

Original Article

Evaluation of the Asthma Control Questionnaire validated for use in Brazil*

Avaliação do Questionário de Controle da Asma validado para uso no Brasil

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Abstract

Objective: To evaluate whether the Portuguese version of the Asthma Control Questionnaire (ACQ) is a valid instrument to measure asthma control in adult outpatients in Brazil. **Methods:** We selected 278 outpatients diagnosed with asthma. All of the patients completed the questionnaire, underwent spirometry and were clinically evaluated by a physician in order to characterize the control of the disease in the first visit. The questionnaire was evaluated in three versions, with 5, 6 and 7 questions, respectively, and scores of 0.75 and 1.50 were used as cut-off points. **Results:** Of the 278 patients, 77 (27.7%) had intermittent asthma, 39 (14.0%) had mild persistent asthma, 40 (14.4%) had moderate persistent asthma and 122 (43.9%) had severe persistent asthma. The sensitivity of ACQ to identify uncontrolled asthma ranged from 77% to 99%, and the specificity ranged from 36% to 84%. The positive predictive value ranged from 73% to 90%, and the negative predictive value ranged from 67% to 95%. The positive likelihood ratio ranged from 1.55 to 4.81, and the negative likelihood ratio ranged from 0.03 to 0.27. In the 5- and 6-question versions of the ACQ, the intraclass correlation coefficient was 0.92. These two versions were both responsive to clinical changes in the patients. **Conclusions:** All three versions of the ACQ satisfactorily discriminated between patients with uncontrolled asthma and those with controlled asthma. The 5- and 6-question versions also presented good reliability and responsiveness. Therefore, the ACQ is a valid tool for evaluating asthma control in adult outpatients in Brazil.

Keywords: Asthma; Therapeutics; Diagnosis; Questionnaires; Reproducibility of results.

Resumo

Objetivo: Avaliar se a versão em língua portuguesa do *Asthma Control Questionnaire* (ACQ, Questionário de Controle da Asma) é um instrumento válido para medir o controle da asma em pacientes adultos ambulatoriais no Brasil. **Métodos:** Foram avaliados 278 pacientes ambulatoriais com diagnóstico de asma. Todos os pacientes, durante a primeira visita, responderam ao questionário, foram submetidos à espirometria e avaliados clinicamente por um médico para a caracterização do controle da doença. Foram analisadas as versões do questionário com 5, 6 e 7 questões, utilizando dois escores distintos (0,75 e 1,50) como pontos de corte. **Resultados:** Dos 278 pacientes, 77 (27,7%) tinham asma intermitente, 39 (14,0%) asma persistente leve, 40 (14,4%) asma persistente moderada e 122 (43,9%) asma persistente grave. A sensibilidade do questionário para identificar asma não-controlada variou de 77% a 99% e a especificidade variou de 36% a 84%. O valor preditivo positivo variou de 73% a 90%, e o valor preditivo negativo variou de 67% a 95%. A razão de verossimilhança positiva variou de 1,55 a 4,81, e a razão de verossimilhança negativa variou de 0,03 a 0,27. Nas versões do ACQ com 5 e 6 questões, o coeficiente de correlação intraclasse foi de 0,92, e estas versões foram responsivas a mudanças no quadro clínico dos pacientes. **Conclusões:** O ACQ, nas suas três versões, teve boa capacidade de discriminar indivíduos com asma não-controlada daqueles com asma controlada. As versões com 5 e 6 questões apresentaram também boa reprodutibilidade e responsividade. Trata-se, portanto, de um instrumento válido para avaliação do controle da asma em pacientes adultos ambulatoriais no Brasil.

Descritores: Asma; Terapêutica; Diagnóstico; Questionários; Reprodutibilidade dos testes.

* Study carried out as part of the 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.

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Financial support: This study received financial support from the Fundação de Amparo à Pesquisa no Estado da Bahia (FAPESB, Foundation for the Support of Research in the State of Bahia), Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES, Coordination of the Advancement of Higher Education) and Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq, National Council for Scientific and Technological Development).

Submitted: 9 August 2007. Accepted, after review: 1 February 2008.

Introduction

Asthma is a chronic inflammatory airway disease, characterized by recurrent wheezing episodes, dyspnea, chest oppression and cough. These episodes are typically associated with variable airflow limitation, which is usually reversible, either spontaneously or through treatment, as well as with increased airway responsiveness (hyperresponsiveness) to various nonspecific stimuli. The objective of the asthma treatment is to reach and maintain control of the disease symptoms, with consequent improvement in the quality of life of the patient.⁽¹⁻³⁾ According to the current guidelines of the Global Initiative for Asthma⁽⁴⁾ and of the Brazilian Thoracic Association,⁽⁵⁾ adequate asthma control should include minimum or absent daily and nocturnal symptoms; no limitation to physical activity; minimum need for use of relief medication; normal or near normal pulmonary function, and no exacerbations, using minimum treatment.

Parameters used in a superficial evaluation in clinical practice can erroneously classify a poorly controlled patient as well controlled,⁽⁶⁾ and this can consequently result in insufficient treatment and greater morbidity risk. In addition, overestimating severity can lead to excessive use of medication, unnecessarily increasing costs⁽⁷⁾ and risks, with potential adverse effects in the treatment. However, many patients with asthma consider their asthma is well controlled, despite frequent symptoms, which demand that the doctor ask specific questions about each of the multiple manifestations of the disease. These patients, who do not recognize or do not perceive the severity of symptoms are the ones who present greater risks of exacerbations⁽⁸⁾ and death by asthma.^(9,10) In this sense, it is important to offer physicians and patients^(11,12) simple, rapid and low-cost instruments to precisely assess asthma control, both in outpatient clinics as in primary health care,⁽¹³⁾ allowing treatment adjustments whenever necessary.

The Asthma Control Questionnaire (ACQ), developed by Juniper et al. in 1999,⁽¹⁴⁾ was specifically prepared to measure asthma control in adults aged 17 or older. It is a simple and user-friendly instrument widely used worldwide, in numerous clinical essays and in medical practice as well.⁽¹⁴⁻¹⁷⁾ It has already been translated and culturally adapted to several languages, including Portuguese⁽¹⁸⁾ by the MAPI

Research Institute⁽¹⁹⁾ located in France. However, this study has not been published. We received the questionnaire already translated to Portuguese from the author herself. However, the questionnaire available in the Portuguese language has not been validated yet as to its discriminative properties and as to its responsiveness in Brazil. Discriminative properties comprise the reproducibility of the measures in stable individuals and the capacity of the questionnaire to discriminate uncontrolled and controlled asthma, whereas responsiveness refers to changes in the score of the questionnaire after changes in control, spontaneously observed or after an intervention. These characteristics are fundamental in order to indicate the usefulness of the questionnaire in clinical practice.

The ACQ, in its complete version, comprises seven questions. Five questions refer to asthma symptoms (nocturnal symptoms, morning symptoms, limitations to daily activities, dyspnea and wheezing), one question refers to the use of rescue β_2 -agonist medication, and the seventh question takes into consideration the diameter of the airways: the forced expiratory volume in one second (FEV_1) in percentage of predicted. The final score of the questionnaire is the average score of the answers chosen by the patient, which can range from 0 (totally controlled) to 6 points (not controlled). When it was validated in the English language, the ACQ presented two cut-off points to discriminate controlled asthma from uncontrolled asthma: the 0.75 score is used in clinical practice, with negative predictive value of 0.85 (meaning that, if the score is ≤ 0.75 , there is 85% chance that the asthma is well controlled); and the 1.50 score is used in clinical studies, with positive predictive value of 0.88 (meaning that, if the score is ≥ 1.50 , there is 88% chance of that the asthma is uncontrolled).

The questionnaire can be applied in three versions: a version with five questions (ACQ-5), another with six questions (ACQ-6) and a third one with seven questions (ACQ-7). In the present study, in order to validate it for the Portuguese language, we assessed ACQ-5 (symptoms), ACQ-6 (symptoms + use of rescue β_2 -agonist) and ACQ-7 (symptoms + use of rescue β_2 -agonist + FEV_1).

Although all ACQ versions are validated to be used in English, Dr Juniper recommends that the complete questionnaire be employed for clinical use (ACQ-7) in order to obtain a more precise

assessment of asthma control. Versions ACQ-5 and ACQ-6, due to their simplicity and lower cost, can be options for large clinical studies and epidemiological studies.^(20,21) Versions ACQ-5 or ACQ-6 can also be used in clinical practice, in places where spirometry cannot be performed.

The objective of the present study was to validate the use of ACQ in its three versions in the Portuguese language in order to assess asthma control in patients with intermittent asthma and mild, moderate and severe persistent asthma. Therefore, we assessed the capacity of the questionnaire to discriminate uncontrolled asthma from controlled asthma, in its three versions, as well as its reproducibility and responsiveness, in versions ACQ-5 and ACQ-6, in an outpatient sample with asthma in Brazil.

Methods

We assessed 278 patients aged 17 years and older diagnosed with asthma, in a convenience sample of consecutive patients, treated at the Pulmonology Department of the University Hospital and at the Bahia State Asthma and Allergic Rhinitis Control Program of the Federal University of Bahia School of Medicine, from May to September of 2005. Patients who did not give written informed consent were not included. The study was approved by the Ethics in Human Research Committee of the Federal University of Bahia School of Medicine.

The study comprised two visits denominated V1 (first visit) and V2 (second visit), 4 to 5 weeks apart. At V1, patients completed the ACQ, underwent spirometry and were clinically evaluated by a pulmonologist. At V2, patients completed the ACQ and were clinically evaluated, always by the same pulmonologist, but did not undergo spirometry.

The questionnaire was applied under the supervision of three trained interviewers (each interviewer evaluated one patient), at a peaceful location, without the help of third parties. The interviewers applied the questionnaire without inducing answers. The patient was informed that the questionnaire would assess asthma control. The patients recalled their experiences in the past seven days and answered the first six questions. At the end of the questionnaire, the patients were referred to spirometry and subsequent evaluation by the pulmonologist, who had no knowledge of the answers to the ACQ.

The objective of the medical visit was to confirm the diagnosis of asthma and define both the severity and the control of the disease. The diagnosis of asthma was based on recurrent episodes of wheezing, dyspnea, chest oppression and cough, especially at night and at dawn, in patients with normal chest X-ray and consistent spirometry. The severity of asthma was classified as intermittent asthma, mild persistent asthma, moderate persistent asthma and severe persistent asthma, according to the criteria of the III Brazilian Consensus on Asthma Management, carried out in 2002.⁽²²⁾

The assessment of asthma control was also performed by the pulmonologist and was used as the gold standard in the evaluation of the control of the disease. Initially, for each patient, the disease was classified as fully controlled, well controlled,

Table 1 - Clinical, demographic and socioeconomic characteristics of the 278 patients.

Characteristics	Values
Age, ^a years	46 (17-81)
Female gender, n (%)	209 (75.2)
Schooling, n (%)	
No schooling	21 (7.6)
Elementary	156 (56.3)
High school	90 (32.5)
College	10 (3.6)
Occupation, n (%)	
Students/employed	122 (44.0)
Unemployed/retired	155 (56.0)
Income, n (%)	
< 2 minimum salaries	192 (70.1)
≥ 2 minimum salaries	82 (29.9)
Use of medication, n (%)	
Did not use inhaled corticosteroids	99 (35.6)
Used inhaled corticosteroids	47 (16.9)
Inhaled corticosteroids/LABA	132 (47.5)
Duration of asthma symptoms, ^a years	24 (0-76)
Severity of asthma, n (%)	
Intermittent	77 (27.7)
Mild persistent	39 (14.0)
Moderate persistent	40 (14.4)
Severe persistent	122 (43.9)
FEV ₁ , ^a % of predicted	65.50 (22-125)
Frequency of uncontrolled asthma at V1, ^b n (%)	173 (62.5)

LABA: long-acting β_2 agonists; FEV₁: forced expiratory volume in one second; and V1: first visit. ^aValues expressed in median and variation. ^bAccording to the opinion of a specialist.

partially controlled, poorly controlled and uncontrolled. The levels of asthma control published in the validation of another questionnaire for the control of the disease were adapted.⁽²³⁾ The patients were classified as having fully controlled asthma when they were asymptomatic; well controlled asthma, when they presented intermittent symptoms; partially controlled asthma, when they presented mild persistent symptoms; poorly controlled asthma, when they presented mild persistent symptoms; and uncontrolled asthma, when they presented severe persistent symptoms. The clinical parameters used were morning symptoms, nocturnal symptoms, physical activity limitation, exacerbations and use of relief medication. Therefore, clinical parameters were used in order to assess symptoms according to their frequency and intensity, based on the same parameters of symptoms used in the classification of the severity of asthma. The physical examination was also performed and the values of FEV₁ of the patients who underwent spirometry were noted. Finally, the patients were characterized into two groups: controlled asthma (fully controlled and well controlled) and uncontrolled asthma (partially controlled, poorly controlled and uncontrolled).

At V2, the physician evaluated whether there had been any change in asthma control in relation to the prior visit (better, worse or stable). The reproducibility of the questionnaire was evaluated in the stable group (controlled and uncontrolled). The evaluation of responsiveness was performed in the group that presented improved asthma symptoms. The parameter used in order to identify improvement was the increase in at least one level in the classification of the 5 levels of asthma control.

Spirometry was performed using a Koko[®] spirometer (PDS Instrumentation Inc., Louisville, CO, USA), according to the protocol of the American Thoracic Society of 1994⁽²⁴⁾ and standards of normality for the Brazilian population.⁽²⁵⁾ The FEV₁ expressed in percentage of predicted was used as a parameter to evaluate airway obstruction.

The data collected were entered into a database using the Statistical Package for the Social Sciences for Windows, version 10.0 (SPSS Inc., Chicago, IL, USA). With the aim of evaluating the capacity of the questionnaire to discriminate between controlled patients and uncontrolled patients, validity measurements of diagnostic test, such as sensitivity and specificity, were used. The balance between sensi-

tivity and specificity was shown through the Receiver Operator Characteristic (ROC) curve. Positive and negative likelihood ratios, as well as positive and negative predictive values, were used. In order to evaluate reproducibility, the intraclass correlation coefficient was used. In order to evaluate responsiveness, the Wilcoxon test was used. Statistical significance was determined using an alpha error of $\leq 5\%$.

Results

At the first visit, all the 278 patients included in the study answered the ACQ-5, 158 answered ACQ-6 and 138 completed the full version (ACQ-7). Table 1 shows the clinical, demographic and socio-economic characteristics of these patients.

In the ROC curve (Figure 1), the area under the ACQ-5 curve was 0.910 (95% CI: 0.864-0.956); of ACQ-6, 0.922 (95% CI: 0.880-0.964); and of ACQ 7, 0.927 (95% CI: 0.886-0.968). The results on Table 2 describe the capacity of ACQ to discriminate between uncontrolled asthma and controlled asthma. Greater

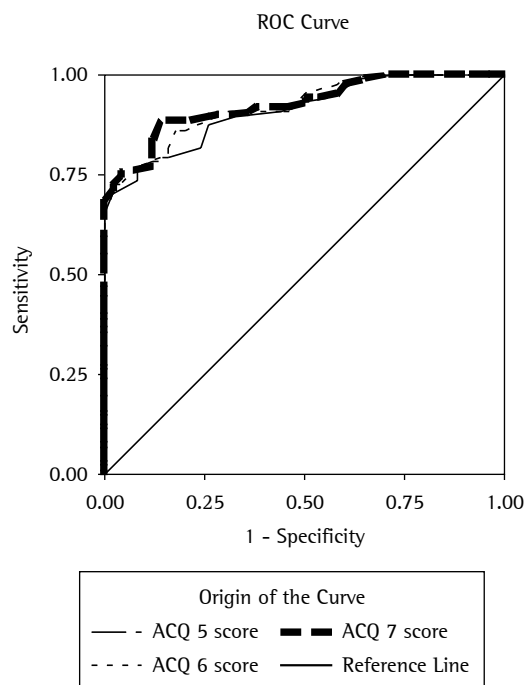


Figure 1 - Receiver operator characteristic (ROC) curve of the Asthma Control Questionnaire (ACQ) with 5, 6 and 7 questions.

sensitivity was obtained with ACQ-7 (99%), using a 0.75 score as a cut-off point, and greater specificity was obtained with ACQ-5 (84%), using a 1.50 score as cut-off point. Positive predictive values ranged from 73% to 90%, and negative predictive values ranged from 67% to 95%. The greatest positive likelihood ratios were obtained with ACQ-5 (3.11) and ACQ-6 (4.81), using a 1.5 cut-off point. The lowest negative likelihood ratios were obtained with ACQ-6 (0.07) and ACQ-7 (0.03), using a 0.75 cut-off point.

At V2, 165 patients were evaluated, but only 50 patients presented stable asthma between V1 and V2. The sixth question of the questionnaire (use of rescue β 2-agonist) was not answered by 39 stable patients. Therefore, it was possible to calculate the reproducibility of ACQ-5 for the 50 patients. However, the reproducibility of ACQ-6 was calculated for only 11 patients. The intraclass correlation coefficient of ACQ-5 was 0.92 (95% CI: 0.85-0.95) and that of ACQ-6 was 0.92 (95% CI: 0.70-0.98). The reproducibility of ACQ-5 was evaluated in 50 patients, and there was no statistically significant variation between V1 (1.70) and V2 (1.60). The reproducibility of ACQ-6 was evaluated in 11 patients, and there was no statistically significant variation between V1 (1.80) and V2 (1.33), despite the small number of patients.

In the evaluation of responsiveness, 165 patients answered ACQ-5 (81 patients improved asthma control) and 59 patients answered ACQ-6 (41 patients improved asthma control), and these patients who improved disease control between V1 and V2 were the ones who were evaluated in relation to responsiveness. Table 3 shows that the median of ACQ-5 decreased from 3.00 to 1.00 and that of ACQ-6

decreased from 3.17 to 1.00, respectively, between V1 and V2, meaning that ACQ-5 and ACQ-6 managed to detect the change in clinical condition (improvement) perceived by the specialist, and this improvement was statistically significant ($p < 0.001$; Figure 2). In relation to ACQ-7, reproducibility and responsiveness were not analyzed, since spirometry was not performed at V2, as already mentioned.

Table 3 shows ACQ scores in pre- and post-observation groups, in relation to the patients analyzed as to reproducibility and responsiveness. In relation to ACQ-7, the median score was 2.28, with variation between 0.00 and 5.42.

Discussion

The results of this study indicate that ACQ, in its three versions, using cut-off points of 0.75 and 1.50, satisfactorily discriminated between patients with uncontrolled asthma and those with controlled asthma, and is therefore a useful instrument for physicians and researchers.

ACQ sensitivity values were high (from 77% to 99%), indicating that a great proportion of patients with uncontrolled asthma tested positive. The sensitivity of a test expresses the probability of this test being positive in the presence of the disease. High sensitivity tests like this, with positive results for the patients who actually suffer from the disease, are useful in tracking programs of asthma control in the clinical practice, since they practically rule out the presence of uncontrolled disease when they are negative. The specificity values found were satisfactory when the 1.50 cut-off point was used (from 73% to 84%). However, they were low for the 0.75 cut-off point. The specificity of a test

Table 2 - Validity of the Asthma Control Questionnaire with 5, 6 and 7 questions in order to discriminate uncontrolled asthma from controlled asthma.

Cut-off point	ACQ-5	ACQ-6	ACQ-7	ACQ-5	ACQ-6	ACQ-7
	n = 278	n = 158	n = 138	n = 278	n = 158	n = 138
	1.50	1.50	1.50	0.75	0.75	0.75
Sensitivity	84%	77%	91%	94%	96%	99%
Specificity	73%	84%	64%	45%	54%	36%
Positive predictive value	84%	90%	81%	74%	79%	73%
Negative predictive value	74%	67%	80%	82%	88%	95%
Positive likelihood ratio	3.11	4.81	2.53	1.71	2.09	1.55
Negative likelihood ratio	0.22	0.27	0.14	0.13	0.07	0.03

ACQ-5: Asthma Control Questionnaire with 5 questions; ACQ-6: ACQ with 6 questions; ACQ-7: ACQ with 7 questions; and n: number of patients in the sample.

Table 3 - Scores of the Asthma Control Questionnaire with 5 and 6 questions.

	ACQ Score, median (variation)	
	Pre-observation (V1)	Post-observation (V2)
Reproducibility		
AQC-5 (n = 50)	1.70 (0.00-6.00)	1.60 (0.00-5.80)
ACQ-6 (n = 11)	1.80 (0.33-5.00)	1.33 (0.00-6.00)
Responsiveness		
ACQ-5 (n = 81)	3.00 (0.00-5.60)	1.00 (0.00-4.60)
ACQ-6 (n = 41)	3.17 (0.00-5.50)	1.00 (0.00-4.00)

ACQ: Asthma Control Questionnaire; V1: first visit; V2: second visit; ACQ-5: ACQ with 5 questions; ACQ-6: ACQ with 6 questions; and n: number of patients in the sample.

expresses the probability of the test to be negative in the absence of the disease. Specific tests are useful in clinical practice in order to reinforce diagnostic suspicion of a certain disease.

Positive and negative predictive values revealed in this study were favorable to the potential use of ACQ. The positive predictive value expresses the probability of a patient who tested positive to have the disease, and the negative predictive value expresses the probability of a patient who tested negative to not have the disease. Therefore, the positive predictive value indicates the probability of people with positive test results to have uncontrolled asthma, and the negative predictive value indicates the probability of people with negative test results to have controlled asthma.

The ROC curves of the three ACQ versions presented a great area under the curve, which also indicates the good performance of this test in

discriminating controlled asthma from uncontrolled asthma.

The positive likelihood ratio had greater values in ACQ-5 and ACQ-6 (1.50 cut-off point). Higher values translate to a stronger association between having a positive test and having uncontrolled asthma. A 4.8 likelihood ratio means that, for this cut-off point, the chance of a positive test to be true is five times greater than the chance to be false. The negative likelihood ratio had more meaningful values in ACQ-6 and ACQ-7 (0.75 cut-off point). Lower values translate to a stronger association between having a negative test and having controlled asthma. Therefore, the chance of uncontrolled asthma in patients with a negative test is quite reduced, indicating this test is of great value in the diagnosis of asthma control. The advantage of the likelihood ratio in relation to the predictive value is that, in the former, the prevalence of the problem studied in the population evaluated does not influence the result of the index, whereas in the latter the calculations necessarily involve the prevalence of the condition being investigated, therefore they cannot be extrapolated to different contexts without an additional careful analysis.

Curiously, the ACQ-7 revealed lower specificity than did ACQ-5 or ACQ-6. This observation probably reflects the fact that a reduction of the pulmonary function in a stable patient was not considered as indicating lack of control by the specialist. The limited specificity of the questionnaire in the evaluation of the disease control reinforces the idea that the ACQ, as well as the spirometry, are screening instruments that should not replace a judicious

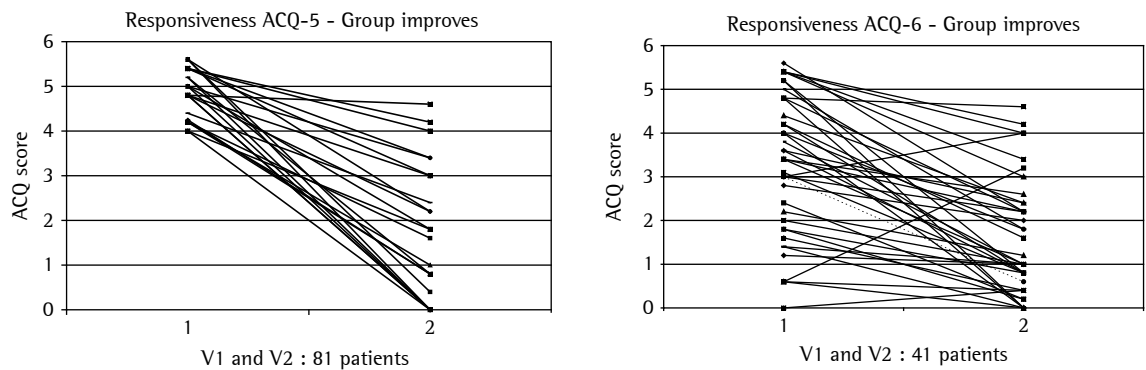


Figure 2 - Responsiveness of the Asthma Control Questionnaire (ACQ) with 5 and 6 questions.

evaluation of the physician, who can evaluate nuances of this varying disease in details during a medical visit.

In order to assess the consistency of results of the questionnaire in the patients who remained in control of their stable asthma (controlled and uncontrolled) between V1 and V2, the intraclass correlation coefficient was used for ACQ-5 and ACQ-6, which demonstrated good test-retest reproducibility. The responsiveness of the questionnaire assessed in ACQ-5 and ACQ-6 was also adequate in the group of patients who presented clinical improvement in the opinion of the physician, indicating that changes in the clinical profile of the patient are adequately identified by the questionnaire.

The ACQ is useful in the evaluation of asthma control in clinical practice and in clinical studies in Brazil, as we determined in our study, and these observations are in accordance with the results previously found by Juniper et al.^(14-18,20,21) Its use in the simplest versions would be especially beneficial in primary health care, in places where access to spirometry is difficult.

In this study, a large number of patients at different levels of asthma severity were evaluated in order to analyze the validity of the questionnaire, which reflects the everyday routine of patients in outpatient clinics and private specialized clinics. Since spirometry was not performed during V2, it was not possible to evaluate the reproducibility and responsiveness of ACQ-7, which is the more complete version. However, considering the good reproducibility of the subjective components of ACQ-7, which were tested in ACQ-5 and ACQ-6, it would be improbable to foresee an inadequate reproducibility of ACQ-7. Even with these limitations, the data from ACQ-6 and ACQ-7 are valuable, and knowing these data is of interest to the reader, even if only to complement the evaluation in new studies.

However, we need to consider that the study was performed in a specialized outpatient clinic, where patients with persistent asthma are predominant, and the questionnaire was applied by researchers. It would be convenient to reproduce this study in primary health care units, where patients with intermittent asthma are predominant, and the questionnaire would be applied by professionals of these units.

In conclusion, the results of this study indicate that the three versions of the ACQ in Portuguese are well able to discriminate individuals with uncontrolled asthma from those with controlled asthma, and that ACQ-5 and ACQ-6 present good reproducibility and responsiveness. It is, therefore, a valid instrument for the evaluation of asthma control in the Portuguese language in adult Brazilian outpatients.

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