to use in daily practice and has adequate validity and reliability is recommended [7].

The aim of our study was to design and validate a questionnaire for evaluating the foot self-care of patients with diabetes.

2. Methods

A cross-sectional validation study was carried out. The assessment questions and the fidelity of the foot self-care assessment questionnaire were examined in a sample of patients with diabetes who were treated at the Diabetes, Nutrition and Metabolic Diseases Clinic of Emergency Clinical Hospital "Sf. Spiridon" Iasi in February-April, 2020.

The sample size was estimated using OpenEpi software [8]. We selected a 95% confidence level and a diabetes prevalence of 11.6%. The PREDATORR study was the first national study analysing the prevalence of diabetes mellitus (DM) and prediabetes in the Romanian adult population. The overall age- and sex-adjusted prevalence of DM was 11.6% (95% CI 9.6% - 13.6%), of which 2.4% (95% CI 1.7%-3.1%) were unaware that they had DM [9]. The Romanian population comprises 19.7 million people. A single-proportion formula $\left(n = (Z\alpha/2)^2 P(1-p)/d^2 \right)$ with a 95% confidence interval where $Z\alpha/2 = 1.96$, $P =$ prevalence of 11.6%, and $d = 5\%$ of marginal error was applied. Based on

these calculations, the minimum sample size required was 185.

Inclusion criteria were having diabetes and being older than 18 years. Patients with cognitive, psychiatric, or other diseases that might adversely affect their understanding of the study objectives or the ability to provide accurate information were excluded.

A total of 210 patients were invited to participate in the study. Ten were excluded from the final analysis due to refusal to participate in the study or inability to fill in the form. To avoid influencing the participants' replies, the questionnaires were self-administered after the participants received appropriate instructions.

A section concerning demographic data and history of diabetes was included at the beginning of the questionnaire. It was completed by direct interview and contained questions concerning demographic data (age, area of residence: rural or urban, duration of formal education), disease duration and type of treatment. In our center the screening of the presence of specific diabetes complications (diabetic retinopathy, diabetic nephropathy, neuropathy, peripheral artery disease) is done during regular check-ups which are carried out yearly and registered in the patients' charts. Thus, the presence of the complications, the glycated hemoglobin value (HbA_{1c}) and the history of ulcers were registered based on the data from the patients' charts. The therapeutic goal is to obtain an Hb A_{1c} below 7% and it represents the glycemic control in the previous 2 - 3 months. Neuropathy assessment was performed by screening protective sensation in the foot with 10-g monofilament, vibration perception using a 128-Hz tuning fork, application of warmth and cold and pinprick sensation [10] [11]. Regular ophthalmic exams are mandatory for detecting diabetic retinopathy [12] and are done by ophthalmologists from our hospital during annual screening. Nephropathy screening [13] is performed by the determination of albumin-to-creatinine ratio, estimated glomerular filtration rate and screening for urinary infection to rule out the false positive results.

The items of the questionnaire were formulated after a review the recommendations of the International Diabetes Federation [1] and International Working Group on the Diabetic Foot [14]. We also take into consideration the recommendations provided during the education sessions, which are known by patients as the "ten rules of the diabetic foot". Patients learn them at their initial education session and during periodic complication screening check-ups. A total of 40 items was generated and proposed to the experts for the evaluation of their appropriateness.

The content validity of the foot self-care questionnaire was assessed qualitatively. The questionnaire items were reviewed by a group of two diabetes, nutrition and metabolic diseases physicians, a nursing professor and three nurses with experience in diabetic foot care and patient education. The experts evaluated 40 items for their clarity, appropriateness and significance in relation to the measurement of foot care behavior. We opted to use two categories of an-

swers (yes and no/not sure) to reduce the time needed to complete the questionnaire and facilitate the processing and quantification of the results [15]. Also this manner of answers was considered to give the respondents the chance to make a response and to reduce the possibility of guessing [16]. Appropriate answers to the questionnaire items received a score of 1 point, while incorrect or “not sure” responses received a score of 0 points. We scored with 0 the positive answers for items which indicated an inappropriate behavior.

Each item was analyzed by the experts in relation with three points of view:

- The relevance in relation with the aim of the questionnaire;
- The relation with the recommendations provided to the patients during the education sessions;
- The importance for foot self-care in diabetic patients.

Each of these three aspects was scored on a Likert scale from 1 to 5 (inadequate, fairly adequate, adequate, very adequate). Items considered by more than two experts as unimportant was deleted. Content validity index scores ranged from 0.62 to 1 and items with scores below 0.78 was excluded [16]. After their review, the final questionnaire had 20 questions.

Face validity is an important aspect of content validity [17]; therefore, the questionnaire draft was tested for user friendliness and item ambiguity in a pilot study with ten patients. The pilot test evaluated whether the terms used were defined in the same way and had the same meaning for all patients. It resulted in changes to five items. After another consultation with the experts, the second version of the questionnaire consisted of 18 items.

The questionnaire comprised the following items:

- 1) Check the feet every day.
- 2) Wash the feet daily with room temperature water.
- 3) Tamponing for drying the feet is recommended (use absorbent materials to dry the feet).
- 4) Check the spaces between toes.
- 5) Moisturizing cream should be used for dry skin.
- 6) Never apply creams or oil between the toes.
- 7) Cut toenails straight across and remove sharp edges.
- 8) Never remove corns or calluses at home or at the manicurist.
- 9) Plasters or chemical agents should never be used.
- 10) Shoes should be worn for shorter periods to accommodate the foot.
- 11) Socks should always be worn with shoes.
- 12) Socks must be made of cotton or linen to avoid sweating and the development of fungal infections.
- 13) Before putting shoes on, check inside them foreign objects to prevent wounds.
- 14) Avoid walking barefoot at all times.
- 15) Avoid the use of heat sources to warm the feet.
- 16) Avoid smoking; it is harmful to the feet.

17) Ask for an exam if a blister, cut or sore develops.

18) Minor procedures should be performed by a health care provider (in Romania, a general surgeon).

The data obtained from the questionnaires were added to a database created using Microsoft Office Excel 2007. Statistical processing was performed using the Statistical Package for Social Sciences version 13.0 (SPSS, Inc., Chicago, IL, USA). For discriminative analysis, the Pearson correlation coefficient was determined, and to assess internal fidelity, the Cronbach's alpha coefficient was used. To test the normality of distribution of the questionnaire scores, the Kolmogorov-Smirnov test was applied. To evaluate construct validity, we determined whether there were significant differences in the mean scores obtained by the Mann-Whitney U test. Factor analysis tested the construct validity. The Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) can signal in advance whether the sample size is large enough to reliably extract factors. The p value of Bartlett's test of sphericity should be significant and lower than 0.05. We performed both simple and forward binominal logistic regression to determine the predictive role of the variables resulting from the factor analyses.

Approval from the Research Ethics Committee of the "Gr. T. Popa" University of Medicine and Pharmacy Iași (approval date 25.02.2020, according to research law 206 from 26 May 2004) and permission to administer the questionnaires and collect the data was received from the "Clinical Emergency Sf Spiridon Hospital" institutional review board was obtained before contacting participants and collecting data. All participants provided signed informed consent. All data were anonymised to maintain participant confidentiality.

3. Results

The study included 200 patients with diabetes, 53% of whom were from a rural environment. A proportion of 52% were women. Most of the patients (49%) had graduated high school, while 41% had a lower level of formal education (primary or secondary school). Only 10% had a university degree. The subjects were aged between 37 and 78 years, with a mean age of 59.53 years. The average time since diagnosis according to the number of years with the disease was approximately 12.3 years.

Most of the patients had chronic diabetes complications (65%), and the frequency of diabetic neuropathy was high (58%). Almost eight percent of the participants had a history of foot ulcers (**Table 1**).

The difficulty index of the questions was determined. This index indicates the percentage of respondents who answered the same question correctly [18]. Four of the items had a proportion of correct answers that was higher than 80%, and 2 ("Never remove corns or calluses at home or at the manicurist" and "Minor procedures should be managed by a health care provider") were answered correctly by more than 90%, indicating a low difficulty of these two questions.

Table 1. Background characteristics of the participants (Iași, România, February - April 2020).

Background characteristics	
Age, years (mean \pm SD)	59.53 \pm 16.81
Sex (male)	96 (48)
Urban environment, N (%)	92 (46)
Formal education, number of years	
• \leq 8%	41
• 9% - 12%	49
• $>$ 12%	10
Duration of DM (years)	12.3 \pm 8.23
Hb A _{1c} (mean \pm SD)	9.71 \pm 1.81
Diabetic complications	
• Neuropathy (N, %)	116 (58)
• Retinopathy (N, %)	130 (65)
• Nephropathy (N, %)	96 (48)
• Peripheral vascular disease (N, %)	75 (35)
History of foot ulcers (N, %)	15 (7.5)

The discrimination capacity determines the extent to which each item measures the same aspect as the test itself. The discrimination index, expressed as a percentage, is determined by calculating the difference between the number of persons in the upper and lower quartile of the total score that gave correct answers [18]. Items with a coefficient of less than 20% do not have the capacity to discriminate among subjects [17]. In the analyzed questionnaire, the questions “Plasters or chemical agents should be never be used”, “Shoes should be worn for shorter periods to accommodate the foot” and “Avoid smoking; it is harmful to the feet” did not have adequate discrimination capacity.

The correlation of items with the total score gives an indication of the relevance of that item to the overall test result. A correlation of less than 0.2 is considered a cut-off point; items with correlations below this cut-off should be omitted [18]. Correlations of less than 0.2 were obtained for the following questions: “Tamponing for drying the feet is recommended”, “Socks must be of cotton or linen to avoid sweating” and “Never apply creams or oil between the toes.” All correlations were statistically significant at $p < 0.001$.

Patients with neuropathy or foot ulcers were more likely to declare that they did not follow foot care advice. They more frequently engaged in inappropriate behaviors, such as walking barefoot or exposing the feet to heat sources, thus increasing the risk of burns or ulcers as a result of the lack of protective sensation associated with neuropathy (Table 2).

Reproducibility testing was performed with a group of 31 patients by administering the same questionnaire after a two-week interval, a period that is considered

Table 2. Descriptive summary of adherence to the “The ten rules of foot care”*.

	Distribution of answers %		Neuropathy %	
	Yes	No	Yes	No
1) Check your feet every day.	57	43	48.8	51.2
2) Wash feet daily with room temperature water.	72	28	32.1	67.9
3) Check the spaces between toes.	76	24	47.6	52.4
4) Use moisturizing cream for dry skin.	32	68	54.8	45.2
5) Cut the toenails straight across.	50	50	75	25
6) Check inside shoes for foreign objects.	65	35	27.4	72.6
7) Walk barefoot sometimes.	29	71	36.9	63.1
8) Wear socks without shoes.	58	42	60.7	39.3
9) Expose feet to heat sources.	23	77	70.2	29.8
10) Ask for an exam if a blister, cut, or sore develops.	65	35	51.2	48.8

*p < 0.001; **p = 0.064.

long enough to ensure that the patients did not remember the answers to the questions. We found that the questionnaire had acceptable reproducibility ($r = 0.715$, $p < 0.001$). Agreement levels varied from kappa 0.64 (95% CI: 0.37 - 0.78) to 0.77 (95% CI: 0.53 - 0.91).

The Cronbach’s alpha coefficient was 0.731 (greater than 0.70), indicating acceptable internal consistency for the use of the scale to conduct comparisons between groups.

The Kaiser-Meyer-Olkin (KMO) value of this dataset was 0.662, indicating that the sample had moderate adequacy for factor analysis. Bartlett's test of sphericity yielded a value of 357.403 ($p < 0.001$), indicating high correlation among items. Factors were extracted by Varimax rotation, and those with factor loading greater than 0.4 were accepted. The number of factors was determined in consideration of the scree plot (**Figure 1**), the cumulative variance explained and the eigenvalue.

A total of three factors were extracted and rotated, and the cumulative variance explained was 54.34% (**Table 3**).

The rotated solution showed a three-factor structure:

- factor 1 = self-care—behaviors aimed at maintaining good foot hygiene and early referral to specialists (items 1, 2, 3, 4, 5);
- factor 2 = footwear—an emphasis on the importance of adequate footwear and seeking medical advice (items 6, 7, 10);
- factor 3 = foot-damaging behavior—actions that increase the likelihood of developing foot ulcers (items 7, 8, 9).

Two factors represented the cure/controllability domains of self-care (five items, e.g., “Check your feet every day”) and the footwear/practitioner aspects of foot ulcer control (three items: “Before putting on shoes, always check inside

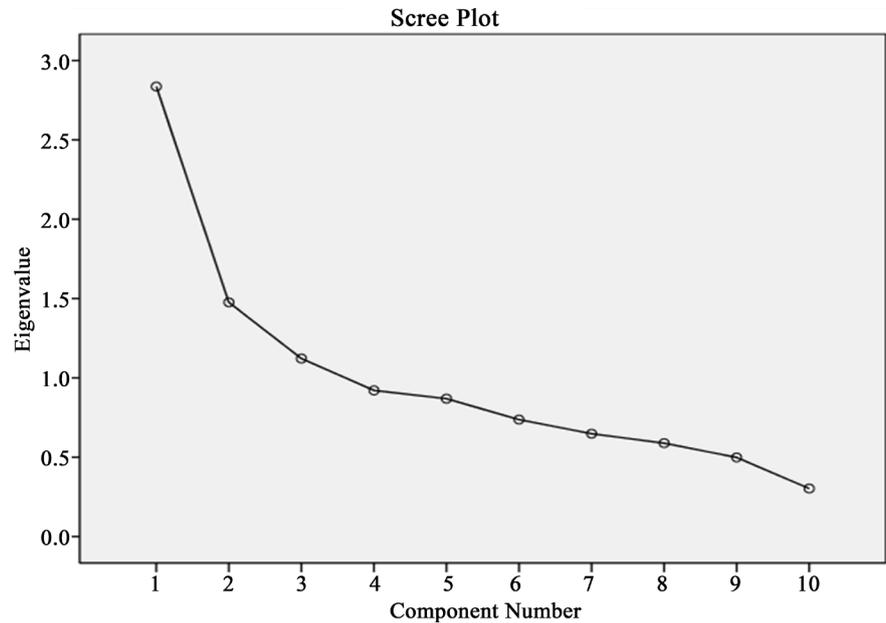


Figure 1. Scree plot—trifactorial structure of self-care foot questionnaire.

Table 3. Total variance explained by the foot care questionnaire.

Component	Initial eigenvalues			Extraction sums of squared loadings			Rotation sums of squared loadings		
	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %
1	2.83	28.36	28.36	2.83	28.36	28.36	2.1	21.72	21.72
2	1.47	14.76	43.12	1.47	14.76	43.12	1.70	17.03	38.76
3	1.12	11.22	54.34	1.12	11.22	54.34	1.55	15.57	54.34
4	0.92	9.21	63.55						
5	0.86	8.69	72.24						
6	0.73	7.37	79.61						
7	0.64	6.48	86.09						
8	0.58	5.88	91.98						
9	0.49	4.98	96.97						
10	0.30	3.02	100.0						

Extraction method: Principal component analysis.

them for foreign objects”, “Avoid walking barefoot at all times”, and “Ask for an exam immediately if a blister, cut, scratch or sore develops”. A single factor captured behaviors that increased the risk of foot ulcers (three items: walking barefoot, exposing the feet to heat sources, and not wearing socks) (**Table 4**).

The items on the foot care questionnaire were summed to create a score. The mean score was 6.06, the median was 6.00, and the standard deviation was 2.539. Patients with diabetic neuropathy had lower scores after completing the foot care questionnaire (5.67 ± 2.42 vs. 8.13 ± 1.19 ; Mann-Whitney U, $p < 0.001$). Factor analyses yielded three components that could reflect different attitudes

Table 4. Diabetic foot care short-form questionnaire—rotated component matrix.

	Component		
	1	2	3
Check your feet every evening.	0.517		
Wash feet daily.	0.757		
Check between toes.	0.739		
Use moisturizing oils or creams.	0.639		
Cut nails straight across.	0.452		
Check inside shoes.		0.758	
Walk barefoot.		-0.468	0.659
Wear socks without shoes.			0.700
Expose feet to heat sources.			0.738
Ask for an exam.		0.724	

towards foot care. Each factor was associated with neuropathy: self-care and foot wear behaviors was associated with the absence of diabetic neuropathy (OR = 0.412, 95% CI: 0.220 - 0.772; and, respectively OR = 0.252, 95% CI: 0.127 - 0.499), while those without neuropathy were more likely to haven't a foot-damaging behavior had a lower risk for the wounds (OR = 0.406, 95% CI: 0.232 - 0.755).

4. Discussion

The goal of developing questionnaires is to get pertinent information in a reliable and valid way [19]. Validity tests assays how well a questionnaire responds to the question if “it measures what is intended to be measured” [20]. The purpose of our study was to develop a manageable questionnaire to assess the foot self-care of patients and which would be able to discriminate the risk for diabetic wounds in patients with DM.

Validity is evaluated through two categories of tests, which evaluate theoretical construct and empirical construct. Theoretical construct, which was called translational or representational validity, is tested through face and content validity. The purpose of content validity is to ascertain that the items of a questionnaire fully represent the domain which is intended to be judged [21]. To use knowledge of the content areas as a reference framework for the interpretation of the scores, the topic from which the test items are to be extracted must be carefully defined. Review of research, critical incidents, direct observations, expert judgment are useful approaches to construct a questionnaire with an acceptable content validity. A literature review to identify if a previously validated questionnaire exists was recommended in order to retrieve, translate and apply them [22]. Although we could identify prior foot self-care questionnaire [7] [23] [24] [25] [26], we considered that the evaluation of the diabetic foot education provided during the sessions was an important aspect which wouldn't be eva-

luated through a preexisting questionnaire. We also took into account that an important aspect was that the items had to be representative for the type of individuals covered by the test. An important step of our study was the evaluation of the questionnaire's content validity. For this purpose, we started with the current foot care guidelines as a foundation for formulating a questionnaire to assess foot care behavior. The questionnaire items included concepts that are communicated during regular check-ups and annual screenings for specific complications associated with diabetes. Face validity aims to evaluate patients' comprehension about each item of the questionnaire and thus, to decide if the questionnaires are proper for the intended population [7] [27]. After testing for face validity, it resulted in changes to five items. The second version of the questionnaire, resulted after testing face and content validity, had 18 items.

Content validity is an important aspect related to empirical construct of the questionnaire. It includes tests for discriminant, factorial and known-group validity [21]. Regarding the analysis of the questions, it is generally not recommended to use questions with a difficulty index higher than 0.8 or lower than 0.2. For questions with multiple-choice answers, an index of difficulty between 0.35 and 0.85 is recommended. These ratios were adjusted based on other knowledge-assessment studies, which recommended the selection of items that more than 90% or less than 30% of the respondents answered correctly [17]. Of the remaining 18 questions, 8 questions were removed after item response analyses. In our study, only 50% cut the toenails straight across, while in a study conducted in China [24], 96.6% participants indicated that they cut their toenails as recommended. Our proportion of patients who cut the nails correctly was similar with that obtained by another author (52%) [28]. In the study conducted in China [24], 90.5% participants stated that they never put heating pads or hot water bags on their feet, while in ours 23% of participants declared exposing feet to heat sources. These results must be interpreted with caution, but are important as they highlight possible cultural differences. Furthermore, this emphasizes the need to adopt the preexisting questionnaires after testing them in the local conditions.

Internal consistency is defined as the correlation between an item and the global score of the measure to which the item contributes. Because all items must reflect a specific attribute, they must have a common variance, and they must correlate with one another and with the score that reflects that attribute [17] [18]. The Cronbach's alpha coefficient of the tested questionnaire was 0.731, indicating its validity.

In the reproducibility study, the correlation coefficient of the total score was 0.717, which is more than the recommended r of 0.70 [17] for reproducibility testing of knowledge questionnaires. This coefficient falls within the range obtained in other studies [27] and can be explained by the small size of the sample on which reproducibility was tested ($n = 31$) and the small number of questions. A previous study showed that correlation coefficients increase with the size of

the sample and the number of items [29].

Factor analysis showed a 3-factor structure. The three factors were named self-care (behaviors aimed at maintaining good foot hygiene), footwear (behaviors related to the importance of adequate footwear and seeking medical advice) and foot-damaging behavior (actions that increase the risk of developing foot ulcers). These factors explained 54.34% of the item variance in our study. In other researches the total variance ranged between 39% [24] and 69% [26]. The Diabetic Foot Self-Care Questionnaire (DFSQ-UMA) of the University of Malaga, Spain, has a 3-factor structure that accounts for 60.88% of the variance observed: personal self-care, podiatric care, and footwear and socks [7]. Two of these factors, foot wear and foot care, were observed in our short questionnaire; this finding reinforced patients' scores of their self-care as good, which is encouraging [7]. A study developed a diabetes foot self-care behaviour scale (DFSBS) with only seven questions. Its psychometric properties were tested, and one factor was found that explained 39.00% of the total sample variance. The DFSBS measures the frequency of foot self-care behaviour and can be used with patients who have not yet received foot care education. The DFSBS was found to differentiate between participants with and without a history of foot ulcers [24]. The Patient Interpretation of Neuropathy (PIN) Questionnaire is a 39-item questionnaire that measures patients' cognitive and emotional representations of neuropathy-related foot self-care. A factor analysis of the PIN questionnaire produced 11 scales, which explained 69% of the item variance. Two of these factors were related to foot care: 10 items were related to foot self-care behaviors, and eight items assessed potentially foot-damaging behaviors [26].

Diabetes mellitus is a chronic disease which requires lifetime adherence [30] and the associated social and demographical characteristics of the patients are important in long-term management. The ulcer high recurrence rates appear to be biologic or behavioral or both [5]. In our study, the questionnaire was tested in patients with diabetes and with and without a history of neuropathy or ulcers who had completed a foot care education programme. This short-form questionnaire could differentiate between participants with previous foot ulcers. In our study, patients with diabetic neuropathy had lower scores after completing the foot care education questionnaire. In another study [23], low mean scores were associated with a lack of formal education, shorter diabetes duration and the absence of medical advice. Foot self-care scores were significantly higher among patients who had received advice on foot care and those whose feet had been examined by a doctor at least once [23].

Although our results highlight the importance of foot care knowledge, we cannot draw conclusions regarding the participants' overall compliance with current recommendations. As this was an observational study, we cannot conclude that information about health hygiene behavior could influence the development of ulcers, although knowledge appears to be an important determinant. Our questionnaire aimed to evaluate patients' behaviour according to the di-

abetic foot education provided at our clinic, which emphasizes the importance of the ten rules of foot care for preventing ulcers. Our findings reflect the knowledge and behaviour of a limited patient population and could differ from other types or methods of patient education.

5. Conclusion

This questionnaire could be used in public health surveys in our population (Romanian adults with DM) to understand the complex relationships among therapeutic education, knowledge and lifestyle factors in people with diabetes. Additionally, it might be a helpful tool for assessing the success of health education in clinical practice.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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