

Translation and cross-cultural adaptation of the Congestion Quantifier Five-Item questionnaire to Brazilian Portuguese

Tradução e adaptação transcultural do questionário Congestion Quantifier Five-Item para o português brasileiro

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ABSTRACT

Background: Allergic rhinitis (AR) is considered the most prevalent disease among chronic respiratory diseases, although it is a benign disease, could impact the quality of life of affected individuals, with nasal congestion being the most bothersome symptom reported by patients. Congestion Quantifier Five-Item (CQ5) questionnaire was validated in American English, and was developed to assess the severity and the impact of nasal congestion in adults with AR. The present study aimed to translate and to perform a cross-cultural adaptation of the CQ5 questionnaire to Brazilian Portuguese and to verify if this translated version can be understood by individuals with AR. **Methods:** Following the guidelines of International Society for Pharmacoeconomics and Outcomes Research (ISPOR), CQ5 questionnaire was translated and adapted to Brazilian Portuguese. The Portuguese version was applied with a comprehension questionnaire to volunteers with allergic rhinitis. **Results:** These steps of: preparation; forward translation; reconciliation; back-translation; back-translation review; harmonization; cognitive debriefing; review cognitive debriefing results and finalization; proofreading; and final report proposed by ISPOR were carried out. The final version was applied in 41 volunteers ($32,2 \pm 7,8$) with good understanding of all items. **Conclusion:** The CQ5 questionnaire was translated, and cross-culturally adapted to Brazilian Portuguese with good understanding in individuals with AR.

Keywords: Nasal obstruction, allergic rhinitis, patient health questionnaire.

Introduction

Allergic rhinitis (AR) is defined as a symptomatic disorder of the nose, induced by an Immunoglobulin E (IgE)-mediated inflammation of the nasal lining

RESUMO

Introdução: A rinite alérgica (RA) é considerada a doença de maior prevalência entre as doenças respiratórias crônicas, e embora seja uma doença benigna, interfere na qualidade de vida dos indivíduos afetados, sendo a congestão nasal o sintoma mais incômodo relatado pelos pacientes. O questionário *Congestion Quantifier Five-Item* (CQ5), validado em inglês americano, foi desenvolvido para avaliar a gravidade e o impacto provocados pela congestão nasal em indivíduos adultos com RA. O presente estudo teve como objetivo traduzir e adaptar transculturalmente o questionário CQ5 para o português brasileiro e verificar se esta versão traduzida pode ser compreendida por indivíduos portadores de RA. **Métodos:** Seguindo as diretrizes da *International Society for Pharmacoeconomics and Outcomes Research* (ISPOR), o questionário CQ5 foi traduzido e adaptado para o português do Brasil. Esta versão em português foi aplicada em voluntários com rinite alérgica juntamente com um questionário de compreensão. **Resultados:** As etapas de preparação, tradução direta, reconciliação, retrotradução, revisão da retrotradução, harmonização, análise cognitiva da tradução, revisão dos resultados da análise cognitiva e finalização, revisão, e relatório final propostas pela ISPOR foram realizadas. A versão final foi aplicada em 41 voluntários ($32,2 \pm 7,8$) com boa compreensão em todos os itens. **Conclusão:** O questionário CQ5 foi traduzido e adaptado para o português (Brasil) com boa compreensão em indivíduos com RA.

Descritores: Obstrução nasal, rinite alérgica, questionário de saúde do paciente.

mucosa.¹ Rhinitis symptoms include rhinorrhea, nasal congestion, itchy nose and sneezing, which improve spontaneously or with treatment.¹ The clinical

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Submitted: 07/30/2021, accepted: 09/13/2021.

Arq Asma Alerg Imunol. 2021;5(4):409-15.

manifestations of AR occur after the susceptible individual is exposed to a sensitizing allergen.²

Rhinitis is considered the most prevalent disease among chronic respiratory diseases, being considered a global public health problem.³ The World Health Organization (WHO) estimates that 400 million people worldwide suffer from AR.⁴ Although it is a benign disease, AR interferes with the quality of life of affected individuals, with high economic costs related to health care.^{5,6}

Among the symptoms of AR, nasal congestion is the most characteristic and uncomfortable.⁷ In general, there is a gradual worsening of nasal congestion, which can contribute to daytime fatigue, drowsiness, decreased productivity and difficulty concentrating at school and at work.^{8,9} Furthermore, it is a symptom considered a risk factor for respiratory and sleep disorders, including snoring and obstructive apnea.¹⁰

To assess nasal congestion in individuals with allergic rhinitis, Stull et al. (2007)¹¹ developed the Congestion Quantifier Seven-Item (CQ7) questionnaire. It is a self-administered instrument in which a simplified version and with the same objective was created by the same authors, the Congestion Quantifier Five-Item (CQ5) questionnaire. The CQ5 has been validated for the American adult population and has similar reliability and responsiveness to the CQ7.

This instrument helps individuals to monitor the evolution of their symptoms and guides health professionals in relation to the clinical and drug treatment of AR. For the CQ5 to be applied in Brazil, it is necessary to translate its items into the local language and semantic and cultural adaptation in a language that can be understood by the general population. Therefore, the general objective of this study is to translate and cross-culturally adapt the Congestion Quantifier Five-Item (CQ5) to Brazilian Portuguese and to verify whether this translated version can be understood by individuals with AR.

Methods

It is a methodological study translation and cross-cultural adaptation of the CQ5 questionnaire into Brazilian Portuguese, which was carried out after approval by the Research Ethics Committee (CEP) of the Instituto Aggeu Magalhães/Fundação Oswaldo Cruz - PE, with a favorable opinion (number

4,529,536). In addition, the translation and adaptation of the CQ5 questionnaire was authorized by the tool's developer, Dr. Donald Stull.

The translation and cross-cultural adaptation process of the CQ5 was carried out in accordance with the recommendations of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)¹² for translation and cultural adaptation of patient-reported outcome measures (Patient-Reported Outcomes - PRO). The final version was applied to volunteers with allergic rhinitis to check their understanding of the CQ5 questionnaire.

Items from the original CQ5 questionnaire were kept confidential for copyright preservation, as the original article is not available to the general public, only to subscribers. The study was carried out in the city of Recife (Pernambuco), between August 2020 and June 2021. The application of the questionnaire for cognitive analysis of volunteers was carried out in March 2021.

Participants were recruited through dissemination on electronic means of social networks. Adult individuals, aged between 18 and 60 years, of both genders, diagnosed with AR by a specialist (allergologist or pulmonologist), Brazilian, literate, with a minimum level of education of completed elementary school and who accepted to participate in the research by signing the Informed Consent Form (FICF).

The exclusion criteria applied were: individuals with other upper respiratory tract diseases or nasal structural abnormalities such as polyps and septal deviation, and cognitive disorders or neurological diseases that made it impossible to understand the questionnaires.

The translation and cross-cultural adaptation were carried out according to the ISPOR steps,¹² described below.

(1) Preparation: an initial contact was made with the main author of the CQ5 questionnaire requesting authorization for its use.

(2) Direct translation: after authorization from the developer and approval of the project by CEP, two direct translations of the questionnaire from the source language (American English) to the target language (Brazilian Portuguese) were carried out independently by two bilingual translators, native speakers of Portuguese and fluent in American English, being a sworn translator of English and a guest researcher, health professional, Master in Health Sciences. The translators were previously clarified so that they

could carry out a translation based on the conceptual meaning of the items, capable of being understood by the target population and not an exclusively literal translation. The translations were developed independently without any contact or consultation between the translators.

(3) Reconciliation: the translations produced by the translators were compared to detect possible differences between them. A reconciled translation version was prepared by the researcher and the project coordinator, with input from the second translator, as provided for in the ISPOR guidelines.

(4) Reverse translation: the reconciled version was submitted to a back-translation. At this stage, the Portuguese version of the questionnaire was translated into American English by a native US teacher who was fluent in Brazilian Portuguese. This translator was not involved in any of the previous steps.

(5) Review of the reverse translation: the back-translated version was reviewed and made available to the author of the original instrument for analysis, and he consented to continue the research.

(6) Harmonization: harmonization was performed by the researcher and project coordinator, who compared the reconciled version and the back-translation with the original instrument in order to identify conceptual differences between the original instrument and the translated version. After completing this step, volunteers with allergic rhinitis were recruited to answer the questionnaire.

(7) Cognitive analysis: study participants were recruited through the dissemination of a “folder” containing basic information on the inclusion criteria on social media. Volunteers with allergic rhinitis who volunteered to participate in the study were duly informed about the research and signed the consent form. Data were collected in person or through the multi-platform WhatsApp messaging application.

Initially, data were collected on personal identification, age, gender, education level, time since diagnosis of allergic rhinitis, regular physical activity (defined as physical activity equal to or greater than 3 times a week) and medications in use for the treatment of RA and general purpose. After collecting general data, the cognitive analysis began and the participants answered the CQ5 questionnaire, consisting of five items and five response options.

To assess the participants' understanding of each item of the CQ5 questionnaire, a questionnaire called the understanding questionnaire was applied. The

response options for the comprehension questionnaire contained the following options: “I understand well”, “I understand a little” and “I don't understand” and the option for written suggestion of word changes from CQ5. Only items with more than 80% comprehension would be included in the final version. If 20% or more of the participants checked the options “I understand little” or “I don't understand”, these items would be reformulated and a new version of the CQ5 questionnaire would be reapplied until reaching the 80% comprehension level, previously defined.

(8) Review of cognitive analysis results and completion: The completed questionnaires were analyzed and reviewed.

(9 and 10) Review and final report: the researcher and the project coordinator performed the final review of the questionnaire to correct spelling or grammatical errors. Finally, a final report was prepared by the researcher with a detailed description of all the steps.

The collected data were organized in a database using the Microsoft Office Excel 2016 software, with double data entry and frequent checks to correct typing errors. In the statistical analysis, descriptive statistics (mean and standard deviation) and frequency distribution of the collected data were used.

Results

The CQ5 questionnaire was translated and adapted to Brazilian Portuguese according to ISPOR recommendations. Figure 1 shows the direct translations (Translation 1 and Translation 2), and the reconciliation version of the five items of the CQ5 questionnaire.

The version was back-translated and sent to the developer for review. There were not pointed out by him, items to be modified. Thus, the final version of the questionnaire was completed.

After the final version of the consolidated questionnaire, the instrument was submitted to a cognitive analysis in a group of 41 volunteers with allergic rhinitis. Table 1 shows the clinical characteristics of the sample.

Thirteen participants responded to the survey in person, and 28 responded through the WhatsApp application, in which all files were sent for reading, knowledge and filling in data, and the files were sent back after completion by the participants. All participants marked “I understand well” for items 1, 2, 4

and 5, totaling 100% of understanding for these items. Regarding item 3, four participants (corresponding to 10% of the sample) indicated “I understand little”. All items were answered by all participants.

Of the four participants who marked “I understand little”, one participant suggested a modification in item 3. The suggestion was to remove the preposition “from” in the excerpt “even after blowing it” in the sentence “How often did you have difficulty cleaning completely your nose, even after blowing it several times?”.

Item 3 was changed to “How often did you have difficulty cleaning your nose completely, even after blowing it several times?”. The item modification was

incorporated into the final version of the questionnaire, as shown in Figure 2.

Discussion

In the present study, the CQ5 questionnaire was translated and cross-culturally adapted to Brazilian Portuguese. Adult volunteers with AR who participated in the study reported understanding of all items in the Portuguese version.

To carry out the translation of this tool, all steps were followed according to the guidelines proposed by ISPOR in order to obtain semantic and conceptual equivalence between the original version and the

Item	Tradução 1	Tradução 2	Reconciliação
1	Com que frequência você teve entupimento, bloqueio ou congestão nasal?	Com que frequência você teve entupimento, obstrução ou congestão nasal?	Com que frequência você teve entupimento, obstrução ou congestão nasal?
2	Com que frequência você precisou respirar pela boca porque não conseguia respirar pelo nariz?	Com que frequência você teve que respirar pela boca porque não conseguia respirar pelo nariz?	Com que frequência você teve que respirar pela boca porque não conseguia respirar pelo nariz?
3	Com que frequência você teve dificuldade de limpar completamente o nariz, mesmo após assoá-lo diversas vezes?	Com que frequência você teve dificuldade para limpar completamente o nariz, mesmo após assoar repetidamente?	Com que frequência você teve dificuldade de limpar completamente o nariz, mesmo depois de assoá-lo diversas vezes?
4	Com que frequência você acordou de manhã com entupimento, bloqueio ou congestão nasal?	Com que frequência você acordou de manhã com entupimento, obstrução ou congestão nasal?	Com que frequência você acordou de manhã com entupimento, obstrução ou congestão nasal?
5	Com que frequência o seu sono foi afetado por causa de entupimento, bloqueio ou congestão nasal?	Com que frequência seu sono foi afetado em decorrência do entupimento, da obstrução ou da congestão nasal?	Com que frequência seu sono foi afetado em decorrência do entupimento, da obstrução ou da congestão nasal?
Escala de respostas	(0) Nenhuma vez, (1) poucas vezes, (2) algumas vezes, (3) quase o tempo todo, ou (4) o tempo todo.	(0) Nunca, (1) Um pouco, (2) Algumas vezes, (3) Na maioria das vezes, ou (4) Sempre.	(0) Nunca, (1) Poucas vezes, (2) Algumas vezes, (3) Na maioria das vezes, ou (4) Sempre.

Figure 1

Translations 1 and 2 and reconciliation version of the CQ5 questionnaire.

Table 1
Clinical characterization of the sample.

Variables	Evaluation n=41
Age (in years)	32.3 ± 7.8
Sex	
Masculine	10 (24%)
Feminine	31 (76%)
Education level	
Complete high school	09 (22%)
Complete higher education	18 (44%)
Specialization/Graduate	11 (27%)
Master's degree	03 (07%)
Diagnosis of allergic rhinitis (years)	
Less than 1 year	00 (00%)
Between 2 and 5 years	07 (17%)
Between 5 and 7 years old	07 (17%)
More than 10 years	27 (66%)
Regular physical activity	
Yes	23 (56%)
Not	18 (44%)
Allergic rhinitis medications	
Yes	32 (78%)
Not	09 (22%)
Other medications in regular use	
Yes	11 (27%)
Not	30 (73%)

Data expressed in average numbers ± standard deviation or absolute numbers (%).

translated version, ensuring the adaptation of the instrument to the local culture and maintenance of properties psychometrics of the questionnaire, aiming at its subsequent validation.¹²

ISPOR's translation and cultural adaptation guidelines recommend the development of at least two direct translations, performed by two independent translators, avoiding the risks of a translation that includes a translator's own writing style and reducing individual speech preferences.^{12,13} Thus, two translators were included to perform the direct translation.

The titles independently translated into Portuguese were “Quantificador de Congestão com Cinco Perguntas (CQ5)” (in english: Congestion Quantifier with Five Questions (CQ5)) and “Cinco Itens do Quantificador de Congestão (CQ5)” (in english: “Five Items of the Congestion Quantifier (CQ5)”). We chose to keep the second option because it was considered by the researcher and coordinator to be easier to understand. In the initial section containing the questionnaire instructions, “last week” was replaced by “last 7 days” to avoid interpretations between individuals regarding the period to which the questionnaire referred.

Some items, in particular items 1, 2, 4 and 5, required a discussion in the translation process, as a literal translation of the instrument would recommend the use of “nasal block”. However, this expression was replaced by “nasal obstruction” (suggested by translator 2), since this common expression is more used in Brazilian daily life.

The word “blocking” is defined as “Act or effect of blocking” and “blocking” means “Preventing the movement or movement of”, and “obstruction” is defined as “Partial or total, mechanical impediment, due to various causes, of the free transit of organ light; occlusion.”¹⁴ In addition, DeCS/MeSH defines “nasal obstruction” as: “Any impediment to the passage of air into or out of the nose. The obstruction can be unilateral or bilateral, and can involve any part of the nasal cavity”, the descriptor being “nasal obstruction”.^{15,16} In this case, it is highlighted that “nasal blockage” and “nasal obstruction” are synonymous terms.

A literature review¹⁷ that included 31 articles with different methods for cross-cultural adaptation of questionnaires shows that although back-translation is a commonly used step, there is no convincing evidence that this step improves the target language version. However, as the objective of the back-translation is to control the quality of the translated version and whether it has the same meaning when translated back into the original language,¹² the step was included in this study and was analyzed by the study developer with a satisfactory opinion.

Among the limitations, it is noteworthy that this study did not assess the degree of nasal congestion of the participants to compare with the information provided by the volunteers, as this was not the objective of the study. This work was also not intended to assess the validity of the questionnaire and the psychometric properties of all of its items.

As perguntas a seguir referem-se aos últimos 7 dias. Para cada pergunta, selecione apenas uma resposta marcando a caixa apropriada.

1. Com que frequência você teve entupimento, obstrução ou congestão nasal?
(0) Nunca (1) Poucas vezes (2) Algumas vezes (3) Na maioria das vezes (4) Sempre

2. Com que frequência você teve que respirar pela boca porque não conseguia respirar pelo nariz?
(0) Nunca (1) Poucas vezes (2) Algumas vezes (3) Na maioria das vezes (4) Sempre

3. Com que frequência você teve dificuldade de limpar completamente o nariz, mesmo após assoá-lo diversas vezes?
(0) Nunca (1) Poucas vezes (2) Algumas vezes (3) Na maioria das vezes (4) Sempre

4. Com que frequência você acordou de manhã com entupimento, obstrução ou congestão nasal?
(0) Nunca (1) Poucas vezes (2) Algumas vezes (3) Na maioria das vezes (4) Sempre

5. Com que frequência seu sono foi afetado em decorrência do entupimento, da obstrução ou da congestão nasal?
(0) Nunca (1) Poucas vezes (2) Algumas vezes (3) Na maioria das vezes (4) Sempre

Figure 2

CQ5 questionnaire translated into Brazilian Portuguese.

The CQ5 questionnaire was translated and cross-culturally adapted to Brazilian Portuguese and was well understood by individuals with AR. Future research may assess the psychometric properties and validate this version for use in clinical practice in individuals with AR.

Special thanks

We thank Dr. Donald Stull for authorizing us to use the questionnaire.

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No conflicts of interest declared concerning the publication of this article.

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