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ORIGINAL RESEARCH

Spanish translation, cross-cultural adaptation, and validation of the Questionnaire for Diabetes-Related Foot Disease (Q-DFD)

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Purpose: To translate, cross-culturally adapt, and validate the Questionnaire for Diabetes-Related Foot Disease (Q-DFD), originally created and validated in Australia, for its use in Spanish-speaking patients with diabetes mellitus.

Patients and methods: The translation and cross-cultural adaptation were based on international guidelines. The Spanish version of the survey was applied to a community-based (sample A) and a hospital clinic-based sample (samples B and C). Samples A and B were used to determine criterion and construct validity comparing the survey findings with clinical evaluation and medical records, respectively; while sample C was used to determine intra- and inter-rater reliability.

Results: After completing the rigorous translation process, only four items were considered problematic and required a new translation. In total, 127 patients were included in the validation study: 76 to determine criterion and construct validity and 41 to establish intra- and inter-rater reliability. For an overall diagnosis of diabetes-related foot disease, a substantial level of agreement was obtained when we compared the Q-DFD with the clinical assessment (kappa 0.77, sensitivity 80.4%, specificity 91.5%, positive likelihood ratio [LR+] 9.46, negative likelihood ratio [LR–] 0.21); while an almost perfect level of agreement was obtained when it was compared with medical records (kappa 0.88, sensitivity 87%, specificity 97%, LR+ 29.0, LR– 0.13). Survey reliability showed substantial levels of agreement, with kappa scores of 0.63 and 0.73 for intra- and inter-rater reliability, respectively.

Conclusion: The translated and cross-culturally adapted Q-DFD showed good psychometric properties (validity, reproducibility, and reliability) that allow its use in Spanish-speaking diabetic populations.

Keywords: diabetes mellitus, peripheral vascular disease, diabetic neuropathy, foot ulcers

Introduction

Diabetes mellitus (DM) remains the most common of the chronic metabolic diseases, with 285 million adults affected worldwide in 2010. This is estimated to increase to 439 million adults affected by 2030, with prevalence rising from 6.4% to 7.7%.[1] In Ecuador, the World Health Organization predicts a prevalence of 921,000 diabetic patients by 2030.[2] In addition, the National Institute of Statistics and Census of Ecuador determined in 2010 that DM was the second cause of mortality in the country, at 6.5%.[3]

Diabetes-related foot disease (DRFD) is one of the main complications of DM and consists of several pathologies, including peripheral vascular disease (PVD), diabetic neuropathy (DN), Charcot's neuroarthropathy, foot ulcerations, osteomyelitis, and limb amputation.[4] Among diabetic patients, the prevalence of foot ulcers ranges from

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4% to 10%, with a lifetime risk as high as 25%.[5] Amputations due to DRFD are preceded by ulceration in 85% of cases, and carry a survival rate of around 50% after 3 years.[6–8]

In Ecuador, a previous study showed a prevalence of 11% for DRFD.[9] Given its high morbi–mortality, early detection is crucial. Although clinical evaluation remains as the gold standard, it is cost- and time-consuming and not widely available in rural populations. To address these issues, many surveys concerning DRFD have been developed. However, most of them only evaluate DN or PVD as individual components of DRFD. After an extensive search, we found that the Questionnaire for Diabetes-Related Foot Disease (Q-DFD) is the only survey that addresses all the components of DRFD within one tool, therefore, we chose this survey for the present study.[10]

The Q-DFD was created in English and validated in an Australian population. The aim of this study was to translate, cross-culturally adapt, and validate the Q-DFD for its use in Spanish-speaking diabetic patients in Ecuador.

Materials and methods

This study, designed as a cross-sectional model, was approved by the Medical Ethics Committee of the Universidad Central del Ecuador. Written and verbal informed consent was obtained from all participants prior to their inclusion in this study. Funding for this project was granted by the Research Center of Universidad Espiritu Santo.

The Q-DFD

The first author of the Q-DFD was contacted and asked for permission and collaboration with the development of this project. This questionnaire was created in the year 2009 by Bergin et al[10] and comprises 12 questions referring to signs and symptoms associated with PVD, DN, amputations, deformities, and foot ulcers.

Translation

The translation and cross-cultural adaptation were carried out based on the guidelines and international criteria proposed by Sperber.[11]

Forward translation

The Q-DFD was translated independently from English into Spanish by two professional translators. Each one provided a written report, which was combined by the authors in a new version that contained the most reliable translation for each question.

Back translation

The new version was back translated to English by two different professional translators, who were blinded to the original version of the Q-DFD. A new English version was developed by combining the written reports. The aim of the back translation process was to compare each item of the new English version with the original Q-DFD.

Cross-language validation

Each item of the new English version was compared with the original questionnaire by 30 raters fluent in English. The success of the translation was evaluated using two scales of comparison: comparability of language and similarity of interpretability. Each one used Likert scales ranging from 1 (extremely comparable/extremely similar) to 7 (not at all comparable/not at all similar). A mean score for each question was obtained. Questions with mean scores of three or less were included in the Spanish version. However, any questions with mean scores greater than three required a formal review and a retranslation until they indicated a valid version. The objective of this process was to identify potentially problematic items and retranslate them until the translated version was interpreted equally in both languages.

Test of the pre-final version

The Spanish version of the Q-DFD was tested on 16 subjects diagnosed with DM. Each subject provided feedback on the survey content, which was used to make final corrections. The authors discussed the information obtained and developed the final Spanish version.

Setting and subjects

A consecutive sample of 138 subjects was recruited and equally divided (46) into three samples: a community-based (sample A), and a hospital clinic-based sample (samples B and C). The inclusion criteria applied in all the samples were as follows: age ≥45 years, a previous diagnosis of DM, permanent residents of Guayaquil, and enough speaking skills to complete a Spanish interview over the phone.

Sample A

This sample was recruited through advertisements in two local newspapers. The advertisements contained the inclusion criteria and a contact number for subjects interested in participating in the study. Those who contacted the investigators were asked for their names, telephone number, and date and time they preferred to be contacted. Prior to the survey being

carried out, participants were asked for verbal consent. The survey was administered by a fourth-year medical student, and data were documented.

After the completion of the survey, subjects were invited to attend clinical evaluation. This was performed in an outpatient clinic by two specialized physicians (a neurologist and a vascular surgeon) with wide experience in these procedures. Data were recorded using a screening tool developed by Frykberg et al,[12] and written informed consent was obtained prior to the clinical evaluation. The evaluation included assessment of DN using the pinprick test and determination of the Achilles reflex; assessment of PVD with manual palpation of pedal pulses and determination of Ankle Brachial Index (with an 8 mHz hand-held Doppler, sphygmomanometer, and standard blood pressure cuff); and determination of foot deformity, foot ulcers, amputation, and ulceration.

Sample B

Sample B was recruited from attendees of an outpatient department at the Hospital Teodoro Maldonado Carbo located in Guayaquil. Members of the research staff assisted during consultation hours and invited patients who met inclusion criteria to participate in the study. For further analysis, sample B (B1) was divided into two groups: sample B2 (patients with known foot complications) and sample B3 (patients without known foot complications). After obtaining written informed consent, the presence of foot complications was determined by reviewing medical records looking for DN, PVD, amputation, and ulceration. Participants were asked to provide contact details to complete the Q-DFD over the telephone in the next few weeks. Verbal consent was confirmed prior to the survey being conducted.

Sample C

Sample C was used to evaluate the intra- and inter-rater reliability. The recruitment process in sample C was similar to that for sample B. Individuals who agreed to participate in the study completed the Q-DFD on three different occasions. Inter-rater reliability was obtained by comparing the first two interviews, which were conducted on the same day by two different interviewers. Both were blinded to each other's results. Intra-rater reliability was determined with the third interview, which was conducted by one of the first two interviewers 7 days later. Verbal consent was obtained prior to the survey being conducted.

Quality control

To guarantee that survey results were reliable, interviewers were asked to complete a training course. It was taught by the investigators and consisted of 10 hours regarding knowledge and familiarity with the survey, diction, interview conduction skills, and ability to interpret answers. Furthermore, all interviewers completed the Good Clinical Practice Course (https://live.blueskybroadcast.com/bsb/client/CL_DEFAULT.asp?Client=6&PCAT=5169&CAT=5169) prior to the beginning of the study.

Statistical analyses

The data collected were transferred from physical forms to electronic spreadsheets (Microsoft® Excel, version 2010; Microsoft Corporation, Redmond, WA, USA), and analyzed using SPSS software version 19.0 (Statistical Package for the Social Sciences; Chicago, IL, USA). Patient characteristics and descriptive data were calculated using means, frequencies, and standard deviations. Criterion and construct validity were estimated using kappa coefficient, sensitivity, specificity, and likelihood ratios (positive likelihood ratio [LR+] and negative likelihood ratio [LR−]). Prevalence rates for individual components of DRFD are reported as percentages. To interpret the kappa coefficient, the following definitions were used: 0, poor agreement; 0.2, slight agreement; 0.21–0.4, fair agreement; 0.41–0.6, moderate agreement; 0.61–0.8, substantial agreement; and 0.81–1, almost perfect agreement.[13]

Results

Translation

Translation and back translation

During the translation and back translation process, minimal discrepancies were encountered.

Cross-language validation

Table 1 shows the items that needed a formal review of the translation after failing to obtain a mean score of at least three in relation to comparability of language or similarity of interpretability from the 30 raters. Only four items were considered problematic and needed a new translation. In terms of comparability of language, items 1, 5c, 8a, and 12d obtained a mean score of 3.13, 3.20, 3.63, and 4.10, respectively; items 8a and 12d obtained an interpretability mean score of 3.70 and 3.90, respectively. After retranslating all the four problematic items, they were re-evaluated by 30 different raters, and each item obtained mean scores of three or less, allowing their use in the Spanish version of the questionnaire. After testing the

Table 1 Summary of adjustments with mean comparison scores for each item pair

Questionnaire and item	Translated version (Spanish)	Back translation	First version		Adjustment	Second version		Final Spanish version
			Comparability of language (mean score)	Similarity of interpretability (mean score)		Comparability of language (mean score)	Similarity of interpretability (mean score)	
Q-DFD Question 1	¿Qué edad tiene y cuál es su código postal?	What is your age and area code?	3.13	2.53	What is your age and what is your postcode?	1.37	1.33	¿Cuál es su edad y cuál es su código postal?
Q-DFD Question 5c	¿Ha sentido dolor en sus glúteos o zona inferior cuando camina, en el último mes?	Have you felt any pain in your gluteus or lower area while walking in the last month?	3.20	2.47	Have you felt any pain in your gluteus or bottom area while walking in the last month?	2.53	2.23	¿Ha sentido dolor en sus nalgas o zona inferior cuando camina, en el último mes?
Q-DFD Question 8a	¿Le ha indicado su médico, podólogo, especialista u otro profesional de la salud (PS) que usted ha perdido parte o toda la sensibilidad de sus pies debido a su diabetes?	Have you indicated your podiatrist, specialist, or other health professional (HP) that you have lost some or all feeling in your feet because of your diabetes?	3.63	3.70	Have your Doctor, specialist, or other health professional (HP) indicated that you have lost some or all feeling in your feet because of your diabetes?	2.33	2.03	¿Le ha indicado su médico, podólogo, especialista u otro profesional de la salud (PS) que usted ha perdido parte o toda la sensibilidad de sus pies debido a su diabetes?
Q-DFD Question 12d	¿Tiene callos en los dedos de sus pies?	Do you have blisters on your toes?	4.10	3.90	Do you have corns on your toes?	2.67	2.57	¿Tiene callos en los dedos de sus pies?

Abbreviation: Q-DFD, Questionnaire for Diabetes-Related Foot Disease.

Q-DFD on 16 subjects, minimal adjustments were made, and the final Spanish version was created.

Patient validation study

Criterion and construct validity

A total of 92 patients were recruited and allocated into sample A (n = 46) and sample B (n = 46). In addition, sample B patients (B1) were divided into samples B2 and B3. Ten patients from sample A were excluded; five who could not be contacted after five repeated phone calls, two who refused to participate, two who did not attend the clinical assessment, and one who was critically ill at the time of the telephone call. In sample B, six patients were excluded: five due to unavailability and one who was recently diagnosed with Alzheimer's disease. Thus, in sample A and B, 36 (78%) and 40 (87%) patients, respectively, were ultimately included in the study. Participant characteristics are shown in Table 2.

For an overall diagnosis of DRFD (defined as presenting with at least one of DN, PVD, ulcer, deformity, or amputation), substantial level of agreement was obtained when we compared the Q-DFD with the clinical assessment (kappa 0.77, sensitivity 80.4%, specificity 91.5%, LR+ 9.46, LR– 0.21), and an almost perfect level of agreement when compared with medical records (kappa 0.88, sensitivity 87%, specificity 97%, LR+ 29.0, LR– 0.13). When we combined both, we obtained a kappa score of 0.82, with a sensitivity of 83.5%, specificity of 94.1%, LR+ of 14.1, and LR– of 0.18. This analysis was made without using deformity because it was not commonly recorded in medical records. Table 3 shows a summary of statistics regarding levels of agreement for samples A, B1, B2, and B3; with components of DRFD individually and combined.

The individual components of DRFD that showed the highest prevalence rates for community-based patients (sample A) were deformity and DN (75% and 44.4%), followed by PVD, ulcer, and amputation (16.7%, 2.8%, and 2.8%). Deformity and DN were the most commonly reported components (60% and 37.5%) for the clinic-based patients (sample B1), followed by ulcer, PVD, and amputation (27.5%, 12.5%, 5%). A more detailed explanation of prevalence rates for sample B can be found in Table 4.

Survey reliability

A total of 41 patients completed the questionnaire on three different occasions. The first two interviews were made on the same day, and the third was completed 7 days later. Patient characteristics are shown in Table 2.

For an overall diagnosis of DRFD, intra-rater and inter-rater reliability obtained a substantial agreement, with a kappa score of 0.63 and 0.73, respectively. Regarding inter-rater reliability, individual components of DRFD showed substantial to perfect agreement with DN (kappa = 0.76), PVD (kappa = 0.72), ulcer (kappa = 1.0), and deformity (kappa = 0.90). Furthermore, for intra-rater reliability, the individual components achieved moderate to perfect agreement with DN (kappa = 0.69), PVD (kappa = 0.53), ulcer (kappa = 1.0), and deformity (kappa = 0.75). No analysis was made for amputation, as no individual reported this component.

Discussion

This study shows that the Spanish version of the Q-DFD is a valid and efficient diagnostic tool that allows the detection of DRFD in adults with DM. As hypothesized, the Spanish version of the Q-DFD showed good criterion and construct validity, and moderate to high intra- and inter-rater reliability.

Table 2 Participant characteristics used to determine validity and reliability of the survey

	Sample				
	A	**B1**	**B2**	**B3**	**C**
Total participants	36	40	18	22	41
Sex, n (%)					
Male	13 (36.1)	21 (52.5)	9 (50)	12 (54.5)	16 (39)
Female	23 (63.9)	19 (47.5)	9 (50)	10 (45.5)	25 (61)
Age, years					
Mean ± SD	61.4 ± 8.7	66.6 ± 9.6	68.3 ± 10.9	65.1 ± 7.8	64.2 ± 9.6
Range	48–85	46–87	48–87	46–75	50–89
Diabetes duration, years					
Mean ± SD	8.7 ± 6.2	18.4 ± 10.1	19.3 ± 9	17.6 ± 10.8	9.4 ± 6.5
Range	1–23	0.58–38	6–33	0.58–38	0.5–23

Notes: Sample A was used to determine criterion validity, sample B was used to determine construct validity (B1 = total clinic-based sample, B2 = clinic-based sample with foot complications, B3 = clinic-based sample without foot complications), sample C was used to determine intra- and inter-rater reliability.
Abbreviation: SD, standard deviation.

Table 3 Summary of statistics used to determine criterion and construct validity

	Kappa	Sensitivity %	Specificity %	LR+	LR–
Samples A and B combined (any diagnosis of DRFD)	0.823	0.835	0.941	14.153	0.175
Samples A and B combined (all components of DRFD)					
DN	0.728	0.839	0.889	7.559	0.181
PVD	0.776	0.688	0.923	8.935	0.338
Ulcer	0.856	0.846	0.969	27.290	0.159
Amputation	1.000	1.000	1.000		
Deformity[a]					
Sample A (any diagnosis of DRFD)	0.774	0.804	0.915	9.459	0.214
Sample A (all components of DRFD)					
DN	0.550	0.750	0.800	3.750	0.313
PVD	0.750	0.667	0.900	6.670	0.370
Ulcer	0.654	0.500	0.971	17.241	0.515
Amputation	1.000	1.000	1.000		
Deformity	0.615	0.893	0.667	2.682	0.160
Sample B1 (any diagnosis of DRFD)	0.880	0.870	0.970	29.000	0.134
Sample B1 (all components of DRFD)					
DN	0.893	0.933	0.960	23.325	0.070
PVD	0.805	0.714	0.943	12.526	0.303
Ulcer	0.875	0.909	0.966	26.735	0.094
Amputation	1.000	1.000	1.000		
Deformity[b]					
Sample B2 (complications group, all components of DRFD)					
DN	0.824	0.933	0.750	3.732	0.089
PVD	0.753	0.714	0.846	4.636	0.338
Ulcer	0.886	0.909	0.875	7.272	0.104
Amputation	1.000	1.000	1.000		
Deformity[b]					
Sample B3 (no complications group, all components of DRFD)					
DN	No respondent reported	0.040	1.000		0.960
PVD	No respondent reported	1.000	1.000		
Ulcer	No respondent reported				
Amputation	No respondent reported				
Deformity[b]					

Notes: Sample A shows correlation between questionnaire and clinical evaluation, while sample B shows correlation between questionnaire and medical records (B1 = total clinic-based sample, B2 = clinic-based sample with foot complications, B3 = clinic-based sample without foot complications). Patients were classed as having "any diagnosis of DRFD" if they presented with either one of DN, PVD, ulcer, amputation, or deformity. [a]Deformity for sample A and B combined could not be obtained because it was not commonly recorded in the medical records of patients in sample B; [b]deformity was not recorded in the medical records of patients in sample B.

Abbreviations: DN, diabetic neuropathy; DRFD, diabetes-related foot disease; LR+, positive likelihood ratio; LR–, negative likelihood ratio; PVD, peripheral vascular disease.

With English being the lingua franca of science,[14] the need to adapt instruments for their use in other languages is of primary importance. However, it is not enough to just translate them; a cross-cultural adaptation of the instrument should also be performed.[11] This is one of the strengths of our study. We also addressed criterion, construct validity, and survey reliability, which allowed us to obtain a successful cross-cultural adaptation, making the Q-DFD suitable for use in Spanish-speaking populations.

The first aim of the present study was to translate the Q-DFD from English into Spanish by following the international guidelines criteria proposed by Sperber.[11] After translation, four items were considered problematic and were reviewed and retranslated. However, as can be seen in Table 1, we found that even after doing this, items 8a and 12d of the first and final Spanish versions were identical. This could be related to the use of synonyms in the first and second English versions.

The second aim of the present study was to validate the Q-DFD in a diabetic population from Guayaquil. Regarding validation, we used the same methodology employed by Bergin et al.[10] Our study had larger samples than those seen

Table 4 Prevalence of individual components of diabetes-related foot disease according to the Q-DFD

	Prevalence (%)				
	DN	PVD	Ulcer	Amputation	Deformity
Sample A	44.4	16.7	2.8	2.8	75.0
Sample B1	37.5	12.5	27.5	5.0	60.0
Sample B2	77.8	27.8	55.6	11.1	55.6
Sample B3	4.5	0.0	4.5	0.0	63.6

Notes: Sample A was used to determine criterion validity, sample B was used to determine construct validity (B1 = total clinic-based sample, B2 = clinic-based sample with foot complications, B3 = clinic-based sample without foot complications).
Abbreviations: DN, diabetic neuropathy; PVD, peripheral vascular disease; Q-DFD, Questionnaire for Diabetes-Related Foot Disease.

in the original article: sample A (36 versus [vs] 21), sample B (40 vs 25), and sample C (41 vs 30). Demographic characteristics were similar in terms of age distribution, with most of our patients in their 60s; but gender distribution differed, and mean diabetes duration was shorter.

In order to determine validity of the questionnaire, we tested the Q-DFD against the gold standard. In most of the components evaluated, our results were consistent with the findings from Bergin et al,[10] which suggests the reproducibility of the original research and the validity of the Q-DFD to determine DRFD. Individually, items that showed the poorest levels of agreement were DN in sample A (kappa = 0.55), and PVD in sample B (kappa = 0.81); while amputation obtained perfect scores (kappa = 1.0) in both samples. This might be explained by the self-report of symptoms. DN and PVD are subjective components; in contrast to amputation. In the Q-DFD, the subjectivity of DN and PVD is taken into consideration by using questions to confirm that these symptoms are related to DRFD. For instance, questions 3a–e are to determine whether patients have self-reported DN by asking for burning, tingling, numbness, tightness, and 'pins and needles' sensation. This self-reported DN is then confirmed by question 4, where the patient should answer that the symptom(s) do not go away. Thus, question 4 assures us that symptoms answered in questions 3a–e are persistent; a feature of DN.[15]

The Q-DFD showed high sensitivity and specificity, proving to be a diagnostic tool with good ability to predict the presence and absence of DRFD. In addition, the Q-DFD presented a high LR+ and a low LR–. This indicates that the Q-DFD performs well in excluding, as well as correctly detecting, DRFD. With regards to the prevalence of individual components of DRFD measured with the Q-DFD, our study shows that deformity is the most common finding in both samples (sample A = 75%, sample B = 60%); followed by DN (sample A = 44.4%, sample B = 37.5%). These data were similar to the original research by Bergin et al,[10] but somewhat differ from other studies conducted in Latin America. For instance, Ibarra et al[16] performed a study in Chile with 240 patients and determined a DN prevalence of 69%; another study conducted in Mexico by Camacho López et al[17] enrolled 207 patients and found a DN prevalence of 54.5%. In addition, Tres et al[18] assessed DN in 340 patients from Passo Fundo, a city in Southern Brazil, and obtained a prevalence of 22.1%. We speculate that the reason for these results is that all the studies used different criteria to determine DN, highlighting the lack of universal guidelines.

When analyses of intra- and inter-rater reliability were performed, we obtained substantial levels of agreement for an overall diagnosis of DRFD. In addition, individual components of DRFD were also evaluated and showed moderate to perfect levels of agreement. We observed that ulcer and amputation scored higher than DN and PVD. As already mentioned, this could be explained by the objectivity of ulcer and amputation, in contrast to the subjectivity that DN and PVD present.

This study has some limitations that need to be considered. First, the recruitment of the clinic-based sample (sample B) was carried out in a single hospital. Thus, results cannot be extrapolated to the diabetic inpatient population from Guayaquil. Second, our participant selection was not random, which has led to a sample bias. Last, the assessment of DN was made using the pinprick test and not the 10 g Semmes-Weinstein Monofilament because it was not available in our city during clinical evaluation.

Conclusion

The results of the present study indicate that the translation of the Q-DFD is linguistically accurate and acceptable for use in Spanish-speaking populations. In addition, it showed good psychometric properties such as validity, reliability, and reproducibility. Although this questionnaire does not replace clinical examination, which is the gold standard of diagnosis, it has certainly been shown to be a simple and cost-effective method for the early detection of DRFD in populations that do not have access to health services.

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The Spanish version of the Q-DFD can be obtained free of charge from the first author: Wilson Castillo-Tandazo: wcastillo@uees.edu.ec. The original English version of the Q-DFD may be obtained by contacting Shan M Bergin: shan.bergin@monashhealth.org.

Disclosure

All authors approved the final version of the manuscript and report no conflicts of interest in this work.

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