Validation of the Short Form of the Spanish Hypertension Quality of Life Questionnaire (MINICHAL) for Portuguese (Brazil)

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Resumo

Background: The assessment of quality of life has been considered an essential parameter in understanding the impact of arterial hypertension.

Objective: To translate into portuguese, cross-culturally adapt and validate the questionnaire specific for the assessment of quality of life known as *"Mini Cuestionario de Calidad de Vida en Hipertensión Arterial"* (MINICHAL).

Methods: Two independent translations of MINICHAL were made into brazilian portuguese. Later, these two translations were harmonized yielding a version that was back-translated into the source language. This version was revised by a committee of judges and the new version was tested in a pilot study. After the cross-cultural adaptation, the final version of the instrument was administered to a sample of 300 patients. The psychometric properties of the questionnaire such as reliability and construct validity were analyzed. The internal consistency of the instrument was measured by Cronbach's alpha coefficient.

Results: In the brazilian version of MINICHAL, Cronbach's alpha coefficients of internal consistency reliability were 0.88 for the Mental Status domain and 0.85 for the Somatic Manifestations domain. As to content validity, the judges' assessment attained a high level of agreement (75.44%). The factor analysis confirmed both domains, with differences in one item which was included in factor 2. The control group presented significant differences relative to hypertensive patients (t=4.86, gl=276.8, p< 0.001).

Conclusion: The brazilian version of MINICHAL was successfully validated and represents a useful and reliable instrument for assessing the quality of life of brazilian hypertensive patients. (Arq Bras Cardiol 2008; 90(2):127-131)

Key words: Hypertension; quality of life; questionnaires; outcome assessment (Health care).

Introduction

The preservation of patients' quality of life through prevention or treatment of illnesses has become increasingly more important in health care. One sign of the growing interest in health-related quality of life (HRQoL) is the increased number of publications on this humanistic outcome. The recommendations set forth by the JNC 7 (Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, 2004)[1], and the V Brazilian Guidelines on Arterial Hypertension[2] are very clear in defining the norms to be followed as to clinical results in hypertension, but they do not set standards for the humanistic outcomes such as quality of life. The lack of standards for HRQoL measurements in hypertension makes it difficult to compare results achieved by different studies, as well as the outcomes observed in clinical practice[3].

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The instruments used to measure quality of life are useful methods of transforming subjective measurements into objective data that can be quantified and analyzed, and are also important for assessing the impact of health care interventions on patients' HRQoL[4-6]. Generic and specific questionnaires are among the instruments used to assess quality of life in patients with hypertension.

It is recommended that a measuring instrument validated in a foreign language be adapted cross-culturally to a new country, instead of developing a new tool to evaluate the same phenomenon[7]. The adapted instrument allows a common measure to investigate quality of life within different contexts which can be used in international and multicentric studies, allowing comparisons to be made, besides saving time and financial resources[8].

Therefore, the concern with data from a humanistic point of view more and more becomes a part of the overall approach to health care, generating a need for validated instruments to measure these parameters[9].

The objective of this paper was to make it feasible to use the *Mini Cuestionario de Calidad de Vida en Hipertensión Arterial (MINICHAL)* in Brazil by translation and validation of the instrument.

Methods

About the instrument

After a systematic review[3] of the MEDLINE database for verification of the instruments available for measuring quality of life in hypertension, the *Mini Cuestionario de Calidad de Vida em Hipertensión Arterial (MINICHAL)* was chosen for cross-cultural adaptation as this is the most widely used specific questionnaire that can be quickly applied. The MINICHAL, in its spanish version, is an adaptation made by Badia et al[10] of the *Cuestionario de Calidad de Vida en Hipertensión Arterial (CHAL)*, an instrument developed by the same group of authors.

MINICHAL is a multiple choice 16-question questionnaire organized in 2 factors: Mental Status (10 questions) and Somatic Manifestations (6 questions), and 1 question to assess the patient's perception of how hypertension and its treatment have influenced his/her quality of life. The patient should answer the questions considering the 7 preceding days. The answers in the domains are distributed on a Likert-type frequency scale, with four answer options from 0 (No, not at all) to 3 (Yes, very much). The maximum score for the Mental Status domain is 30, whereas for the Somatic Manifestations domain it is 18. With this scale and considering the set of questions, the closer the result is to 0 (zero), the better the quality of life. Question number 17, which assesses the patient's overall perception of his/her own health, is also scored with the Likert scale but is not included in either of the two domains.

Translation and cross-cultural adaptation

The process of translation and cross-cultural adaptation followed the methodology proposed by Guillemin et al[7] and modified by Falcão[11].

Two independent translations from spanish into portuguese were made by two brazilian health experts fluent in the spanish language who were familiar with the goals of the study, the characteristics of the disease, the concepts underlying the document and the quality of life concept. Both translations were harmonized into one document, Version 1 of the instrument. Version 1 was back-translated by a native speaker of spanish who had no knowledge of the objectives of the study or the original version of the instrument. This back-translation produced Version 2. After comparing the back-translation (Version 2) with the original text, Version 1 was considered equivalent to the original and appropriate for submission to the committee of judges.

The committee consisted of three judges, who were part of a multidisciplinary team specialized in hypertension and fluent in the spanish language. They evaluated Version 1 of MINICHAL focusing on the analysis of semantic, idiomatic, cultural and conceptual equivalence. This committee was responsible for ensuring that the translation was accurate, and for changing or eliminating any items considered irrelevant, inadequate or ambiguous, replacing them with others considered appropriate for the target population. Items were carefully evaluated, taking into account the agreement among the judges and individual suggestions that contributed towards improving comprehension of the items. Thus, Version 3 of the instrument was produced and submitted to pre-testing or pilot-testing by its application to 20 patients, 10 from each group (10 normotensive and 10 hypertensive patients), who expressed their doubts and gave suggestions for improving understanding of the instrument. This generated Version 4 which was used for the validation.

Validation

The study was carried out in Curitiba, PR, between July and September 2006, with a total of 300 individuals enrolled (155 hypertensive and 145 normotensive patients). Inclusion criteria were age above 18 years and use of antihypertension medication for the hypertensive patients.

The portuguese version of MINICHAL (MINICHAL - Brasil) was self-administered under supervision[12]. Data were analyzed using the 12.0 version of the SPSS (Statistical Package for the Social Sciences) for Windows, and the level of statistical significance adopted was 0.05.

Unidimensionality analyses were carried out (exploratory factor analysis, extraction of principal components and promax rotation), as well as construct validity (through analysis of factor loadings), criterion validity (differentiation between the normotensive group and the hypertensive group using Student's t test), and reliability or accuracy (Cronbach's alpha was used for each factor extracted of the factor analysis) assessments.

The authors of the original instrument consented to the cross-cultural adaptation and validation of the MINICHAL for the brazilian situation. The study was conducted in accordance with standards for research involving human subjects and was approved by the Institutional Review Board of the *Centro Universitário Positivo* under number 119/2006.

Results

The study population consisted of 155 hypertensive and 145 normotensive patients, totalling 300 patients, 73 of them hypertensive women, and 87 normotensive women. The median age was 50 years (SD=13.74) for the hypertension group and 26 years (SD=10.04) for the normotension group. In the hypertensive group, 42.6% (n=66) had finished high school and 36.1% (n=56) had completed higher education, whereas in the group of normotensive patients, 80% (n=116) had gone to college. Most hypertensive (80%) and normotensive (93.1%) patients were white.

Validation

Unidimensionality

Unidimensionality was the first psychometric parameter to be evaluated[13] in order to verify whether the instrument was, in fact, assessing the two factors it was supposed to measure in the spanish version of MINICHAL[10]. With the factor analysis (Table 1), it was possible to obtain 2 distinct factors as in the original version of the instrument. The correlation between the factors was high: $r=0.485$ and $p<0.001$.

Construct validity

The construct validity was evaluated using factor analysis,

Table 1 - Factor analysis of Minichal-Brazil

Questions	Factor loadings	
	1	2
Q3	0.862	
Q4	0.851	
Q2	0.841	
Q6	0.839	
Q5	0.833	
Q7	0.740	
Q8	0.724	
Q9	0.650	
Q1	0.622	
Q15		0.819
Q11		0.774
Q16		0.757
Q13		0.731
Q12		0.671
Q14		0.670
Q10		0.506

Method - principal component extraction, promax rotation.

since it shows how many common constructs are needed to explain the covariances. Therefore, construct validity is determined by the magnitude of factor loadings (which are correlations that range from -1 to 1) of the factor variables, that, in turn, is the latent trait for which factor loadings were initially developed as an empirical representation.

In this case, factors 1 and 2, which are first-order factors, were found to be subordinated to a higher-order factor, i.e., quality of life (second order). If both factors were independent of each other, there would be no need to include them in a higher domain.

Criterion validity

The criterion validity was determined using Student's t test by means of a comparison between hypertensive and normotensive patients. Table 2 displays the results.

In comparing hypertensive and normotensive patients using Student's t test, a significant difference was found in 81.25% of the questions. Considering 0.05 as the level of significance for this process, the questions that did not fit within this margin (p=0.05) did not influence the significance of both factors, since the p value obtained was < 0.001 for both, factor 1 and factor 2.

The overall analysis between the control group (normotensive) and the hypertensive group showed significant differences (t=4.86, gl=276.8 and p< 0.001).

Reliability

The reliability of the MINICHAL (Brasil) instrument was tested using Cronbach's alpha coefficient for internal consistency analysis. This coefficient ranges from 0 to 1 and the greater the value, the better the reliability. The analysis was carried out for both factors (Mental Status and Somatic Manifestations), considering the total number of patients (300 participants).

For Bowling[14], Cronbach's alpha values above > 0.50 are acceptable, whereas for Pasquali[13], values close to 0.90 are adequate, around 0.80 are moderate, and those below 0.70 are insufficient.

Factor 1 (Mental Status) included 9 items, and factor 2 (Somatic Manifestations) included 7 items. The alpha coefficients for factors 1 and 2 were 0.88 and 0.86, respectively. The exclusion of any of the items would not increase the alpha value, as is shown in Tables 3 and 4.

Internal consistency

The analysis of the internal consistency of MINICHAL – BRASIL revealed an alpha value of 0.88 for Mental Status and 0.86 for Somatic Manifestations, a result very close to that of the original SPANISH MINICHAL in which the α value for Mental Status was 0.87 and the α value for Somatic Manifestations was 0.75.

Figure 1 displays the portuguese version of the *Mini Cuestionario de Calidad de Vida en Hipertensión Arterial (MINICHAL-BRASIL)*.

Discussion

Quality of life is a subjective concept influenced by several factors inherent to human existence. The concept

Table 2 - Analysis of criterion validity using Student's t test. Curitiba - PR. 2006

	Student's t test – Normotensive x Hypertensive				
	0= Normotensive 1= Hypertensive	N	Average	Standard deviation	P
FACTOR 1 (Mental status)	0 1	145 155	3.172 5.309	3.68 5.39	< 0.001
FACTOR 2 (Somatic manifestations)	0 1	145 155	0.751 1.877	1.61 2.31	< 0.001
TOTAL	0 1	145 155	3.924 7.187	4.74 6.76	< 0.001

Table 3 - Results of the internal consistency analysis between items in FACTOR 1

Questions	Cronbach's alpha value if the item is excluded
Q1	0.87
Q2	0.86
Q3	0.86
Q4	0.86
Q5	0.86
Q6	0.85
Q7	0.88
Q8	0.86
Q9	0.86

Cronbach's alpha = 0.88.

Table 4 - Results of the internal consistency analysis between items in FACTOR 2

Questions	Cronbach's alpha value if the item is excluded
Q10	0.84
Q11	0.83
Q12	0.85
Q13	0.84
Q14	0.84
Q15	0.84
Q16	0.84

Cronbach's alpha = 0.86.

of health-related quality of life seeks to restrict the study of these factors to those more closely linked to the individual's physical, psychic and social conditions. Therefore, the effort to assess the quality of life of hypertensive patients based on the MINICHAL questionnaire corresponds to an attempt to measure the main factors linked to hypertension which can influence the patient's feeling of well-being. This is an important approach, as it can serve as a guide for health interventions addressing aspects which may positively impact quality of life. Consequently, it is necessary to use reliable measurement instruments.

The process of translating and validating a quality-of-life assessment instrument requires efforts beyond merely

Figure 1 - Quality-of-life questionnaire in Arterial Hypertension (MINICHAL-BRASIL)

During the past 7 days...	No, not at all.	Yes, somewhat.	Yes, a lot.	Yes, very much.
1. Have you been sleeping poorly?				
2. Have you had difficulty maintaining your usual social relationships?				
3. Have you had difficulty interacting with other people?				
4. Have you felt that you are not playing a useful role in life?				
5. Have you felt unable to make decisions and start new things/projects?				
6. Have you felt continuously distressed and tense?				
7. Have you felt that life is a constant struggle?				
8. Have you felt incapable of enjoying your daily activities?				
9. Have you felt worn-out and powerless?				
10. Have you felt sick?				
11. Have you had difficulty breathing or felt breathless for no apparent reason?				
12. Have your ankles been swollen?				
13. Have you noticed that you are urinating more frequently?				
14. Has your mouth been dry?				
15. Have you felt pain in the chest without doing any physical exertion?				
16. Have you noticed numbness or a tingling sensation in any part of the body?				
17. Would you say that your hypertension and its treatment have affected your quality of life?				

idiomatic and semantic aspects. Language has to be culturally and conceptually adapted so as to bring it as close as possible to the context of the population of interest. Particularly in the case of Brazil, regional, social and cultural differences, low level of schooling, and high prevalence of functional illiterates make this task even more difficult. All these aspects were taken in consideration in this study.

The number of studies published that assess quality of life in hypertension has grown over the past few years. Although less frequently used, specific questionnaires have the advantage of being more sensitive to changes. The translation into brazilian portuguese and validation of a specific questionnaire such as MINICHAL make it a feasible instrument that can be used not only in research, but also in clinical practice to assess quality of life in hypertension.

The analyses carried out during the process of MINICHAL-BRASIL validation provided very similar outcomes compared to the process of development and validation of the original instrument. As to the unidimensionality analysis, however, despite the fact that 2 distinct factors were obtained, as in the original questionnaire, the original study question number 10 *(¿Ha tenido la sensación de que estaba enfermo?)* was included in factor 1 (Mental Status), whereas in the process of cross-cultural adaptation, the same question ("Have you felt sick?") was included, according to the factor analysis, in factor 2 (Somatic Manifestations). So, in the brazilian context, differently from the spanish experience, "feeling sick" is correlated with the factor loadings in factor 2 - Somatic Manifestation.

MINICHAL-BRASIL consists of 17 questions and 2 domains. The answers in the domains are distributed on a Likert-type frequency scale, with four answer options ranging from 0 (No, nothing at all) to 3 (Yes, very much). According to this scale, the closer the result is to 0 (zero), the better the quality of life. The Mental Status domain comprises questions 1 to 9, and its maximum score is 27. The Somatic Manifestations domain comprises questions 10 to 16, and its maximum score is 21.

The results of this study allow us to conclude that the reliability and validity aspects of the portuguese version of MINICHAL are adequate for its utilization as a quality of life assessment instrument in hypertensive adults. This instrument can be used both for population-based studies and clinical trials to assess a patient's quality of life.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

This study is not associated with any graduation program.

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