

## CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE INSTRUMENT DIABETES – 39 (D-39): BRAZILIAN VERSION FOR TYPE 2 DIABETES MELLITUS PATIENTS – STAGE 1<sup>1</sup>

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*The study aimed to accomplish a cross-cultural adaptation of the “Diabetes - 39 - D-39” instrument for Brazil, to test the validity of the adapted version in a sample of type 2 diabetes mellitus patients and to describe the participants of the study, according to the scores obtained on the Likert-type scale. The instrument adaptation process followed several steps: instrument translation; achievement of the consensus in Portuguese; evaluation by an expert committee; back-translation; achievement of the consensus in English; comparison of the original and consensus versions in English; semantic analysis and pre-test of the Portuguese version. Results showed that the instrument items, in the first stage of cultural adaptation to Portuguese, presented high internal consistency levels.*

*DESCRIPTORS: quality of life; diabetes mellitus, type 2; validation studies*

## ADAPTACIÓN CULTURAL Y VALIDACIÓN DEL INSTRUMENTO DIABETES – 39 (D-39): VERSIÓN PARA BRASILEÑOS CON DIABETES MELLITUS TIPO 2-FASE 1

*Este estudio tuvo como objetivos adaptar, culturalmente, para el Brasil el “Diabetes – 39 – D-39”, comprobar la validez de la versión adaptada, en una muestra de personas con diabetes mellitus tipo 2, y describir los participantes del estudio, según los puntajes obtenidos por medio de la aplicación de la escala tipo Likert. El proceso de adaptación del instrumento siguió las siguientes etapas: traducción del instrumento, obtención del consenso en portugués, evaluación por un comité de jueces, back-translation, obtención del consenso en inglés, comparación de las versiones originales y consenso en inglés, análisis semántica y prueba piloto de las versiones en portugués. Los resultados mostraron que el instrumento, en su primera fase de adaptación cultural para el portugués, presentó índices elevados de consistencia interna de sus ítems.*

*DESCRIPTORES: calidad de vida; diabetes mellitus tipo 2; estudios de validación*

## ADAPTAÇÃO CULTURAL E VALIDAÇÃO DO INSTRUMENTO DIABETES – 39 (D-39): VERSÃO PARA BRASILEIROS COM DIABETES MELLITUS TIPO 2 - FASE

*Este estudo teve como objetivos adaptar, culturalmente, para o Brasil o “Diabetes – 39 – D-39”, testar a validade da versão adaptada, em uma amostra de pessoas com diabetes mellitus tipo 2, e descrever os participantes do estudo, segundo os escores obtidos por meio da aplicação da escala tipo Likert. O processo de adaptação do instrumento seguiu as seguintes etapas: tradução do instrumento, obtenção do consenso em português, avaliação por um comité de juizes, back-translation, obtenção do consenso em inglês, comparação das versões originais e consenso em inglês, análise semântica e pré-teste das versões em português. Os resultados mostraram que o instrumento, em sua primeira fase de adaptação cultural para o português, apresentou índices elevados de consistência interna dos seus itens.*

*DESCRITORES: qualidade de vida; diabetes mellitus tipo 2; estudos de validação*

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## INTRODUCTION

**D**iabetes mellitus (DM) is a heterogeneous group of metabolic disorders with hyperglycemia as the common characteristic, resulting from insulin action and/or secretion defects. The current classification is etiology-based. In the present study, type 2 DM is highlighted, which is present in 90-95% of cases and is characterized by defects in the action and/or secretion of insulin. Its importance for public health is justified by the increasing prevalence rates, the impact of mortality and the health problems that affect the quality of life (QoL) of patients and their relatives<sup>(1)</sup>.

Research on the relation between altered glucose metabolism and quality of life showed a gradual decrease in QoL through the categories glucose tolerance, recently diagnosed DM and previously known DM. The authors showed that poor QoL can increase the probability of developing type 2 DM, and can also be associated with less healthy lifestyle options<sup>(2)</sup>. On the other hand, DM can cause poor QoL due to the increased symptoms of hyperglycemia and other diseases related to DM and obesity<sup>(3)</sup>.

The importance of specific instrument to assess DM patients' QoL is due to the fact that this type of instrument is directed at the most relevant characteristics of the disease or condition that is being studied, and of the patients, considering that QoL measures support intervention strategies in the attempt to minimize the impact of type 2 DM<sup>(4)</sup>.

Health-related quality of life (HRQoL) represents the intent to quantify the consequences of a disease and its treatments, according to how people perceive their capacity to have a useful life and develop their skills. Hence, its measurement is subjective, as many of its dimensions cannot be measured in a physically direct way and, also, because it is related to how people see the impact not of their dysfunction, but of its existence<sup>(5)</sup>.

Nowadays, many instruments have been developed to assess HRQoL, based on different definitions of the concept. In this respect, the proliferation of measurement instruments partially affects the growing need to demonstrate the efficacy of a given care or treatment, thus expanding the consensus about the need to stabilize the effects of a given disease or treatment in the patient's life, or even to look beyond the disease, in order to guarantee

a more holistic view on the patient and incorporate the patient's perspective into the assessed interventions<sup>(6)</sup>.

Although a range of instruments is available to assess the HRQoL of DM patients, the researchers did not identify any research in literature that described the use of Portuguese-language instruments to assess HRQoL and which are specific for Brazilian DM patients, independently of the type.

Diabetes-39 (D-39) is a multidimensional scale elaborated in the USA. It consists of 39 items that assess HRQoL with respect to five domains in the patient's life: *energy and mobility* (15 items), *diabetes control* (12 items), *anxiety and worry* (4 items), *social burden* (5 items) and *sexual functioning* (3 items). Each item is calculated based on the DM patients' self-assessment of their quality of life, the extent to which it was affected during the previous month by the action or activity expressed in each item, placing an "X" on a scale in the form of a straight line, divided by vertical marks into spaces numbered from 1 to 7, in which 1 represents quality of life not affected at all, and 7 extremely affected. For reliability analysis, the scale authors<sup>(6)</sup> used Cronbach's alpha coefficient ( $\alpha$ ), ranging from 0.81 to 0.93 in the five dimensions, considering levels of 0.70 or more as acceptable.

In 2006, the D-39 was adapted and validated for the Mexican culture in a sample of 249 patients. It revealed to be a reliable and valid instrument to measure the quality of life of Mexican type 2 DM patients (Cronbach's alpha = 0.95 for the total score)<sup>(7)</sup>.

Considering that type 2 DM is the most prevalent type of diabetes with different clinical characteristics than type 1, thus generating different care needs, this study focused on type 2 DM patients. The study aimed to perform the cross-cultural adaptation of the "Diabetes - 39 - D-39" to the Brazilian culture, to test the reliability and validity of the adapted version in a sample of type 2 DM, and to describe the study participants according to the scores obtained by applying the Likert-type scale.

## METHOD

The study was developed after approval by the Ethics and Research Committee at *Faculdade de Medicina de Rio Preto - FAMERP*, São José do Rio Preto, SP, Brazil.

The instrument used was the Diabetes-39 which, in this study, took the form of a horizontal bar divided in boxes that were numbered from 1 to 7, to replace the straight line used in the original instrument. This change was suggested by the research participants and previously authorized by the original author<sup>(6)</sup>. To analyze the answers, the number marked with an "X" was considered, without any 0.5-point approximations (upwards or downwards, from 1 to 7) in case the participant marked one of the borders of the box, so as to simplify the classification<sup>(6)</sup>. The sum of scores for each section, the total score and classifications of self-perceived quality of life and diabetes severity were transported to a scale from 0 to 100 by applying the formula below, with a view to their linear transformation in the respective domains:  $(\text{gross classification} - \text{minimum value}) / (\text{maximum value} - \text{minimum value}) \times 100$ . This is a generic formula to transform any values ranging between two – upper and lower - limits, on a scale with 0% as the minimum and 100% as the maximum, and does not depend on any specific instrument. This device was only used to facilitate comparisons between the scores of this and any other scale, provided that both are expressed between 0 and 100%.

## CROSS-CULTURAL ADAPTATION PROCEDURES

Initially, the researchers obtained permission to use the D-39. Next, the cross-cultural adaptation process used in this study is described, which follows the proposal presented in literature<sup>(8)</sup>, together with the change in the order of the steps proposed for this adaptation process<sup>(9-10)</sup>.

The expert committee assessment before the back-translation permits the detection of possible errors or comprehension problems that can be modified in the translated version<sup>(9-10)</sup>. Each of the instrument items was subject to semantic analysis before performing the pre-test, with a view to having a group of representatives from the target population check the understandability of all instrument items<sup>(9)</sup>.

### Translation of D-39 to Portuguese

The translation was carried out by two Brazilians, one of whom had more than 20 years of experience as an English teacher, while the other was

an experienced nurse and had taught English at a language school for more than five years. This step resulted in two Portuguese versions, called version translated to Portuguese (VTP), VTP -1 and VTP - 2, respectively.

### Achievement of first consensus version in Portuguese

The researchers involved in the project (student and advisor) compared the version translated to Portuguese and elaborated a consensus version in Portuguese, called consensus of versions in Portuguese - 1 (CVP - 1).

### Assessment by expert committee

An expert committee with seven members was set up, comprising: one expert on quality of life and measurement instruments (nurse, Ph.D., faculty member), one endocrinologist, one bilingual translator, one nurse experienced in diabetes, one DM patient (laboratory technician at *Hospital das Clínicas* of Ribeirão Preto Medical School - HCFMRP) and the two researchers responsible for the project. All committee members were fluent in English. During this meeting, coordinated by the project researchers, the participants were informed that the goal of their participation in this committee was to assess the semantic, idiomatic, cultural and conceptual equivalence of the translated version items (CVP - 1). In this step, each Committee member received a copy of the original version of D-39 (VO), together with its respective Portuguese translation (CVP - 1). Next, one of the researchers read the translation and the participants discussed equivalences between the English and the translated version for each of the 39 instrument items. When any of the participants did not agree with the translation, suggestions were made to change the writing, and changes were approved when at least six participants (more than 80%) agreed with the new proposal. At the end of this step, consensus version 2 in Portuguese was obtained (CVP - 2).

### Back translation and consensus version in English

Two independent translators who were fluent in English and lived in Brazil and had lived in the USA for several years carried out this step. These translators were unaware of the study objectives and

did not know the original version of the instrument. Each of them elaborated an English version, called English version translator 1 and translator 2, called VI-1 and VI-2. A meeting was held between the student and the translators, who did not know each other's version. Then, the researcher presented the study goals, the purpose of D-39<sup>(6)</sup> and its applicability. Next, both versions were assessed and a final version in English (VIF) was defined.

#### Comparison between original and consensus versions in English

After defining the VIF, each translator received a copy of the original instrument (VO) for comparison with the VIF. At that moment, each part of the instrument (instructions, items and answer scale) was read and the translations were assessed with a view to finding the most adequate version in terms of conceptual and cultural equivalence. Writing adjustments were made in the English version of some items, which then needed reformulations in the Portuguese version CVP-2. This resulted in consensus version 3 in Portuguese.

The final version in English (VIF) of D-39 was compared with the original version of the instrument (in English), with a view to checking the replicability of the scale that was being subject to cross-cultural adaptation. After completing these steps, the VIF was sent to the author of the original instrument<sup>(6)</sup> for suggestions. Three days later, the author answered that he had carefully reviewed the back translation and that each question seemed to reflect the actual meaning of the original version, and gave his permission to continue the research.

#### Semantic analysis of items

Semantic analysis aims to verify whether the target population of an instrument can understand all of its items. Therefore, it is recommended that this procedure be performed with small groups (three to four)<sup>(9)</sup>. In this research, four patients were involved who were under follow-up at a basic health service, aiming to analyze their understanding of the 39 items' writing and their answers. The patients gave suggestions in terms of changing words that were little used in their daily life by other more colloquial terms, however, without any change in meaning. Thus, consensus version 4 in Portuguese (CVP- 4) was

obtained. The patients reported that questions were easy to understand. As for the answer scale, all of them affirmed that they could give answers more easily when these were directly related to the number shown on the scale, as shown by options 1 to 7. Thus, the researchers decided to follow the patients' suggestions, that is, the answer options were as shown by the numbers, without any 0.5 approximations. This differed from the original scale, where 0.5 was subtracted from or added to the score in case the "X" marked approached the left or right margin of the answer box, respectively. Other authors<sup>(7)</sup> also adopted this form of analyzing answers in the study that performed the cross-cultural adaptation and validation of D-39 for Mexican type 2 DM patients.

#### Psychometric property analysis

*Reliability analysis:* was analyzed by the internal consistency of items in each domain of D-39, applying Cronbach's alpha – levels of 0.70 or higher<sup>(11-12)</sup>. Pearson's product-moment correlation test was used to assess intercorrelations between each item of D-39 and the total scale score.

*Validity analysis:* construct validity (convergent and discriminant validity) of D-39 was studied through the correlation between items and domains, using multitrait-multimethod analysis. Multitrait Analysis Program (MAP) software was used for this purpose<sup>(13)</sup>. Discriminant validity was also assessed descriptively by comparing the scores of patients using insulin or not.

*Data collection:* data were collected according to the service routine, at a time before the nursing and/or medical consultations, in a private room. Participants previously received the necessary information and a free and informed consent term (FICT), signed by the participant and the researcher if the former agreed. Next, the adapted D-39 was applied.

The study population consisted of type 2 diabetes mellitus (DM-2) patients followed at a basic health service in São José do Rio Preto, SP, Brazil. Inclusion criteria were: older than 30 years of age, independently of gender and treatment, preserved reasoning skills and without limitations or disabilities to fill out the instrument and agree to participate in the study at the times before the medical or nursing consultations. The sample comprised 52 patients who attended a consultation at the health service between October 2007 and January 2008. In this research,

sociodemographic and clinical data were obtained from the records contained in the (adapted) HIPERDIA file of the service and from the medical records, using a specific instrument elaborated by the researcher.

## RESULTS

Upon the patients' suggestions, three items were modified, as all patients mentioned that *glucose* and *sugar* are understood in the same way, so that glucose was maintained; the word *proveniente* (coming from) was not well accepted either and replaced by *due to diabetes*; the same happened with the word *frequency*, replaced by... *relax several times per day*.

*Pre-test of the adapted version:* the final version in Portuguese (VFP) of D-39 was submitted to a pretest, involving four patients from the target population. After completing the instrument, each patient was asked about the understandability and relevance of the D-39. In this step, no problems were met, neither for understanding nor completing the instrument. Thus, it was considered terminated and the researchers decided to move on to the preliminary validation of the instrument. After the pretest, the version of D-39 was called final version in Portuguese (VFP).

The Portuguese version of the Diabetes-39 (D-39 VFP) was applied to a group of DM-2 patients between October 2007 and January 2008. Fifty-two

participants complied with the inclusion criteria, of whom 18 (34.6%) were men. Ages ranged from 45 to 84 years, with 62.8 (SD=8.6) as the mean and 63 years as the median age. Low education levels were found (31/52; 59.6%), with either unfinished basic education, not knowing how to read and write or alphabetized. The mean duration of the disease among the participants was 9.15 (SD=4.2) years and the median 9 years, with a minimum of 1 year and a maximum of 20 years. Women predominated among insulin users, with 20 (68.9%) out of 29 users. As to the body mass index (BMI) in the study sample, eight patients (15.38%) fell within the normal range and 44 (84.6%) were classified as overweight and obese<sup>(14)</sup>. Mean disease (DM-2) time of study participants was 9.2 (SD:4.2) years and glucose control levels were inadequate, with a mean level of 175.37 (35;67.3%); overweight and obesity in a large part of the sample (44;84.6%); insulin users totaled 29 participants, 20 of whom were women. As for comorbidities, a large number of hypertensive women was founds (28; 82.3%). This clinical profile is similar to what was found in the study that developed the original version of the D-39<sup>(6)</sup>.

Pearson's correlation coefficients varied between each item of D-39 and the total scale coefficient (from 0.24 to 0.70), which did not considerably interfere in the Cronbach's alpha levels, which varied from 0.913 to 0.918.

Results for the domains of the D-39 are shown in Table 1.

Table 1 – Descriptive statistics and reliability of D-39 domains and total score for study sample (n=52). São José do Rio Preto, SP, 2008

D-39 Domains	No of items	Cronbach's Alpha	Possible interval	Obtained interval	Median	Mean	(SD)
Diabetes control	12	0.85	12-84	14-77	51.5	48.8	(14.5)
Anxiety and worry	4	0.58	4-28	6-27	18	17.8	(5.2)
Social burden	5	0.62	5-35	5-30	18.5	17.2	(6.5)
Sexual functioning	3	0.83	3-21	3-21	13	12	(5.5)
Energy and mobility	15	0.79	15-105	20-83	60	56.5	(15.3)
Total score	39	0.92	39-273	49-217	163	152.5	(38.6)

Cronbach's alpha coefficients ranged from 0.58 (*anxiety and worry*) to 0.85 (*diabetes control*), which are considered adequate<sup>(11)</sup> to assess the internal consistency of items in the different domains. The total score, with a coefficient of 0.917, showed good internal consistency.

The participants' distribution was described according to their answers to the instrument, with a view to checking for the existence of floor and ceiling effects. These effects were not found in the domains of the D-39, as each domain concentrated less than 15% of answers in the minimum and maximum scores,

with the following concentration of minimum and maximum scores, respectively: *diabetes control*: 2.78 equal to 1 (1.9%) and 90.28 equal to 1 (1.9%); *anxiety and worry*: 8.33 equal to 1 (1.9%) and 95.83 equal to 2 (3.8%); *social burden*: 0 equal to 3 (5.8%) and 83.33 equal to 1 (1.9%); *sexual functioning*: 0 equal to 7 (13.5%) and 100, equal to 3 (5.8%); *energy and mobility*: 56 equal to 1 (1.9%) and 75.56 equal to 1 (1.9%). The instrument's convergent and discriminant validity was assessed through multitrait-multimethod analysis (MTMM), which examines the correlations between items and domains. MTMM analysis explores the relations between the instrument's items and dimensions, through which it evidences convergent and discriminant validity. The method is quite useful when the instrument contains a large number of items, which implies a considerable quantity of correlations. In initial validation studies, convergent validity is satisfied if the correlation between an item and the domain it belongs to exceeds 0.30 and, in final studies, if it exceeds 0.40. Discriminant validity is satisfied whenever the correlation between an item and the dimension it hypothetically belongs to is higher than its correlation with the other dimensions<sup>(15)</sup>.

To test for construct validity, convergent and discriminant validity were observed according to MTMM

analysis, assessing the correlations between the item and the dimension it belongs to and between the item and the dimension it does not belong to. In case the correlation coefficient between the item and the dimension it belongs to is higher than that with a dimension it does not belong to, convergent validity exists. In case an item is moderately correlated ( $r=0.3$ ) with the dimension it belongs to, convergent validity also exists<sup>(15)</sup>.

According to the MAP program<sup>(15)</sup>, the percentages of items in a given dimension, with correlations that are significantly higher, or merely higher than their correlations with the dimensions, are shown in Table 2. Values from -2 to 2 shown in Table 2 mean the following: 2 indicates that the correlation between the item and the scale it belongs to is significantly higher than its correlation with the scale it does not belong to, 1 indicates that the correlation between the item and the scale it belongs to is higher than its correlation with the scale it does not belong to, -1 indicates that the correlation between the item and the scale it belongs to is lower than its correlation with the scale it does not belong to and -2 indicates that the correlation between the item and the scale it belongs to is significantly lower than its correlation with the scale it does not belong to.

Table 2 – MAP analysis results for D-39 scores, Brazilian version. São José do Rio Preto, SP, 2008

Scales	Domains											
	Diabetes control		Anxiety and worry		Social burden		Sexual functioning		Energy and mobility		Total score	
	No of remaining items	%	No of remaining items	%	No of remaining items	%	No of remaining items	%	No of remaining items	%	No of remaining items	%
-2	0	0	0	0	0	0	0	0	1	1.7	1	0.6
-1	7	14.7	3	18.8	9	45	0	0	12	20	31	19.9
1	32	66.7	11	68.8	10	50	7	58.3	40	66.7	100	64.1
2	9	18.7	2	12.4	1	5	5	41.7	7	11.6	24	15.4

Considering that, for discriminant validity, answer percentages should be concentrated in the sum of scales 1 and 2, it is given that: *diabetes control* (85.4%), *anxiety and worry* (81.2%), *social burden* (55%), *sexual functioning* (100%), *energy and mobility* (78.3%) and *total score* (79.5%). Hence, discriminant validity in the *social burden* domain is low.

In addition, Mann-Whitney's U-test was applied for discriminant validity between the groups that used insulin or not for metabolic control of DM – 2. And it was observed that patients who used insulin obtained statistically significant *p* values ( $p<0.05$ ) for

*diabetes control* and *social burden*. The comparison of medians in each domain, considering participants who used insulin or not, shows discrimination between the groups with respect to *diabetes control* and *social burden*, with the following scores 56/47; 20/16.

## DISCUSSION

This study aimed to accomplish the cross-cultural adaptation of a health-related quality of life assessment instrument for patients with type 2

diabetes mellitus, considering that no instruments for this target population exist in the Brazilian cultural context.

The sample consisted of 52 people with a mean age of 62.8 years, predominantly female, married or living with their children and with low education level.

An expert committee assessed the instrument's semantic, idiomatic, conceptual and cultural equivalences after the first translated version (CVP – 1). This committee involved professionals from different health areas with particular knowledge in the fields of diabetes, quality of life and adaptation of assessment instruments, as well as a DM-2 patient. These members contributed to the assessment of D-39 items in terms of pertinence and understandable writing. After this assessment of the revised version, the instructions of the instrument were rewritten, mainly the part referring to the options that affect people's quality of life, as well as the example it referred to – *during the past month, how much was the quality of your life affected by: having an automobile*, which was changed to – *during the past month, how much was the quality of your life affected by: having a health problem*. Other modifications were minimal and are related to the insertion of prepositions before each instrument item (*por, pelo[a]*).

In this methodological process, the order in which the back-translation was performed was modified, as it occurred after the expert committee's assessment of the instrument. The translation of consensus version 2 in Portuguese (CVP - 2) to English and its comparison with the original version of D-39, in English, guaranteed that no alterations were made in the items' meaning, as confirmed by the author of the original instrument.

Construct validity was assessed through convergent validity, which was described by comparing the scores obtained between each item of D-39 and the respective domain scores, so as to assess, in this initial study, if the item is moderately correlated ( $r \geq 0.3$ ) with the domain it belongs to. Discriminant validity was assessed through the correlation between an item and the dimension it belongs to, in order to check if its correlation with the other domains was higher.

To analyze the internal consistency of the items in the adapted version with the total and the respective domains, Cronbach's alpha coefficients were calculated, generally obtaining levels that were considered adequate: alpha equal to 0.91 for the total score, and variation between 0.58 and 0.85 for the domains. The domain with the lowest coefficient was *anxiety and worry* (0.58), while *diabetes control* obtained the highest coefficient (0.85). Knowing that Cronbach's alpha coefficients below 0.70 can impair the instrument's internal consistency<sup>(11-12)</sup>, the authors clarify that, in this initial phase of the adaptation and validation of D-39, the sample revealed to be small for the number of items. Hence, more respondents would be needed.

In most cases, the analysis of the intercorrelation between the instrument's items and domains showed significant and positive correlations, with strong and very strong correlation coefficients for the total instrument score and median to strong coefficients for the respective domains. Exceptions refer to the correlation between the *sexual functioning* and *anxiety and worry* domains, with lower correlation coefficients, ranging from 0.21 (*anxiety and worry*) to 0.34 (*social burden*).

## CONCLUSION

The D-39, originally in English, was translated to Portuguese, following all steps indicated in the methods section. According to the results, the idiomatic, semantic, cultural and conceptual equivalences of the original instrument were maintained, as well as its validity and reliability (internal consistency) characteristics. Hence, the results show that the version of D-39 adapted to the Brazilian culture can be a valid and reliable instrument to measure the HRQoL of DM-2 patients.

This kind of research is important because it contributes to understand the factors involved in quality of life in the context of people's values and culture and in the assessment of a given health-disease situation, according to different physical, psychological, cultural and social components<sup>(16)</sup>, thus contributing to clinical nursing practice.

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