Asthma

Validation of the Brazilian Version of the Childhood Asthma Control Test (c-ACT)

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Summary. Background: Children's perception of their symptoms has proved reliable and relevant to disease management and should be considered when assessing their asthma control. The aim of the study is to validate the Brazilian Portuguese version of the Childhood Asthma Control Test (c-ACT) in children aged 4–11 years. Methods: This is a cross-sectional study in children diagnosed with asthma undergoing treatment in a pediatric pulmonology outpatient clinic in Porto Alegre, Brazil. The translation and linguistic adaptation of the instrument were performed in accordance with international recommendations for questionnaire validation. Results: A total of 105 participants were included, aged 4–11 years. Validity: all correlations between the total score and items on the questionnaire were significant and obtained values of $r \geq 0.3$, and c-ACT means showed statistically significant differences between the GINA categories ($P < 0.01$). The controlled asthma group showed significantly higher c-ACT scores than those of uncontrolled asthma group (controlled 22.0 ± 2.9 vs. uncontrolled 16.3 ± 5.3 $P < 0.01$); and partially controlled asthma group showed significantly higher c-ACT scores than those of uncontrolled asthma group (partially controlled 20.0 ± 4.0 vs. uncontrolled 16.3 ± 5.3 $P = 0.03$). Correlations between the c-ACT total score and spirometry and nitric oxide were poor ($r = 0.020$; $P = 0.866$ and $r = 0.035$; $P = 0.753$, respectively). Reliability: the α–C coefficient for the c-ACT total score was 0.677 (95% CI 0.573–0763). Sensitivity to change had an effect size of 0.8 and an intraclass correlation coefficient of 0.598. No floor or ceiling effects were observed. Conclusion: The Brazilian version of the Childhood Asthma Control Test proved to be valid and reliable in children aged 4–11 years. **Pediatr Pulmonol.**

Key words: validation studies; questionnaire; child; asthma; disease management.

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INTRODUCTION

Asthma is a major public health problem,[1] with high morbidity and mortality worldwide,[2–4] and is the most common chronic disease among children and adolescents.[4–8] Despite advances in diagnostic techniques and treatment, lack of disease control remains important in a significant number of children.[9] As such, these individuals often seek emergency care and a important number require hospitalization. This affects both their quality of life and that of their parents, generating high direct and indirect healthcare costs.[10] A recent systematic review found that the highest direct asthma-related costs were hospitalization and medication, while indirect costs were absences from school and work and the resulting loss in productivity.[2]

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Conflict of interest: All authors approved the manuscript and there are no conflict of interests involved.

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According to the guidelines from the Global Initiative for Asthma (GINA) and the American Thoracic Society (ATS), asthma control reflects how the disease affects patients and addresses the extent of its manifestations. As such, one of the main objectives of asthma management is disease control, reducing the occurrence of adverse outcomes such as exacerbations and loss of lung function over time.[11–13] Controlling the disease involves aspects related to the absence of daytime and nighttime symptoms, pulmonary function near normal or within normal range, unrestricted daily activities, and minimal need for relief medication.[12] Thus, in order to achieve asthma control, individual and systematically monitored strategies aimed at improving patients' quality of life, are very important.[14]

Clinical control of asthma is typically based on assessing the presence of symptoms associated with pulmonary function data.[15–19] However, this requires greater financial resources given the need for equipment, specific settings, and trained personnel to conduct the tests, which limits the availability of these in daily clinical practice. In addition, these measures may not fully reflect disease control given that they do not include an assessment of patient's opinion.[15]

Children's perception of their symptoms has proved reliable and relevant to disease management and should be considered when assessing their asthma control.[20] Several instruments have been developed to evaluate asthma control in different age groups,[21] but only three questionnaires have been validated in Brazil: the Asthma Control Questionnaire (ACQ),[22] the Asthma Control Test (ACT),[23] and the Asthma Control Scoring System (ACSS).[24] However, none of these questionnaires evaluates children under the age of 12, limiting their use in clinical practice.[25–28]

Among questionnaires available for this population, the Childhood Asthma Control Test (c-ACT) is one of the most widely used in different countries to assess asthma control in children under 12 years of age. The questionnaire stands out in that it contains items considered key standards for evaluating asthma control at outpatient level, it can be applied in primary care and observational research, it is easy to understand and apply, and its psychometric properties have shown good performance.[21]

There is no Brazilian Portuguese version of the c-ACT, thus, the aim of this study is to validate the Childhood Asthma Control Test (c-ACT) for use in Brazilian population.

METHODS

This is a cross-sectional study of children aged 4–11 years, diagnosed with asthma and undergoing treatment in the pediatric pulmonology outpatient clinics of Hospital São Lucas in Porto Alegre, Brazil. Exclusion criteria were children with, heart disease or other chronic lung diseases. Data collection took place between November 2013 and April 2014.

The study was divided into two phases: phase one included the translation and linguistic adaptation of the instrument, in accordance with international recommendations for questionnaire validation (Fig. 1).[29] The resulting version was applied to 10 children of the target population for minor adjustments, making sure it was clear, understandable, and feasible.[29]

During phase two, psychometric properties regarding validity and reliability were analyzed. Participants were evaluated on two separate occasions; the first, on the day of inclusion (Assessment 1), and the second, 4–6 weeks after the initial evaluation (Assessment 2).

The first assessment involved clinical and physical evaluation of participants as well as collecting demographic and socioeconomic data. Next, asthma control was assessed applying both, GINA criteria and c-ACT, and then children performed lung function tests (spirometry and exhaled nitric oxide).

Asthma Control Criteria

Asthma control, according to the Global Initiative for Asthma (GINA) criteria, includes five parameters: three clinical (daytime symptoms, limitation of activities, and nocturnal symptoms/awakenings), the use of short-acting beta-agonist and one lung function parameter (FEV1). The combination of these renders three possible levels of disease control: Controlled, Partially Controlled, and Uncontrolled.[8]

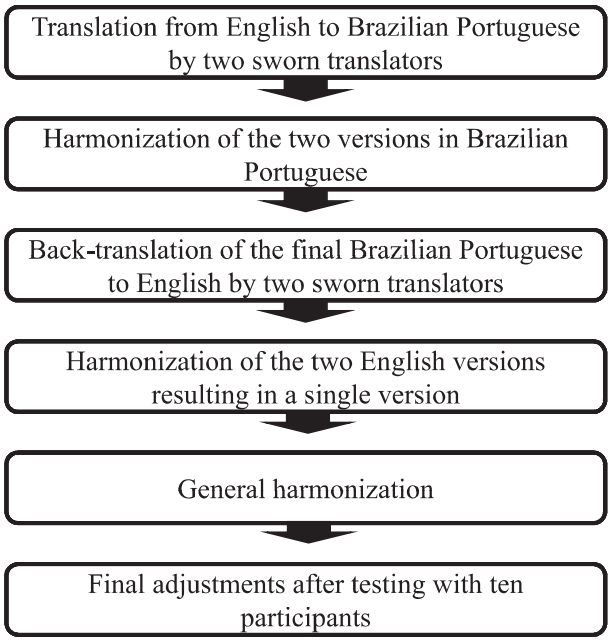

Fig. 1. Translation and back-translation of c-ACT.

The c-ACT contains seven short-answer questions; the first four are answered by participating children and inquire about their own perception of their current asthma control, restrictions on their activities, coughing episodes, and sleep disturbances at night. To answer these questions children must choose one of four child faces representing emotions in a continuum from sad to happy. The remaining three questions are answered by a parent or legal guardian and inquire about the child's respiratory symptoms (asthma symptoms during the day, wheezing episodes and nighttime wakefulness) over the previous 4 weeks.[28] A cut-off point ≤ 19 indicates uncontrolled asthma.

Lung Function

Lung function tests were performed after asthma control questionnaires were answered. Spirometry testing followed the American Thoracic Society/European Respiratory Society (ATS/ERS) recommendations for acceptability and reproducibility and KOKO spirometers (Ferraris) were used. Exhaled nitric oxide was measured using a Niox-Mino equipment (Aerocrine, Stockholm, Sweeden). Following ATS/ERS recommendations. Interpretation for this age group was: <20 ppb, no airway inflammation; 21–44 ppb, intermediate level of inflammation, and 45 ppb, high levels of inflammation.[30,31]

During Assessment 2, the asthma control (c-ACT and GINA control) was evaluated again, to assess changes over time. Additionally, participants answered the asthma Global Index of Change (GIC) in order to assess overall change between both assessments. The GIC is a single question that inquires on how the patient considers his/her asthma is, compared to the previous visit; to answer, patients choose one of nine options from a Likert scale ranging from "much better" to "much worse;" depending on their answers, subjects were grouped as "changed" (those who either felt better or worse) and "no change" (those who did not experience any change in clinical status between visits).[32]

Psychometric Properties

Validity and reliability were the psychometric properties assessed. Validity was assessed through concordant validity, by comparing the c-ACT's means with the three GINA categories. Other correlations sought were between questionnaire items and its total score and between the total score of the questionnaire and functional measures (pulmonary function and nitric oxide).

Reliability was assessed by means of internal consistency, sensitivity to change and reproducibility. Internal consistency assesses specific correlations within the instrument's items using Cronbach's Alpha's (α–C). Sensitivity to change determines whether there is a significant difference between the two interviews and it is assessed by calculating the effect size (ES); reproducibility determines if the instrument obtains similar results in two different points in time when there have been no changes, and it is assessed by calculating the intraclass correlation coefficient (ICC). Sensitivity to change and reproducibility were evaluated based on the GIC; in the "changed" group, ES was calculated, while the ICC was calculated in the "no change" group. We also calculated the proportion of children with minimum and maximum scores in the c-ACT, which is the floor/ceiling effect.

Statistical Analysis

Continuous variables were represented by mean and standard deviation and categorical variables by absolute and relative frequency. Correlations assessed for validity were analyzed using the Spearman's correlation test, with $r > 0.3$ considered acceptable.[33] ANOVA and the Bonferroni post-hoc test were used to compare the c-ACT's means in the three GINA's categories. Internal consistency was evaluated using Cronbach's alpha (α-C), sensitivity to change by estimating the effect size (ES), and reproducibility, by estimating the intraclass correlation (ICC). For α-C, values ≥ 0.6 were considered adequate.[34] ES was calculated in the group of children categorized as "changed" in the GIC. The interpretation used for ES is: 0.2 = small; 0.5 = medium; 0.8 = large.[35] The ICC was calculated for those categorized as "no change," deemed acceptable when ≥ 0.7. Paired two-sample *t*-tests were applied to compare the mean total scores between interviews. The number of patients accepted with minimum (floor effect) and maximum score (ceiling effect) was < 20%.[36] Data were analyzed using version 17.0 of SPSS software (SPSS Inc, Chicago).

Sample Size

The sample size was 36 participants, considering a minimum difference of 0.5 points in the total c-ACT score between interviews, an alpha of 5%, and a beta error of 20%. Considering the other psychometric properties assessed, we included 70 participants to enable the inclusion of 10 subjects for each item of the instrument to be validated.

The study was approved by the PUCRS Research Ethics Committee under CAAE: 19464313.9.0000.5336. Children as well as their parents and/or guardians gave written informed consent (IC).

RESULTS

A total of 115 individuals were included in the study. The first 10 children only participated in the pilot study. Thus, our final sample was composed of 105 individuals. The mean age of participants was 7.8 ± 2.13, of which 65 (61.9%) were male and 63.8% Caucasian. Table 1 shows

TABLE 1— Participant Characteristics of the Brazilian c-ACT Validation Study

Characteristics	n = 105
Demographics	
Gender (male), n (%)	65 (61.9)
Age (years), mean ± SD	7.8 ± 2.13
Race (caucasian), n (%)	67 (63.8)
Pulmonary function	
Spirometry, percent of predicted	
FVC, mean ± SD	107.6 ± 16.2
FEV_1, mean ± SD	104.3 ± 18.5
FEV_1/ FVC, mean ± SD	89.6 ± 2.11
FEF 25–75, mean ± SD	96.0 ± 32.2
Exhaled nitric oxide	
No inflammation, n (%)	52 (49.5)
Intermittent inflammation, n (%)	12 (11.42)
High inflammation, n (%)	24 (22.8)
Asthma control	
c-ACT	
Uncontrolled asthma, n (%)	43 (41.0)
Controlled asthma, n (%)	62 (59.0)
GINA control	
Uncontrolled, n (%)	18 (17.1)
Partially controlled, n (%)	45 (42.9)
Controlled, n (%)	42 (40.0)
Global Index of Change	
Change n (%)	28 (75.6)
No change n (%)	5 (13.5)

FVC, forced vital capacity; FEV_1, forced expiratory volume in one second; FEF 25–75, forced expiratory flow at 25–75% of FVC.
Values expressed as mean and ± standard deviation.

TABLE 2— Correlations Between the Total Score of c-ACT, the Items of the Instrument and the Parameters of Pulmonary Function

	r	*P*
Question 1	0.340*	<0.001
Question 2	0.476*	<0.001
Question 3	0.399*	<0.001
Question 4	0.543*	<0.001
Question 5	0.761*	<0.001
Question 6	0.610*	<0.001
Question 7	0.661*	<0.001
FEV_1	−0.006	0.932
FeNO	0.035	0.753

Question 1, How is your asthma today?; Question 2, How much of a problem is your asthma when you run, exercise or play sports?; Question 3, Do you cough because of your asthma?; Question 4, Do you wake up during the night because of your asthma?; Question 5, During the last 4 weeks, how many days did your child have any daytime asthmasymptoms?; Question 6, During the last 4 weeks, how many days did your child wheeze during the day because of asthma?; Question 7, During the last 4 weeks, how many days did your child wake up during the night because of asthma?
FEV_1, forced expiratory volume in one second, as percent of predicted; FeNO, nitric oxide exhaled.
*$P < 0.05$ Spearman correlation coefficient.

the demographic characteristics and pulmonary function of the participants. In the assessment of asthma control using c-ACT, most patients (59.0%) exhibited controlled asthma on the day of evaluation, while GINA criteria showed partial control for 42.9% and controlled asthma for 40%. (Table 1). The mean age of parents/guardians of participants was 38.74 ± 12.32 years, with most having completed their elementary schooling. The mean time required for the c-ACT interview with parents and/or guardians was 2 min, and 3 min for children.

Validity

The c–ACT score for the sample studied varied from two to 27. All correlations between the total score and questionnaire items were significant and obtained values of r = >0.3. However, correlations between the total score and spirometry and nitric oxide were r = 0.020; $P = 0.866$ and r = 0.035; $P = 0.753$, respectively (Table 2). The spirometry and FeNO means did not also show difference between GINA categories ($P = 0.205$ and $P = 0.135$, respectively). However, c-ACT means showed statistically significant difference between the GINA categories ($P < 0.01$). In post-hoc testing the controlled asthma group showed significantly higher c-ACT scores than those of uncontrolled asthma group (controlled 22.0 ± 2.9 vs. uncontrolled 16.3 ± 5.3 $P < 0.01$); and partially controlled asthma group showed significantly higher c-ACT scores than those of uncontrolled asthma group (partially controlled 20.0 ± 4.0 vs. uncontrolled 16.3 ± 5.3 $P = 0.03$) (Fig. 2).

Reliability

The α–C coefficient for the total c-ACT score was 0.677 (95%CI 0.573–0763). There was no statistically significant difference between the overall mean c-ACT scores for the first 21.48 (3.23) and second visit, 21.43 (3.18), respectively ($P = 0.934$). Assessment of sensitivity to change found an effect size of 0.8 in the group that exhibited clinical changes, suffering worsening symptoms. ICC was 0.598, varying from −0.358 to 0.953. No floor or ceiling effects were observed in the sample studied.

DISCUSSION

The present study led to the development and cultural validation of the Brazilian version of the Childhood Asthma Control Test. The validated questionnaire showed good psychometric performance in all properties assessed, proving to be a valid and reliable version for the proposed population. As expected, it was also easy to apply and to understand for children 4–11 years of age.

When validating an instrument, it is not easy to find an established questionnaire with similar purposes as a control, in order to test its validity. The original c-ACT used the opinion of an expert as a standard to identify the

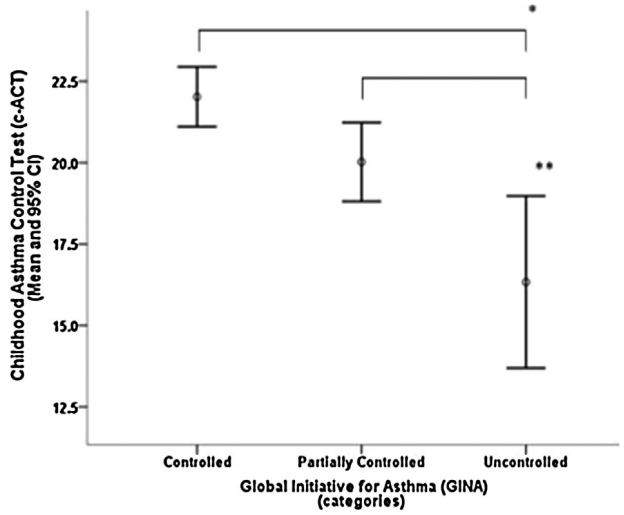

Fig. 2. Childhood Asthma Control Test (c-ACT) score accorsing to Global Initiative for Asthma (GINA) categories. *The controlled asthma group showed significantly higher c-ACT scores than those of uncontrolled asthma group (controlled 22.0 ± 2.9 vs. uncontrolled 16.3 ± 5.3 $P < 0.01$). **Partially controlled asthma group showed significantly higher c-ACT scores than those of uncontrolled asthma group (partially controlled 20.0 ± 4.0 vs. uncontrolled 16.3 ± 5.3 $P = 0.03$). All data were analyzed by one-way ANOVA with Bonferroni post hoc test.

level of asthma control; we opted to use GINA criteria as our standard, which we thought less subject to bias, and it has been already applied in both clinical and research settings successfully. Regarding our results, when grouping youngster's c-ACT mean values by GINA sub-groups, the comparison between these subgroups makes it clear who is really controlled and partially controlled versus who is really not controlled (Fig 2). Different than GINA criteria, which have a "partially controlled" category, the c-ACT aimed at separating those well controlled than the rest, and our results tell us it succeeded in doing so. Different from our results, a recent study from the Netherlands found that c-ACT was not a sensitive enough measure to determine asthma control when compared to GINA.[37] We took a different approach, and found that both GINA criteria and the c-ACT are able to separate well controlled than the rest. Certainly, the definition of what constitutes asthma control is still being debated, and that includes asthma in children.[20]

Further studies in children are still needed to properly compare physician's rating versus composite scores to identify asthma control status in this age group.

Associations between c-ACT and functional measurements (spirometry and nitric oxide) were not significant. Other studies have encountered similar results, at least in children.[38–40] In fact, the literature suggests that this result might be expected, since objective and subjective measures are complementary; frequently, in terms of correlations, functional measures are often less correlated with subjective measures.[32,35–38,41]

As for reliability of the Brazilian version of the c-ACT, the internal consistency was adequate, reflecting a degree of coherence between items of the questionnaire, with values close to those of existing validations.[28,38,39,42] Since the c-ACT aims to identify clinical stability or changes in disease control, it is important to test these characteristics. In the original validation of c-ACT it is not clear whether these properties were assessed. However, similar to other versions of the c-ACT validated in other languages, the Brazilian version showed good sensitivity to change and good reproducibility.[42]

Considering the sociocultural diversity of Brazil, the main limitation of our study could be the inclusion of asthmatics from a single center. Nevertheless, the brevity of the questionnaire and clarity of the questions facilitated the use of standard expressions, common to all regions of the country. Ideally, new studies should be conducted in other states to confirm this.

Thus, we conclude that it was possible to successfully develop and culturally validate the Brazilian Portuguese version of the Childhood Asthma Control Test, which proved to be valid and reliable to use in Brazilian children under 12 years of age, diagnosed with asthma.

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