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

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

Jaqueline Petroni Faria Roxo, Eduardo Vieira Ponte, Daniela Campos Borges Ramos, Luciana Pimentel, Argemiro D'Oliveira Júnior, Álvaro Augusto Cruz

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.

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Correspondence to: ProAR, a/c Álvaro A. Cruz. Rua Carlos Gomes, 270, Centro de Saúde Carlos Gomes, 7º andar, CEP 40060-330, Salvador, BA, Brasil. Tel 55 71 3321-8467. E-mail: jaque_pfaria@hotmail.com

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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. 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). 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. According to the guidelines of the Global Initiative for Asthma, 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.

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. Various studies have shown that physicians and patients differ in their perception of the degree of asthma control and underestimate the severity of the symptoms. There is evidence that approximately 50% of the patients who report severe persistent symptoms consider the disease to be well controlled. 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. 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. 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. Such questionnaires are useful in clinical practice and in research protocols, since they constitute an inexpensive method for standardizing and reproducing the measures proposed.

Nathan et al. recently developed a questionnaire designated the Asthma Control Test (ACT). 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. 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. 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.

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Roxo JPF, Ponte EV, Ramos DCB, Pimentel L, D’Oliveira Júnior A, Cruz AA

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The variable FEV₁, 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). 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).

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) were regrouped and designated the same asthma group.
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. 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 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
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 for evaluating the questionnaire’s ability to identify clinical changes in the patients (Figure 2).

**Discussion**

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).

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

<table>
<thead>
<tr>
<th>Cut-off point (ACT score)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive predictive value</th>
<th>Negative predictive value</th>
<th>Likelihood ratio positive</th>
<th>Likelihood ratio negative</th>
<th>Patients correctly classified</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>44.505</td>
<td>98.148</td>
<td>97.590</td>
<td>51.208</td>
<td>24.033</td>
<td>0.565</td>
<td>64.5</td>
</tr>
<tr>
<td>11</td>
<td>50.000</td>
<td>98.148</td>
<td>97.849</td>
<td>53.807</td>
<td>27.000</td>
<td>0.509</td>
<td>67.9</td>
</tr>
<tr>
<td>12</td>
<td>59.341</td>
<td>94.444</td>
<td>94.737</td>
<td>57.955</td>
<td>10.681</td>
<td>0.431</td>
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</tr>
<tr>
<td>13</td>
<td>66.484</td>
<td>89.815</td>
<td>91.667</td>
<td>61.392</td>
<td>6.527</td>
<td>0.373</td>
<td>75.2</td>
</tr>
<tr>
<td>14</td>
<td>72.527</td>
<td>86.111</td>
<td>89.796</td>
<td>65.035</td>
<td>5.222</td>
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</tr>
<tr>
<td>15</td>
<td>78.571</td>
<td>84.259</td>
<td>89.375</td>
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<tr>
<td>16</td>
<td>84.066</td>
<td>82.407</td>
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<td>87.978</td>
<td>80.374</td>
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<td>18</td>
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<td>85.787</td>
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<td>3.582</td>
<td>0.096</td>
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<tr>
<td>19</td>
<td>93.956</td>
<td>61.111</td>
<td>80.282</td>
<td>85.714</td>
<td>2.416</td>
<td>0.099</td>
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<td>20</td>
<td>96.154</td>
<td>53.704</td>
<td>77.778</td>
<td>89.231</td>
<td>2.077</td>
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<td>40.741</td>
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<td>0.000</td>
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<td>62.976</td>
<td>100.000</td>
<td>1.009</td>
<td>0.000</td>
<td>63.1</td>
</tr>
</tbody>
</table>

ACT: Asthma Control Test.

**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).
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.\(^\text{27}\) 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\(^\text{18}\) and to the cut-off point adopted in the studies that validated the Chinese-language version\(^\text{28}\) and the Spanish-language version\(^\text{29}\) 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\(^\text{18,19}\) or the Spanish-language version\(^\text{29}\) 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.\(^\text{30}\) 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.

References


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**About the authors**

**Jaqueline Petroni Faria Roxo**  
Physical Therapist. University of São Paulo School of Medicine Hospital das Clínicas, São Paulo, Brazil.

**Eduardo Vieira Ponte**  
Collaborating Physician. Programa de Controle da Asma e Rinite Alérgica na Bahia – ProAR, Bahia State Asthma and Allergic Rhinitis Control Program – Faculdade de Medicina da Bahia, Universidade Federal da Bahia – UFBA, Federal University of Bahia School of Medicine – Salvador, Brazil.

**Daniela Campos Borges Ramos**  
Resident in Clinical Medicine. Faculdade de Medicina da Bahia, Universidade Federal da Bahia – UFBA, Federal University of Bahia School of Medicine – Salvador, Brazil.

**Luciana Pimentel**  
Medical Student. Faculdade de Medicina da Bahia, Universidade Federal da Bahia – UFBA, Federal University of Bahia School of Medicine – Salvador, Brazil.

**Argemiro D’Oliveira Júnior**  
Associate Professor. Faculdade de Medicina da Bahia, Universidade Federal da Bahia – UFBA, Federal University of Bahia School of Medicine – Salvador, Brazil.

**Álvaro Augusto Cruz**  
Adjunct Professor. Faculdade de Medicina da Bahia, Universidade Federal da Bahia – UFBA, Federal University of Bahia School of Medicine – Salvador, Brazil.