

Quality of life in people with coronary artery disease: translation and cross-cultural adaptation of a questionnaire

Qualidade de vida em pessoas com doença arterial coronariana: tradução e adaptação transcultural de questionário
Calidad de vida em personas con enfermedad de la arteria coronária: traducción y adaptación transcultural de cuestionario

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ABSTRACT

Objective: to carry out translation, cross-cultural adaptation to Portuguese and assess the reliability of the four versions of the Coronary Revascularization Outcome Questionnaire - adapted. **Methods:** a methodological study of translation and cross-cultural adaptation into Portuguese, as proposed by Beaton et al., and reliability analysis, by calculating Cronbach's alpha coefficient and item-total correlation of the four versions of the Coronary Revascularization Outcome Questionnaire - adapted. **Results:** the adaptations made facilitated the understanding of the items. All domains had Cronbach's alpha above 0.70, except two in the post-percutaneous coronary intervention version and two in the post-myocardial surgical revascularization version. All items had item-total correlation values greater than 0.20, except two in the post-percutaneous coronary intervention version, one in the pre-coronary intervention version and six in the post-myocardial surgical revascularization version. **Conclusion:** the cross-cultural adaptation to Portuguese was considered satisfactory. Pre-procedure versions were considered reliable, while the post-procedures require other psychometric analyses.

Descriptors: Quality of Life; Coronary Artery Disease; Myocardial Revascularization; Translating; Validation Study.

RESUMO

Objetivo: realizar tradução, adaptação transcultural para língua portuguesa e avaliação da confiabilidade das quatro versões do *Coronary Revascularisation Outcome Questionnaire* - adaptado. **Métodos:** estudo metodológico de tradução e adaptação transcultural para língua portuguesa, conforme proposto por Beaton et al., e análise da confiabilidade, pelo cálculo do coeficiente de alfa de Cronbach e correlação item-total das quatro versões do *Coronary Revascularisation Outcome Questionnaire* - adaptado. **Resultados:** as adaptações realizadas facilitaram a compreensão dos itens. Todos os domínios apresentaram alfa de Cronbach acima de 0,70, exceto dois na versão pós-intervenção coronária percutânea e dois na versão pós-revascularização cirúrgica do miocárdio. Todos os itens obtiveram valores de correlação item-total maiores que 0,20, exceto dois na versão pós-intervenção coronária percutânea, um na versão pré e seis na versão pós-revascularização cirúrgica miocárdica. **Conclusão:** a adaptação transcultural à língua portuguesa foi considerada satisfatória. As versões pré-procedimento foram consideradas confiáveis, já as pós-procedimento, requerem outras análises psicométricas.

Descritores: Qualidade de Vida; Doença da Artéria Coronariana; Revascularização Miocárdica; Tradução; Estudo de Validação.

RESUMEN

Objetivo: realizar traducción, adaptación transcultural al portugués y evaluar la confiabilidad de las cuatro versiones del *Coronary Revascularisation Outcome Questionnaire* - adaptado. **Métodos:** estudio metodológico de traducción y adaptación transcultural al portugués, propuesto por Beaton et al., y análisis de confiabilidad, mediante el cálculo del coeficiente alfa de Cronbach y la correlación ítem-total de las cuatro versiones del *Coronary Revascularisation Outcome Questionnaire* - adaptado. **Resultados:** las adaptaciones realizadas facilitaron la comprensión de los ítems. Todos los dominios mostraron un alfa de Cronbach superior a 0,70, excepto dos en la versión posterior a la intervención coronaria percutánea y dos en la versión posterior a la revascularización miocárdica quirúrgica. Todos los ítems obtuvieron valores de correlación ítem-total superiores a 0,20, excepto dos en la versión posintervención coronaria percutánea, uno en la versión pre y seis en la versión posrevascularización miocárdica. **Conclusión:** la adaptación transcultural a la lengua portuguesa se consideró satisfactoria. Las versiones previas al procedimiento se consideraron fiables, mientras que las posteriores al procedimiento requieren otros análisis psicométricos.

Descriptorios: Calidad de Vida; Enfermedad de la Arteria Coronária; Revascularización Miocárdica; Traducción; Estudio de Validación.

INTRODUCTION

Cardiovascular diseases (CVDs) are defined by the World Health Organization (WHO) as a group of diseases that affect the heart and blood vessels, with the main causes being smoking, sedentary lifestyle and bad lifestyle habits, including unhealthy diet and use abusive of alcohol. Among the CVDs, cerebrovascular diseases, systemic arterial hypertension, peripheral arterial disease, heart failure and coronary artery disease (CAD) stand out⁽¹⁾.

According to the WHO, in 2016, CVD resulted in 17.9 million deaths⁽²⁾, being the leading cause of death from chronic non-communicable diseases (CNCDs). In relation to Brazil, in that same year, CNCDs were responsible for 74% of all mortality in the country, with CVDs as the leading cause, which accounted for 28% of this total⁽³⁾. From 2004 to 2014, ischemic heart diseases account for 1,069,653 deaths in Brazil⁽⁴⁾.

CAD treatment consists of pharmacological therapeutic measures, with the objective of relieving symptoms and reducing the area of myocardial ischemia due to the adverse effects caused by adrenergic discharge and platelet aggregation, in addition to providing coronary reperfusion⁽⁵⁾.

Studies show that people with CAD can present changes in quality of life due to the signs and symptoms triggered by the disease, such as chest pain and dyspnea and, consequently, the limitation in carrying out physical activities⁽⁶⁾. It is also noteworthy that the type of treatment for coronary obstructions can influence individuals' quality of life in the short and medium term, whether surgical or percutaneous⁽⁶⁻⁹⁾.

Quality of life is defined by the WHO as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"⁽¹⁰⁾. Research aimed at determining health-related quality of life has been increasing, as it is in the interest of healthcare professionals and patients to know what results will be caused by a given procedure in the short, medium and long term, to guide the choice of a treatment that not only prolongs life, but also guarantees years of biopsychosocial well-being⁽¹¹⁾.

Several instruments, both generic and specific to certain health conditions, have been developed and validated to assess quality of life⁽¹²⁻¹⁴⁾. However, none of these instruments specifically assess the quality of life of people undergoing CAD treatment, whether percutaneous or surgical⁽¹⁵⁾. In this sense, Schroter developed a questionnaire called the Coronary Revascularization Outcome Questionnaire (CROQ), which assesses quality of life before and after the coronary reperfusion procedure specifically for this population⁽¹⁵⁾.

CROQ was developed and published in 2004⁽¹⁵⁾. In 2017 it was adapted for use by the National Health Service in England. The changes made were related to time of application of the questionnaire after the procedure, the method for applying the questionnaire and the wording of the items regarding the adverse effects of the post-percutaneous coronary intervention version of the questionnaire to include the radial arterial route as puncture site of the procedure, in addition to the femoral arterial route⁽¹⁶⁾. Considering the psychometric tests performed, the adapted CROQ versions (CROQv2) proved to be reliable, valid and responsive for this population⁽¹⁶⁾.

CROQv2 has four versions, two versions for patients undergoing percutaneous coronary intervention (pre- and post-procedure) and

two versions for patients undergoing myocardial revascularization surgery (pre- and post-procedure). Post-procedural versions must be completed three to six months after coronary reperfusion. The two pre-procedural versions are composed of 32 items each, divided into four domains: symptoms, physical function, psychosocial function, and cognitive function. The post-myocardial revascularization surgery version consists of 50 items, and the post-percutaneous coronary intervention version consists of 45 items; in addition to the same four domains present in pre-procedure versions, they have two others, adverse effects and satisfaction⁽¹⁶⁾.

During the development of the CROQ, for the elaboration of each version, the following steps were carried out: extensive research in the area of CAD and instruments for measuring health outcomes, both for assessing quality of life and specific for heart disease; consultation of expert opinion in the care of patients undergoing coronary reperfusion; qualitative research with ten patients undergoing percutaneous coronary intervention and ten patients undergoing myocardial revascularization surgery on the experiences experienced after the procedure⁽¹⁵⁾.

Next, a conceptual model was defined, consisting of the following domains: symptoms, physical function, psychosocial function and cognitive function, in accordance with the domains presented in other instruments for assessing the quality of life of patients with CAD⁽¹³⁻¹⁵⁾. In addition to these domains, two others were added for the post-revascularization instruments, adverse effects and satisfaction, due to evidence of concerns regarding these issues, which are not addressed in existing health measurement instruments specific to heart disease. Then, with the participation of experts in the development of health measurement questionnaires and consultation of existing instruments, the items related to each of the domains were established⁽¹⁵⁾.

The items in each version of the questionnaire are assessed using a Likert-type scale, which ranges from three to six responses. The score of all items in each domain is added, this total being subtracted by the lowest possible raw score in that domain; then, this result is multiplied by 100 and divided by the possible gross score range for the respective domain. This results in a score ranging from 0 to 100, with 100 representing the best possible result. Only one item, present in post-procedure versions, is not counted in any of the domains, descriptively portraying, through a Likert-type scale, how many times patients felt afraid that their symptoms would return⁽¹⁵⁻¹⁶⁾.

In order for a questionnaire to be applied to a culturally and linguistically distinct population, it is necessary to carry out translation and cross-cultural adaptation, as well as validation for the language in which it is intended to be used so that an assessment can be carried out rigorously and reliably, in addition to enabling the comparison between data generated in surveys conducted in different countries⁽¹⁷⁾.

Currently, the CROQ has been adapted for several languages, such as Korean⁽¹⁸⁾, Greek⁽¹⁹⁾, Italian⁽²⁰⁾, Japanese⁽²¹⁾ and Persian⁽²²⁾; and the CROQv2, being more recent, has been translated and validated into Norwegian⁽²³⁾. The adapted versions for these languages were considered valid and reliable to assess the quality of life of these populations⁽¹⁸⁻²³⁾.

Taking into account the fact that the CROQv2 has its sustained importance in the cardiac context and the versions of this questionnaire have not yet been translated and validated into Brazilian Portuguese, studies that carry out such a proposal are necessary.

OBJECTIVE

To carry out translation, cross-cultural adaptation into Brazilian Portuguese and reliability assessment of the four versions of the Coronary Revascularization Outcome Questionnaire – adapted (CROQv2): pre- and post-percutaneous coronary intervention and pre- and post-surgical myocardial revascularization.

METHODS

Ethical aspects

Cross-cultural adaptation of the four versions of the questionnaire (pre- and post-percutaneous coronary intervention and pre- and post-surgical myocardial revascularization) into Brazilian Portuguese was authorized by the author of the original instrument via email. The project was submitted and approved by an Institutional Review Board. All participants were asked to complete the Informed Consent Form (ICF).

Study design, period, and place

This is a methodological study, in which translation, cross-cultural adaptation into Brazilian Portuguese and reliability assessment of the four versions of the CROQv2 instrument were carried out: percutaneous coronary pre-intervention instrument, percutaneous coronary post-intervention instrument, pre-surgical myocardial revascularization instrument and post-surgical myocardial revascularization instrument.

To carry out translation and cross-cultural adaptation of the four versions of the CROQv2 questionnaire, translation of instruments, synthesis of translations, back-translation and assessment by a committee of experts of each of the four versions of the questionnaire were followed, with these steps taking place between January and March 2018. The test of the pre-final version of the four Brazilian Portuguese versions was conducted from March 2018 to November 2019. This occurred in the clinical cardiology and cardiac surgery inpatient units and in the cardiology outpatient clinic of a large public and university hospital in the city of São Paulo. The reliability analysis of each of the four versions of the instrument took place in December 2019.

Population; inclusion and exclusion criteria

The population and the inclusion and exclusion criteria were different according to the stages of the study. In the step of translating the four versions of the CROQv2, the following inclusion criteria were established: accepting to participate in the study and filling out the ICF, translators over 18 years of age, native Brazilians and fluent in English. Moreover, one of the translators must be a healthcare professional.

In the back-translation stage of the four versions, the inclusion criteria determined for the invited translators were: being over 18 years of age, being born in a country with English as the official language, being fluent in Brazilian Portuguese, living in Brazil for over a year, accept to participate in the study and fill in the ICF. The exclusion criterion at this stage was: being a health care professional and having prior knowledge of CROQv2 and its versions.

In the assessment stage by an expert committee, judges over 18 years of age, who agreed to participate in the study and filled

out the ICF and who had experience in one of the following areas were included: methodological studies of cross-cultural adaptation; care for people with CAD; linguistics.

In the test of the pre-final version of the pre-percutaneous coronary intervention instrument, patients over 18 years of age admitted to the clinical cardiology units of the hospital where the study was conducted and who were awaiting elective percutaneous coronary intervention were included. Additionally, for the assessment of the pre-final version of the pre-myocardial surgical revascularization instrument, patients over 18 years of age admitted to the cardiac surgery inpatient unit of that same hospital and who were electively awaiting performing myocardial revascularization surgery.

For assessing the pre-final version of the instrument after percutaneous coronary intervention, patients aged over 18 years and who were in consultation at the cardiology clinic of that hospital after four to six months of the procedure were included. For assessing the pre-final version of the post-myocardial surgical revascularization instrument, patients aged over 18 years and who attended the outpatient consultation after four to six months of surgery were included.

To participate in the test stage of the pre-final version of each of the four instruments, all patients had to voluntarily agree to participate in the study, filling out and signing the ICF. Illiterate patients were not included.

According to recommendations by Beaton et al.⁽¹⁷⁾, the questionnaires must be answered by at least 30 individuals in the test stage of the pre-final version of the instrument. Therefore, the pre- and post-percutaneous coronary intervention versions and the pre-myocardial surgical revascularization version were applied in 40 patients, and the post-myocardial revascularization version was answered by 33 patients.

Study protocol

The method of translation and cross-cultural adaptation adopted in this study followed the six phases proposed by Beaton et al.⁽¹⁷⁾. In the first phase, two native Brazilian translators, an English teacher and another nurse, fluent in English, were invited to translate the CROQv2 versions into Brazilian Portuguese. At the end of this phase, two versions in Brazilian Portuguese of each instrument were obtained. In the second phase, the two translators participating in the first stage, together with a mediator (in this case, one of the researchers), met with the objective of synthesizing the translations prepared in the previous phase, producing, by consensus, a common translation into Brazilian Portuguese for each version of the questionnaire.

In the back-translation phase, the third stage of the process, two foreign translators, one North American and one British, residing in Brazil and fluent in Brazilian Portuguese, independently translated the four Brazilian Portuguese versions into English, creating two back-translations of each version. Both translators were not trained in the health area, were unaware of the original version of the instrument and were not aware of the content addressed in the questionnaires.

To assess each of the translated versions in relation to semantic, idiomatic, experimental and conceptual equivalence with the original instrument, an expert committee was formed, consisting of ten professionals: a doctor, nursing professor, author and supervisor of a study with this methodology; four clinical nurses, specialized in cardiology, who had been working for at least three years in the care

of people with CAD; a language professional majored in languages and linguistics; the four translators participating in first and third stages. A focus group was carried out to assess the questionnaires and develop the pre-final versions of the instruments (CROQ-PCI v2 pre-Br, CROQ-PCI v2 post-Br, CROQ-CABG v2 pre-Br and CROQ-CABG v2 post-Br) by means of consensus among its participants.

During the stages of translation and cross-cultural adaptation of the questionnaire versions into Brazilian Portuguese, the main researcher and the author of the original instrument were in contact. The documentation of the new translated and adapted versions of the questionnaire was sent to the author, obtaining her approval of the entire process.

In the test phase of the pre-final version, each of the four versions of the questionnaire was answered by patients undergoing the elective procedure of percutaneous coronary intervention or myocardial surgical revascularization. At the end of completing the questionnaire, all participants in this phase were asked about the presence or absence of doubts related to the instrument's questions and their respective answer options; in addition, they were asked whether or not they agreed with the general appearance of the questionnaire in the following items: structure and layout of the questionnaire elements, font size and understanding of the item instructions. The following demographic and clinical data were also collected to characterize the patients: education, medical diagnosis and age.

Analysis of results, and statistics

Descriptive statistical analysis of sociodemographic and clinical characterization of patients included in the test phase of the pre-final version was performed by calculating absolute and relative frequency for qualitative variables and calculating central tendency (mean, standard deviation, median, quartiles, minimum, and maximum) for quantitative variables.

Since the process of assessing the reliability of an instrument is essential to guarantee its accuracy, at this stage, Cronbach's alpha was adopted - which is expressed as a number between 0 and 1, in which values between 0.70 and 0,90 are considered acceptable - to

measure the internal consistency of the questionnaire⁽²⁴⁾. The calculation of item-total correlation was also performed, in order to verify the consistency of each item in relation to the test as a whole, considering the value of 0.20 as the minimum acceptable⁽¹⁵⁾. These analyzes were performed using the SPSS statistical program, version 22.0.

RESULTS

Cross-cultural adaptation into Brazilian Portuguese

In translation and back-translation phases, the differences found were related to the use of synonyms, in addition to differences in verb tenses and in the number flexion of nouns used in the writing of some items. After these phases, the questionnaire was assessed by a committee of experts, and cultural adaptations were made in the wording of the items to facilitate their understanding. Descriptions of terms common to healthcare professionals, but not common to the vocabulary of lay people in Brazil, were included, such as the inclusion of the definition of the term "angina" and examples of drugs from the nitrate class, as well as the adaptation of terms used in formal language to informal language, such as adapting a literal translation of the term "heart condition" to "problema cardíaco" and replacing the term "mandíbula" with "queixo".

Testing the pre-final versions of the questionnaire

The pre-final versions of the questionnaire were tested by 40 patients, except for the post-myocardial surgical revascularization version, which was answered by 33 individuals. Regarding the interrogation carried out at the end of each questionnaire, participants unanimously reported that they had no doubts regarding the instrument's questions and their respective answers. Furthermore, all respondents agreed with the general appearance of the questionnaire, not presenting criticisms or suggestions regarding the items assessed (structure and arrangement of the questionnaire elements, font size and understanding of instructions for the items).

Participant characterization in this step can be seen in Table 1.

Table 1 - Characterization of test participants of the final versions of the questionnaires adapted to Brazilian Portuguese, São Paulo, São Paulo, Brazil, 2018-2019

Characteristics	CROQ-PCI v2 pre-Br ⁽³⁾ (n=40)	CROQ-CABG v2 pre-Br ⁽⁴⁾ (n=40)	CROQ-PCI v2 post-Br ⁽⁵⁾ (n=40)	CROQ-CABG v2 post-Br ⁽⁶⁾ (n=33)
Education n (%)				
Incomplete Elementary School	13 (32.5)	13 (32.5)	13 (32.5)	11 (33.3)
Complete Elementary School	7 (17.5)	6 (15)	6 (15)	5 (15.2)
Incomplete High School	5 (12.5)	2 (5)	3 (7.5)	2 (6.1)
Complete High School	10 (25)	14 (35)	10 (25)	12 (36.4)
Incomplete Higher Education	3 (7.5)	2 (5)	0 (0)	1 (3)
Complete Higher Education	2 (5)	3 (7.5)	8 (20)	2 (6.1)
Medical Diagnosis n (%)				
AMI without SSE ⁽¹⁾	20 (50)	11 (27.5)	23 (57.5)	5 (15.2)
AMI without SSE ⁽²⁾	5 (12.5)	9 (22.5)	8 (20)	7 (21.2)
Unstable Angina	9 (22.5)	10 (25)	9 (22.5)	8 (24.2)
Stable Angina	6 (15)	10 (25)	0 (0)	13 (39.4)
Age (years)				
Mean (standard deviation)	58 (9.1)	63 (10.2)	59 (10.9)	62 (8.8)
Median (1st quartile 3rd quartile)	58 (50.3 66.5)	61 (54.3 71)	60 (54 64)	62 (58 68)
Maximum minimum	74 37	83 42	87 38	78 38

⁽¹⁾Acute Myocardial Infarction with ST-segment elevation; ⁽²⁾Acute Myocardial Infarction without ST-segment elevation; ⁽³⁾Pre-percutaneous coronary intervention version of the Coronary Revascularization Outcome Questionnaire - adapted to Brazilian Portuguese; ⁽⁴⁾Pre-myocardial surgical revascularization version of the Coronary Revascularization Outcome Questionnaire - adapted to Brazilian Portuguese; ⁽⁵⁾Post-percutaneous coronary intervention version of the Coronary Revascularization Outcome Questionnaire - adapted to Brazilian Portuguese; ⁽⁶⁾Post-myocardial surgical revascularization version of the Coronary Revascularization Outcome Questionnaire - adapted to Brazilian Portuguese.

Results of the reliability test of the domains of the questionnaires

The results of the reliability test of the versions of the questionnaire applied to patients undergoing percutaneous coronary intervention are shown in Table 2, in which adequate internal consistency is observed through Cronbach's alpha and item-total correlation in all domains, except for values of Cronbach's alpha of adverse effects and satisfaction domains of the post-percutaneous coronary intervention version.

Table 2 - Results of the reliability test of pre- and post-percutaneous coronary intervention versions of the questionnaire adapted to Brazilian Portuguese, São Paulo, São Paulo, Brazil 2018-2019

	Item-total correlation minimum-maximum (mean)	Cronbach's alpha
CROQ-PCI v2 pre-Br ⁽¹⁾		
Domain 1 - Symptoms (7 items)	0.24 - 0.70 (0.53)	0.80
Domain 2 - Physical Function (8 items)	0.71 - 0.81 (0.77)	0.93
Domain 3 - Psychosocial Function (14 items)	0.37 - 0.62 (0.53)	0.87
Domain 4 - Cognitive Function (3 items)	0.65 - 0.79 (0.71)	0.84
CROQ-PCI v2 post-Br ⁽²⁾		
Domain 1 - Symptoms (7 items)	0.29 - 0.77 (0.59)	0.83
Domain 2 - Physical Function (8 items)	0.65 - 0.82 (0.73)	0.92
Domain 3 - Psychosocial Function (14 items)	0.33 - 0.80 (0.68)	0.93
Domain 4 - Cognitive Function (3 items)	0.47 - 0.81 (0.67)	0.81
Domain 5 - Adverse Effects (6 items)	0.18 - 0.53 (0.31)	0.55
Domain 6 - Satisfaction (6 items)	0.04 - 0.79 (0.41)	0.61

⁽¹⁾Pre-percutaneous coronary intervention version of the Coronary Revascularization Outcome Questionnaire - adapted to Brazilian Portuguese; ⁽²⁾Post-percutaneous coronary intervention version of the Coronary Revascularization Outcome Questionnaire - adapted to Brazilian Portuguese.

Regarding the instruments for patients undergoing coronary artery bypass graft surgery, Table 3 shows adequate internal consistency through Cronbach's alpha and item-total correlation in all domains, except for Cronbach's alpha values of cognitive function and adverse effects domains of the post-myocardial surgical revascularization version.

Table 3 - Results of the reliability test of the pre- and post-myocardial surgical revascularization versions of the questionnaire adapted to Brazilian Portuguese, São Paulo, São Paulo, Brazil, 2018-2019

	Item-total correlation minimum-maximum (mean)	Cronbach's alpha
CROQ-CABG v2 pre-Br ⁽¹⁾		
Domain 1 - Symptoms (7 items)	0.34 - 0.76 (0.54)	0.81
Domain 2 - Physical Function (8 items)	0.52 - 0.77 (0.62)	0.87
Domain 3 - Psychosocial Function (14 items)	0.16 - 0.70 (0.48)	0.84
Domain 4 - Cognitive Function (3 items)	0.62 - 0.80 (0.70)	0.82
CROQ-CABG v2 post-Br ⁽²⁾		
Domain 1 - Symptoms (7 items)	0.33 - 0.63 (0.50)	0.77
Domain 2 - Physical Function (8 items)	0.32 - 0.75 (0.57)	0.83
Domain 3 - Psychosocial Function (14 items)	0.43 - 0.86 (0.61)	0.90
Domain 4 - Cognitive Function (3 items)	0.24 - 0.54 (0.39)	0.55
Domain 5 - Adverse Effects (6 items)	0.02 - 0.60 (0.31)	0.61
Domain 6 - Satisfaction (6 items)	0.38 - 0.64 (0.47)	0.70

⁽¹⁾Pre-myocardial surgical revascularization version of the Coronary Revascularization Outcome Questionnaire - adapted to Brazilian Portuguese; ⁽²⁾Post-myocardial surgical revascularization version of the Coronary Revascularization Outcome Questionnaire - adapted to Brazilian Portuguese.

DISCUSSION

Cross-cultural adaptation to Brazilian Portuguese

Regarding the differences found in translation and back-translation phases, other studies that performed translation and cross-cultural adaptation of instruments to Brazilian Portuguese, also using the method proposed by Beaton et al.⁽¹⁷⁾, showed similar results in which most of the discrepancies was related to the use of synonyms⁽²⁵⁻²⁶⁾.

In this study, in the assessment phase of the questionnaire versions by an expert committee, ten professionals were selected extremely qualified in their areas of expertise, according to the minimum composition suggested by Beaton et al.⁽¹⁷⁾. The research that carried out the cross-cultural adaptation of the Selfcare of Hypertension Index used a committee of experts similar to the one adopted in this study⁽²⁶⁾. On the other hand, it appears that this minimum composition was not always fully adopted in other studies that used this method for cross-cultural adaptation of instruments^(25,27-28), which can bring difficulties in adapting to the culture of the target population. Compared to other works that also carried out translation and cross-cultural adaptation of the CROQ, although other methods of translation and cross-cultural adaptation were used⁽¹⁸⁻²²⁾, it was observed that the translations were also assessed by expert committees. However, in some, there is no description of the number of professionals participating in this stage^(19,22-23) and/or the method used to reach consensus⁽¹⁸⁻²²⁾.

The choice of conducting the focus group at this stage was due to the recommendation by Beaton et al. that consensus must be reached among an expert committee regarding the wording of all items in the instrument; using the focus group, the possible differences identified can be discussed and resolved through consensus, without delaying the subsequent phase⁽¹⁷⁾. In this study, the discussions of the experts who made up this group focused mainly on adaptations, to facilitate the understanding of the items. These results are similar to those presented by other studies that used this method⁽²⁵⁻²⁶⁾. It is noteworthy that, according to Beaton et al., the instruments, translated and adapted, must be understood by individuals with a reading level equivalent to that of 12-year-old children⁽¹⁷⁾. In this sense, the footnote referring to the definition of the term angina, adapted from the Brazilian Society of Cardiology, was included in item "1.a". This inclusion was necessary because the term angina is not commonly used by the Brazilian population. It is noteworthy that this is one of the main symptoms that motivate individuals with CAD to seek emergency services and that compromises quality of life⁽²⁹⁾. Thus, if a person does not understand the meaning of the term angina, it will likely interfere with the results when applying the CROQv2.

In question 2, common to all versions of the questionnaire, in the statement, examples of drugs from the nitrate class were included in parentheses, in order to make the relationship between the drug class and their respective drugs easier for respondents. Although the items in question 4, common to all versions of the questionnaire, were removed from the SF-36 health research instrument, it was decided to use the verb limit in the response options, as well as written in the statement, in order to maintain the standardization in the wording of the question. This adjustment was made in order to facilitate the understanding of the question.

Testing the pre-final versions of the questionnaires

Regarding an analysis of reliability of the domains of the versions adapted to Brazilian Portuguese, the pre-procedure versions showed values considered acceptable for both Cronbach's alpha coefficient and the mean item-total correlation, demonstrating good internal consistency of these two versions. Results similar to these were found in comparison to the development studies of the original and adapted versions of the CROQ and to other cross-cultural adaptation studies of this questionnaire^(15-16,18-23).

In an analysis of the internal consistency of the post-percutaneous coronary intervention version adapted to Brazilian Portuguese, symptoms, physical function, psychosocial function and cognitive function presented Cronbach's alpha coefficient values above the pre-established value as the minimum acceptable. These results are in agreement with those shown in the study of the development of the original and adapted versions of the CROQ, and with the other studies of cross-cultural adaptation of this questionnaire^(15-16,18-23).

In an analysis of the internal consistency results of the post-myocardial surgical revascularization version adapted to Brazilian Portuguese, the values were also above those pre-established as minimum in the symptoms, physical function, psychosocial function and satisfaction domains. Satisfactory Cronbach's alpha results for this version of the questionnaire were demonstrated both in studies assessing the psychometric properties of the CROQ, in its original language, and in studies of cross-cultural adaptation to other languages^(15-16,18-23). However, it was observed that domains 5 (adverse effects) and 6 (satisfaction) of the post-percutaneous coronary intervention version and domains 4 (cognitive function) and 5 (adverse effects) of the post-myocardial surgical revascularization version had alpha values less than 0.70 in the post-procedural versions translated and adapted to Brazilian Portuguese in this study. Assessing domain 5 (adverse effects) of these versions, the low values of Cronbach's alpha coefficient may be related to the application of the questionnaire to patients in a period in which they no longer had adverse effects related to the procedures. Another factor that may be related to the results found is item-total correlation coefficient values lower than 0.20, presented by some items in the post-percutaneous coronary intervention and post-myocardial surgical revascularization versions.

In a study that assessed the problems in the recovery of patients undergoing myocardial surgical revascularization during the first month after hospital discharge, it was shown that only 4% of them had infection of the thoracic surgical incision and mediastinum, requiring hospitalization⁽³⁰⁾. Other problems tend to be temporary and gradually improve, with complete resolution between six weeks and six months after surgery, such as pain in the chest region, changes in the sleep pattern and changes in the motricity pattern caused by neuromuscular injuries⁽³⁰⁾.

Compared with other cross-cultural adaptation studies of the CROQ, only in the South Korean study, a Cronbach's alpha value of less than 0.70 was also demonstrated for the adverse effects domain in the post-percutaneous coronary intervention version, a result corresponding to 0.47⁽¹⁸⁾. The authors of the South Korean study hypothesize that the items in the domain adverse effects related to percutaneous coronary intervention, in the original version of the CROQ, are related to the puncture of the femoral

artery to perform the procedure, indicating that, perhaps, the adverse effects scale of the CROQ may not be adequate, even with the adaptation of the domain items, in places that mostly use the radial artery as an access route for the procedure (as in the South Korean study)⁽¹⁸⁾.

In domain 6, referring to satisfaction with the procedure, of the post-percutaneous coronary intervention version of the questionnaire adapted to Brazilian Portuguese, Cronbach's alpha value presented below 0.70 can be related to the low variability in the distribution of answers to question 10. In this question, 67.5% of the answers focused on only one alternative, and this fact was reflected in the item-total correlation value of the question, which was equivalent to 0.04. Compared to other CROQ validation studies, the Norwegian study also had alpha values less than 0.70 in this domain⁽²³⁾. However, in the validation studies of the CROQv2⁽¹⁶⁾ and the Japanese version⁽²¹⁾, despite Cronbach's alpha values greater than 0.70 being presented, this domain represented the lowest value. These results may be related to the lack of evidence in the literature of the relationship between satisfaction with the procedure and change in the quality of life of people with CAD. A study that aimed to investigate quality of life in people with CAD demonstrated the influence of physical, psychological, social and behavioral factors in determining such quality, but does not specify satisfaction as one of these factors⁽³¹⁾. Thus, the results of this study show that, possibly, satisfaction is a domain that does not assess quality of life, both due to the lack of evidence of a relationship between these themes and the little interrelationship between the items in this domain.

In the post-myocardial surgical revascularization version adapted to Brazilian Portuguese, domain 4, referring to cognitive function, also presented Cronbach's alpha value lower than the pre-established value as acceptable, this fact being possibly related to this domain being the one with the fewest number of items – only three – and the alpha values being highly influenced by the total number of items in each domain. Moreover, another factor that can justify this result is due to the low variability in the responses of the items in this domain. This domain is also present in the other three versions of CROQv2 and obtained acceptable internal consistency values. However, it can be observed that, in these versions, greater variability was shown in the distribution of responses to items belonging to this domain. When comparing the profile of the subjects in the post-myocardial surgical revascularization sample in relation to the samples of the other versions of the questionnaire, it is observed that only the post-surgical revascularization sample presented a prevalence of medical diagnosis of stable angina, the other samples being predominantly composed of patients diagnosed with Acute Myocardial Infarction with ST-segment elevation. Discrepancies related to the distribution of responses in this domain can be justified by the fact that Acute Myocardial Infarction with ST-segment elevation causes involvement of the cardiac muscle, which can progress to heart failure and cause several limitations, including cognitive changes⁽³²⁾. Therefore, samples composed mostly of individuals diagnosed with Acute Myocardial Infarction with ST-segment elevation may present variations in the levels of impairment of cognitive function, a fact demonstrated by the better distribution of responses to the items.

Limitations of the Study

As limitations of this study, we list that this was developed in a single center, that the sample of individuals who answered pre- and post-reperfusion questionnaires, both percutaneous and surgical, were different, and that, due to the reduction in the number of procedures in the institution during the data collection period, the final sample size made other psychometric analyzes impossible. For a better assessment of these results and analysis of the possibility of excluding items or domains that presented internal consistency values below the pre-established minimums, it is suggested that other studies be carried out with larger samples of participants so that it is possible to carry out the confirmatory factor analysis; additionally, the time after percutaneous coronary intervention and after myocardial surgical revascularization accessed for patient interview should be before four months, in order to analyze the reliability of the adverse effects domain. This is important, due to the unsatisfactory item-total correlation result presented by: one item in the adverse effects domain and one item in the satisfaction domain of the post-percutaneous coronary intervention version; an item in the psychosocial function domain of the pre-myocardial surgical revascularization version; six items in the adverse effects domain of the post-myocardial surgical revascularization version. It is also necessary the concomitant application of other instruments that assess quality of life for purposes of concurrent analysis, in addition to the application of the same version of CROQv2 itself in two moments to analyze its temporal stability through test-retest analysis.

Contributions to the Field

Translation and cross-cultural adaptation of the CROQv2 to Brazilian Portuguese can help healthcare professionals to investigate the changes in quality of life reported by people with CAD after the coronary reperfusion procedure, in addition to enabling the comparison of outcome measures in different contexts.

CONCLUSION

Cross-cultural adaptation to Brazilian Portuguese of the four versions of the CROQv2 was considered satisfactory, and the objective of offering the public an easy-to-understand questionnaire was achieved. It was shown that the pre-procedure versions are reliable and the post-procedure versions require other psychometric analyzes and with a larger sample, as they present values below those established as minimum for internal consistency in some domains. It is suggested that further studies are carried out to assess the validity evidence to confirm the domains of the instrument's construct for the Brazilian population.

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