

Portuguese-language version of the Asthma Control Test: validation for use in Brazil*

Validação do Teste de Controle da Asma em português para uso no Brasil

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Abstract

Objective: To develop and validate a Portuguese-language version of the Asthma Control Test (ACT) for use in Brazil. **Methods:** The study comprised 290 asthma outpatients over 12 years of age. The patients completed the ACT questionnaire and had an appointment with a pulmonologist in order to assess asthma control in two visits. In the first visit, the patients also underwent spirometry. The second visit took place at least four weeks later. **Results:** We found that a cut-off score of 18 points—to differentiate between subjects with controlled asthma and those with uncontrolled asthma—had a sensitivity of 93%, a specificity of 74%, a negative predictive value of 86% and a positive predictive value of 85%. The positive and negative likelihood ratios were 3.58 and 0.09, respectively. The questionnaire has an outstanding capacity to differentiate uncontrolled asthma from controlled asthma, with an area under the ROC curve of 0.904. The patients whose symptoms remained stable between the two visits had similar scores, demonstrating good test-retest reproducibility, with an intraclass correlation coefficient of 0.93. The patients whose symptoms improved in the second visit had significantly higher scores, demonstrating good responsiveness of the questionnaire in the identification of changes in disease control. **Conclusions:** The Portuguese-language version of the ACT showed good test-retest reproducibility and was capable of discriminating the levels of asthma control and detecting changes in asthma control in a population of patients with a low level of education and low family income at a public health facility in Brazil.

Keywords: Asthma; Questionnaires; Validation studies; Signs and symptoms.

Resumo

Objetivo: Desenvolver e validar uma versão do *Asthma Control Test* (ACT, Teste de Controle da Asma) em português para uso no Brasil. **Métodos:** Foram estudados 290 pacientes ambulatoriais com asma maiores que 12 anos. Os pacientes responderam ao ACT e foram examinados por um pneumologista para avaliar o controle da asma em duas visitas. Na primeira visita, também realizaram prova de função pulmonar. A segunda visita foi realizada ao menos quatro semanas depois da primeira. **Resultados:** Utilizando-se como ponto de corte um escore de 18 para diferenciar asma controlada de asma não controlada, foram encontradas sensibilidade de 93%, especificidade de 74%, valor preditivo negativo de 86% e valor preditivo positivo de 85%. As razões de verossimilhança positiva e negativa foram, respectivamente, 3,58 e 0,09. O questionário tem grande capacidade de discriminar asma controlada de asma não controlada, com uma área sob a curva ROC de 0,904. Os pacientes que mantiveram os sintomas estáveis na segunda avaliação tiveram pontuação semelhante no questionário, indicando uma boa reprodutibilidade teste-reteste, com um coeficiente de correlação intraclassa de 0,93. Os pacientes que melhoraram os sintomas na segunda avaliação tiveram pontuação do questionário significativamente melhor, indicando uma boa responsividade do questionário para identificar mudanças no controle da doença. **Conclusões:** A versão em português do ACT apresentou boa reprodutibilidade teste-reteste e foi capaz de discriminar o nível de controle da asma, assim como detectar mudanças no controle da asma em uma população de baixa escolaridade e renda familiar em um serviço público de saúde no Brasil.

Descritores: Asma; Questionários; Estudos de validação; Sinais e sintomas.

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Introduction

Asthma is one of the most common chronic diseases in all age groups. It is characterized by chronic inflammation of the airways and varying degrees of reversible airway obstruction, together with bronchial hyperresponsiveness.⁽¹⁾ According to the International Study of Asthma and Allergies in Childhood, which compared 155 centers in 56 countries (including Brazil) at two time points, with a 5-year interval between the surveys, the prevalence of asthma and allergic symptoms continues to increase in some but not all regions of Brazil. In Salvador, Brazil, the prevalence of asthma remained stable among children (6-7 years of age) and increased among adolescents (13-14 years of age).⁽²⁾ In developed countries, there is a trend toward a higher prevalence of the disease. Although Brazil is a developing country, some regions of the country follow this pattern. The most concerning aspect of asthma is the associated morbidity rate, which is high. Data from 2005 show that hospitalizations due to asthma accounted for 18.7% of the hospitalizations due to respiratory complaints and for 2.6% of all hospitalizations under the Brazilian Unified Health Care System.⁽¹⁾ According to the guidelines of the Global Initiative for Asthma,⁽³⁾ the primary objective of the treatment is to achieve optimal control of the disease, with few or no daytime and nighttime symptoms, no limitation of physical activity, minimal need for the use of rescue medication, normal or near normal pulmonary function and no exacerbations. All of this should be achieved using the least amount of medication possible, according to a treatment plan in which doses are titrated based on the control and severity of the disease.^(1,4,5)

Although international guidelines recommend that asthma symptoms be fully controlled, there are major difficulties in achieving that objective, which is partly due to limitations in evaluating asthma patients.⁽⁶⁾ Various studies have shown that physicians and patients differ in their perception of the degree of asthma control⁽⁷⁾ and underestimate the severity of the symptoms.⁽⁸⁻¹⁰⁾ There is evidence that approximately 50% of the patients who report severe persistent symptoms consider the disease to be well controlled.^(11,12) A recent study conducted by our group demonstrated that the incidence of poor perception of asthma control in asthma patients is high, especially in elderly patients

with mild persistent asthma.⁽¹³⁾ These patients, who do not recognize or do not perceive the severity of the symptoms, can be at a higher risk for exacerbations and death due to asthma.

Poor patient perception of asthma control can lead to inappropriate evaluation of asthma by physicians and, consequently, to under- or over-treatment.⁽⁵⁻⁷⁾ In order to address this limitation of asthma control management, symptoms should be evaluated through the use of questionnaires that reflect the multidimensional nature of the disease and that are easily administered and interpreted.^(14,15) Such questionnaires are useful in clinical practice and in research protocols, since they constitute an inexpensive method for standardizing and reproducing the measures proposed.⁽¹⁴⁻¹⁷⁾

Nathan et al. recently developed a questionnaire designated the Asthma Control Test (ACT).⁽¹⁸⁾ This questionnaire, which can be self-administered, includes five items regarding the symptoms, use of rescue medication and effect of asthma on activities of daily living, precluding the need for pulmonary function measurements.^(18,19) This instrument was evaluated in patients from English-speaking countries and was recognized as being reproducible, valid and responsive to the clinical changes, as well as presenting internal consistency.^(18,19) The validation of this questionnaire for use in Brazil is important in order to allow us access to a simple tool for the evaluation of outpatients in the country. The objective of the present study was to validate a Portuguese-language version of the ACT questionnaire for use in Brazil. To that end, we evaluated the reproducibility and responsiveness of the questionnaire, as well as its ability to discriminate between controlled and uncontrolled asthma.

Methods

The first step of this study was the translation and linguistic validation of the questionnaire. The ACT was translated from English to Portuguese by two physicians who were proficient in both languages, experienced in translating questionnaires and aware of the objectives of the present study, as well as of the concepts involved in the study. The two translators and the principal investigator discussed the differences between the translations and developed the working version of the instrument.⁽²⁰⁻²²⁾

Subsequently, this version was translated from Portuguese into English by another physician who was proficient in both languages and who was unaware of the objectives of the questionnaire. The translators and the principal investigator discussed the differences between the original version in English and the back-translated version in English.⁽²⁰⁻²²⁾ The necessary adjustments were made in order to guarantee the semantic, idiomatic, cultural and conceptual equivalence of the ACT.

The second step of this study was to evaluate the ability of the Portuguese-language version of the questionnaire to discriminate asthma control. The test-retest reproducibility and the responsiveness of the questionnaire were also evaluated.

We consecutively interviewed a convenience sample of 290 asthma outpatients over 12 years of age—monitored at the Pulmonology Clinic of the Professor Edgard Santos University Hospital and via the Bahia State Asthma and Allergic Rhinitis Control Program⁽²³⁾ of the Federal University of Bahia School of Medicine. All of the patients gave written informed consent. Patients with respiratory comorbidities and patients with cognitive deficit were excluded from the study. The present study was approved by the Human Research Ethics Committee of the Federal University of Bahia School of Medicine.

The patients included were evaluated in two visits (visit 1 and visit 2). Visit 2 took place 4 to 5 weeks after visit 1. At visit 1, patients completed the ACT questionnaire, underwent spirometry and were clinically evaluated by a pulmonologist. At visit 2, patients completed the ACT and were clinically evaluated by the same pulmonologist.

The ACT questionnaire was applied as an interview due to the low level of education of the population studied. The interviewers were instructed not to modify the questions or otherwise influence the answers given by the interviewees. Patients were asked to recall their experiences with asthma in the last 4 weeks and to answer the questions on the questionnaire. Subsequently, patients were referred for pulmonary function testing. A spirometer (Koko; PDS Instrumentation Inc., Louisville, CO, USA) was used in accordance with the 1994 protocol of the American Thoracic Society⁽²⁴⁾ and the standards of normality for the Brazilian population.⁽²⁵⁾

The variable FEV_1 , expressed as the percentage of predicted, was used as a parameter to evaluate the degree of airway obstruction.

The last step of visit 1 was the evaluation by the pulmonologist, who was unaware of the answers given by patients on the ACT. However, this physician had access to the results of the pulmonary function test in order to complement the clinical evaluation, since the pulmonary function test is considered the gold standard for asthma control. Patients were submitted to clinical examination in order to confirm the diagnosis of asthma, as well as to evaluate the severity and control of the disease. The diagnosis of asthma was based on recurrent episodes of wheezing, dyspnea, chest tightness and cough, especially at night or at dawn, in patients with normal chest X-ray findings and spirometry results consistent with the diagnosis. Patients were classified as having intermittent asthma, mild persistent asthma, moderate persistent asthma or severe persistent asthma, according to the criteria established in the III Brazilian Consensus on Asthma Management (2002).⁽²⁶⁾ In order to determine the control of asthma in the last 4 weeks, the physician evaluated the degree of adherence to the objectives of asthma treatment, according to the aforementioned consensus. We used data obtained from the clinical history, clinical examination and spirometry in order to classify asthma as uncontrolled (severe persistent symptoms), poorly controlled (moderate persistent symptoms), partially controlled (moderate and mild persistent symptoms), well controlled (mild persistent symptoms) or fully controlled (asymptomatic).⁽³⁾ Finally, the participants were regrouped into two categories: controlled asthma and uncontrolled asthma. Those who had been classified by the physician as having fully controlled asthma or well controlled asthma were grouped and designated the controlled asthma group. Those classified as having partially controlled asthma, poorly controlled asthma and uncontrolled asthma were grouped and designated the uncontrolled asthma group.

At visit 2, the same steps were used for the classification of asthma control. In order to analyze reproducibility, the patients who were classified as having the same type of asthma (uncontrolled asthma, poorly controlled asthma, partially controlled asthma, well controlled

asthma or fully controlled asthma) in the two visits (visit 1 and visit 2) were considered to be stable. In order to evaluate responsiveness in a group presenting with improvement in the symptoms, we selected the patients who presented with an increase of at least two levels of asthma control at visit 2 in relation to the classification at visit 1.

For the statistical analysis, patients were classified as having controlled asthma or uncontrolled asthma according to the ACT score, which ranges from 5 to 25 points.^(18,19) In order to evaluate the ability of the questionnaire to discriminate the level of control of asthma, validity measurements of diagnostic tests, such as sensitivity, specificity, likelihood ratio, positive predictive value and negative predictive value, were used for each of the scores obtained. The balance between sensitivity and specificity was demonstrated by means of a ROC curve, which was used to calculate the proportion of correctly classified patients. In order to evaluate reproducibility, the intraclass correlation coefficient was used. In the evaluation of responsiveness, the Wilcoxon test was used to identify the statistically significant variations in the ACT scores. The statistical analyses were performed using the program Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA). Values of $\alpha < 0.05$ were considered statistically significant.

Results

Chart 1 shows the final Portuguese-language version of the questionnaire after the steps of cross-cultural adaptation.

Of the patients studied, 75 (26%) were male, and 216 (74%) were female. The median age was 45 years (range, 32-56 years). With regard to the educational level, 167 (58%) of the patients had 9 or fewer years of schooling, 92 (32%) had finished high school, only 10 (3%) had finished college, and 21 (7%) were illiterate. With regard to the family income, 186 (65%) of the patients reported having an income lower than the national minimum wage. With regard to the pulmonary function, 36% of the patients presented $FEV_1 < 60\%$ of predicted, 38% presented FEV_1 ranging from 60% to 79% of predicted, and 26% presented $FEV_1 \geq 80\%$ of predicted. With regard to the severity of asthma, 80 (28%) of the patients presented intermittent

Chart 1 – Portuguese-language version of the Asthma Control Test.^a

<i>Teste de controle da asma</i>
<i>Nas últimas quatro semanas:</i>
<i>Q1. A asma prejudicou suas atividades no trabalho, na escola ou em casa?</i>
<i>Nenhuma vez</i>
<i>Poucas vezes</i>
<i>Algumas vezes</i>
<i>Maioria das vezes</i>
<i>Todo o tempo</i>
<i>Q2. Como está o controle da sua asma?</i>
<i>Totalmente descontrolada</i>
<i>Pobremente controlada</i>
<i>Um pouco controlada</i>
<i>Bem controlada</i>
<i>Completamente controlada</i>
<i>Q3. Quantas vezes você teve falta de ar?</i>
<i>De jeito nenhum</i>
<i>Uma ou duas vezes por semana</i>
<i>Três a seis vezes por semana</i>
<i>Uma vez ao dia</i>
<i>Mais que uma vez ao dia</i>
<i>Q4. A asma acordou você à noite ou mais cedo que de costume?</i>
<i>De jeito nenhum</i>
<i>Uma ou duas vezes</i>
<i>Uma vez por semana</i>
<i>Duas ou três noites por semana</i>
<i>Quatro ou mais noites por semana</i>
<i>Q5. Quantas vezes você usou o remédio por inalação para alívio?</i>
<i>De jeito nenhum</i>
<i>Uma vez por semana ou menos</i>
<i>Poucas vezes por semana</i>
<i>Uma ou duas vezes por dia</i>
<i>Três ou mais vezes por dia</i>

^aThe score of the questionnaire is calculated by adding the points for each question, which can range from 1 to 5 points. The answers that indicate greater asthma control should be awarded more points. Therefore, the score of the questionnaire ranges from 5 to 25 points: a higher score indicates greater asthma control.

symptoms, 41 (14%) had mild asthma, 43 (15%) had moderate asthma, and 126 (43%) had severe asthma. The clinical examination performed at the first visit revealed that 181 (63%) of the patients had uncontrolled asthma.

Table 1 shows sensitivity values, specificity values, predictive values, likelihood ratios and the percentage of patients who were correctly classified on the basis of the ACT scores. At the

Table 1 – Sensitivity, specificity, predictive values, likelihood ratios and percentage of patients correctly classified in function of the Asthma Control Test score.

Cut-off point (ACT score)	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Likelihood ratio		Patients correctly classified
	%	%	%	%	positive	negative	%
10	44.505	98.148	97.590	51.208	24.033	0.565	64.5
11	50.000	98.148	97.849	53.807	27.000	0.509	67.9
12	59.341	94.444	94.737	57.955	10.681	0.431	72.4
13	66.484	89.815	91.667	61.392	6.527	0.373	75.2
14	72.527	86.111	89.796	65.035	5.222	0.319	77.6
15	78.571	84.259	89.375	70.000	4.992	0.254	80.7
16	84.066	82.407	88.953	75.424	4.778	0.193	83.4
17	88.462	79.630	87.978	80.374	4.343	0.145	85.2
18	92.857	74.074	85.787	86.022	3.582	0.096	85.9
19	93.956	61.111	80.282	85.714	2.416	0.099	81.7
20	96.154	53.704	77.778	89.231	2.077	0.072	80.3
21	96.703	40.741	73.333	88.000	1.632	0.081	75.9
22	97.802	29.630	70.079	88.889	1.390	0.074	72.4
23	100.000	17.593	67.159	100.000	1.213	0.000	69.3
24	100.000	6.481	64.311	100.000	1.069	0.000	65.2
25	100.000	0.926	62.976	100.000	1.009	0.000	63.1

ACT: Asthma Control Test.

cut-off score of 18 points, the percentage of patients who were correctly classified was higher (86%). The values of sensitivity and specificity were high (93% and 74%, respectively), as were the negative predictive value (86%) and the positive predictive value (85%). The positive likelihood ratio was 3.58, and the negative likelihood ratio was 0.09. The area under the

ROC curve was 0.904 (95% CI: 0.869-0.939; Figure 1).

In order to calculate reproducibility, we used the data of the 52 patients who remained stable between visits 1 and 2. The intraclass correlation coefficient showed a value of $\alpha = 0.93$, which indicated that the questionnaire presented good reproducibility. In order to evaluate responsiveness, we analyzed the questionnaires of 45 patients who presented with improvement in the symptoms at visit 2, according to the clinical evaluation. The median ACT score was 9 points (range: 5-23) at visit 1 and 20 points (range: 12-25) at visit 2 ($p < 0.001$), which showed that the questionnaire had the ability to identify clinical changes in the patients (Figure 2).

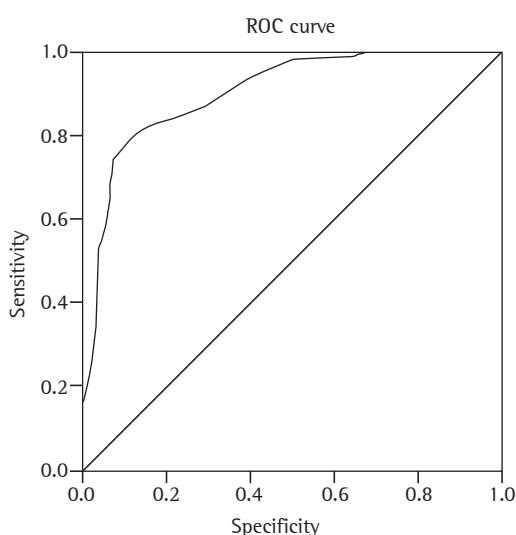


Figure 1 – ROC curve of the Asthma Control Test to identify patients with uncontrolled asthma. Area under the curve = 0.90 (95% CI: 0.87-0.94).

Discussion

The results presented in the present study show that the Portuguese-language version of the ACT had an outstanding ability to discriminate between controlled asthma and uncontrolled asthma in this group of patients in Brazil. The sensitivity (93%) indicates the proportion of patients with uncontrolled asthma who tested positive for asthma (according to the pre-established cut-off point). Sensitivity tests are useful in programs designed to monitor asthma control in clinical practice, as well as

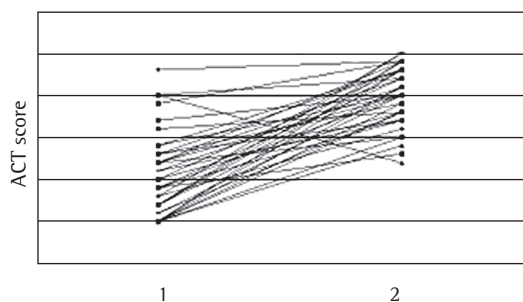


Figure 2 – Responsiveness of the Asthma Control Test (ACT) of 45 patients who presented with improvement in the symptoms after treatment and who were evaluated in two visits (1 and 2), visit 2 taking place 4-5 weeks after visit 1 ($p < 0.001$).

in research aimed at identifying patients who require more attention and in whom the causes of uncontrolled asthma should be investigated. In the present study, the specificity, which indicates the proportion of patients with controlled asthma who were identified by a negative test result (score below the cut-off point), was high (74%).

The ROC curve is a didactic means of representing the relationship between sensitivity and specificity. A greater proximity between the curve and the upper left corner of the graph indicates greater test accuracy, the percentage of true positives being close to one and the percentage of false negatives being close to zero.⁽²⁷⁾ By means of the ROC curve, we were able to calculate the proportion of patients who were correctly classified by the test. In the present study, the cut-off score was set at 18 points, because that was the score that allowed greater accuracy (Table 1). This score is quite similar to that defined by the author of the original questionnaire in English⁽¹⁸⁾ and to the cut-off point adopted in the studies that validated the Chinese-language version⁽²⁸⁾ and the Spanish-language version⁽²⁹⁾ of the questionnaire. In those studies, the patients who had a score ≥ 20 were classified as having controlled asthma.

High positive and negative predictive values indicate that the performance of a given test is good in a given study population. If a positive result indicates uncontrolled asthma, for example, a positive predictive value of 85%, as was found in the present study, means that there is an 85% chance that an individual actually has uncontrolled asthma. If a negative result indicates

controlled asthma, a negative predictive value of 86% means that there is an 86% chance that the individual actually has controlled asthma. The predictive values are influenced by the prevalence of the event in the study population. Since the present study was not a population-based study and investigated a sample of outpatients, the likelihood ratios provided important information, since they are independent of the prevalence of the event studied. The positive likelihood ratio observed in the present study (3.58) revealed that the ACT was 3.5 times more likely to identify uncontrolled asthma in patients who were identified by the gold standard as having uncontrolled asthma. The negative likelihood ratio (0.09) confirmed the reliability of the test, since it revealed that the ACT was more likely to identify controlled asthma in patients who were identified as having controlled asthma during the clinical evaluation.

The test-retest reproducibility was quite satisfactory, the value obtained in the present study being higher than those obtained in the studies using the original (English-language) version^(18,19) or the Spanish-language version⁽²⁹⁾ of the questionnaire. The way the Portuguese-language version of the questionnaire was administered might have influenced the result. In the present study, the questionnaire was applied by trained interviewers, whereas in the studies that used the original version in English or the Spanish-language version, the questionnaires were self-administered. The literature describes some advantages and disadvantages of using interviewer-administered questionnaires. The advantages include the certainty that the patients themselves are answering the questions and are willing to participate in the interview and the elimination of the issue of reading difficulties, which is a common problem among individuals with a low level of education.⁽³⁰⁾ It should be borne in mind that the interviewers who participated in the present study were properly trained, in accordance with the norms for the administration of questionnaires. However, inter-rater reliability was not evaluated in the present study. We found no reports in the literature describing discrepancies between the validity of self-administered instruments and that of interviewer-administered instruments.

The evaluation of responsiveness demonstrated that the test was able to identify, in patients who showed clinical improvement, treatment-related changes in the control of the disease. A similar result was described by the authors of the Spanish-language version of the ACT, who reported a correlation between the number of exacerbations and the ACT score.⁽²⁹⁾

Since the patients were selected from the outpatient clinics of a tertiary hospital, the results should be interpreted carefully when the questionnaire is administered to patients from primary care facilities, because the latter are less familiar with the disease and present with symptoms that are more sporadic. However, the favorable results of the present study were obtained in a population with a low level of education, which demonstrates that the questionnaire can be administered to patients treated via the Brazilian Unified Health Care System.

These results are relevant because they speak in favor of the use of this instrument for evaluating asthma control in clinical research, in daily practice and in public health programs. Since the ACT has few questions and few response options, and since the ACT score is obtained through simple addition, the instrument allows rapid and objective evaluation of asthma control even in the absence of pulmonary function measurements, thereby making it easier to conduct large studies in localities where pulmonary function tests are not available. In conclusion, the Portuguese-language version of the ACT administered by a trained interviewer proved to be a valid, reproducible and sensitive questionnaire for the evaluation of asthma control in a sample of Brazilian outpatients who had a low level of education and were treated at a tertiary hospital via the Unified Health Care System.

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