Pediatric Pulmonology 47:113–118 (2012)

Original Articles

Assessing Asthma Control: Symptom Scores, GINA Levels of Asthma Control, Lung Function, and Exhaled Nitric Oxide

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Summary. Background: The childhood asthma control test (C-ACT) is a validated symptom score for assessing asthma control in children. We used a slightly modified version (C-ACT^{M}) of the German C-ACT and compared our results with the literature, correlated the children's part of C-ACT (C-ACT^{children}) with a visual analogue scale (VAS^{children}), explored the agreement between C-ACT^{M} and GINA levels of asthma control, as well as the relationship between C-ACT^{M} and lung function and exhaled nitric oxide (FeNO). Methods: We investigated 107 children with a diagnosis of asthma. The study protocol consisted of a clinical examination, assessment of asthma control according to GINA guidelines, administration of C-ACT^{M}, VAS^{children}, lung function, and FeNO. Results: Of our patients 66% had, according to GINA, partly controlled-/uncontrolled asthma, 18% were uncontrolled according to C-ACT^{M}. Children with partly controlled-/uncontrolled asthma according to GINA had lower C-ACT^{M} scores than did children with controlled asthma (16.1 ± 3.6 SD vs. 25.4 ± 1.8 SD; $P < 0.000$), and children with a C-ACT^{M} score $\leq$ 19 had poorer lung function (mean FEV1% predicted 81.5 ± 13.5 SD vs. 94.2 ± 12.1 SD; $P = 0.002$). Spearman's rank correlation coefficients revealed significant correlations between all symptom scores. Multiple linear regression adjusted for age, gender, FEV1 and FeNO demonstrated a significant relationship between C-ACT^{M}, VAS^{children}, and FEV1 ($P = 0.003$, resp. <0.000), but no significant correlation between C-ACT^{M}, VAS^{children}, and FeNO. Conclusions: The German version of C-ACT^{M} is valid and useful for monitoring children with asthma along with tests aimed to follow up lung function and airway inflammation. Concordance between C-ACT^{M} and GINA is moderate, because asthma control assessed by C-ACT^{M} allows more symptoms and lung function is not included in the scoring. **Pediatr Pulmonol. 2012; 47:113–118.**

Key words: C-ACT; symptom score; FeNO; pulmonary function.

Funding source: none reported.

INTRODUCTION

The characteristics of asthma are airway inflammation and peripheral airway obstruction resulting in cough, wheezing, shortness of breath and physical activity limitations. The goal of asthma treatment is to achieve symptom control for prolonged periods, prevent asthma exacerbations, control airway inflammation, and maintain pulmonary function. The former Global Initiative for Asthma (GINA) classification by asthma severity was replaced with a classification by level of asthma control, using clinical symptoms and lung function to define whether the patient's asthma is controlled, partly controlled or uncontrolled.[1] Reliable assessment of asthma control is essential for asthma management, but otherwise challenging because symptom perception in

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Received 21 December 2010; Accepted 25 May 2011.

DOI 10.1002/ppul.21529
Published online 24 August 2011 in Wiley Online Library (wileyonlinelibrary.com).

children and parents may not be accurate and correlation between the reports of children and parents is poor.[2–4] The English-language version of the childhood asthma control test is a validated tool for assessing the level of disease control in asthmatic children, complementary to lung function testing.[5] The German-language version available on the Internet has not been validated to date.[6]

Aim of the study was to detect uncontrolled asthma using C-ACT, GINA levels of asthma control, lung function, and FeNO. We investigated children with asthma using a slightly modified version ($C\text{-}ACT^{M}$) of the German-language C-ACT. In a first step we compared our results of the $C\text{-}ACT^{M}$ with the literature to document the validity of the German-language version and correlated the children's part of C-ACT ($C\text{-}ACT^{children}$) with a 5-point visual analogue scale ($VAS^{children}$) containing identical questions. In the second step we explored the agreement between $C\text{-}ACT^{M}$ and levels of asthma control as defined by GINA and examined the relationship between $C\text{-}ACT^{M}$ score and objective parameters, such as lung function and exhaled nitric oxide (FeNO).

METHODS

Study Participants and Study Protocol

We investigated 107 children with a diagnosis of asthma in our outpatient clinic, a tertiary care hospital for Pediatric Pulmonology. Asthma was defined as a history of recurrent wheezing and/or a positive bronchodilator test (increase of $\geq$12% in forced expiratory volume in one second (FEV1) 10 min after salbutamol inhalation). A minimum age of 6 years ensured the performance of reproducible lung function tests. Children with an unscheduled emergency visit were not included in the study. The study was approved by the local Medical Ethics Review Board. After parental informed consent and child assent the children and their accompanying parent answered the questionnaires without the other being present, after which exhaled nitric oxide (FeNO) was measured, and spirometry, clinical examination and assessment of asthma control according to GINA guidelines were performed.

Modified Childhood Asthma Control Test ($C\text{-}ACT^{M}$), Score Range 0–27

The C-ACT is a 7-item self-administered tool for assessing asthma control in children between 4 and 11 years of age. Four questions are answered by the child ($C\text{-}ACT^{children}$) and three questions by the accompanying parent ($C\text{-}ACT^{parents}$). A C-ACT score $\leq$19 identifies inadequately controlled asthma.[5] With permission of the copyright holder, GlaxoSmithKline, we used the German-language translation of the C-ACT that is available on the Internet. Since our previous experience was that when using the original version of the C-ACT parents found it difficult to spontaneously recall the number of symptom days experienced by the child during the past four weeks, we changed the original answer options slightly for the parents' part of the C-ACT as follows: never = never (5 points); 1–3 days = at least once a month (4 points); 4–10 days = several days a month (3 points); 11–18 days = at least once a week (2 points); 19–24 days = several days every week (1 point); daily = daily (0 points). Additionally, we asked the parents one question about "exercise-induced asthma," but this question was excluded from $C\text{-}ACT^{M}$ scoring. Although C-ACT was developed for children between 4 and 12 years of age, we used it in all our study participants.

Children's Numeric Visual Analogue Score ($VAS^{children}$), Score Range 0–20

Our 5-point $VAS^{children}$ contained the validated items from $C\text{-}ACT^{children}$ plus the additional question "how was your asthma last week?" After instruction by our respiratory nurse the children had to rate each question on a 5-point numeric scale from 0 (very bad) to 4 (very good) with corresponding smilies on both ends.

Measurement of Lung Function and Exhaled Nitric Oxide (FeNO)

After the symptom reports, FeNO and lung function were measured. Flow volume curves were measured with a JAEGER Spirometer (Würzburg, Germany). Spirometry was performed according to ATS/ERS standards.[7]

Values were expressed as percentage predicted for normal for height and sex.[8] FEV1/FVC $\geq$80%, FEV1 $\geq$80% predicted and MEF50 $\geq$65% predicted were considered to be within the normal range.[9,10] Airway reversibility was defined as an increase in FEV1 of $\geq$12% obtained 10 min after inhalation of 300 μg salbutamol using a spacer.

Fractional exhaled nitric oxide levels were measured with an NIOX MINO® device (Aerocrine AB, Solna, Sweden). NIOX MINO is based on electrochemical analysis in line with the procedures published for FeNO measurement.[11]

Statistical Analysis

Data were analyzed using SPSS 15. Since symptom scores were not normally distributed, the Mann–Whitney Test was used to compare scores between various groups. Spearman's rank correlation coefficients were calculated to investigate univariate correlations

TABLE 1— Characteristics of the Study Group

Age years, mean	12.0 (±2.9 SD)
Female, n	30 (28%)
Male, n	77 (72%)
C-ACT^{M}, n, mean	85; 22.5 (±4.7 SD)
VAS^{children}, n, mean	107; 16.8 (±3.3 SD)
GINA controlled, n	36 (34%)
GINA partly-/uncontrolled, n	71 (66%)
C-ACT^{M} controlled, n	70 (82%)
C-ACT^{M} uncontrolled, n	15 (18%)
FEV1% predicted, mean	91.3 (±12.6 SD)
FEV1% FVC, mean	82.5 (±7.4 SD)
MEF50% predicted, mean	68.0 (±20.7 SD)

between various scores. Multiple linear regression analysis was used to adjust for age, gender, FEV1, FeNO in order to examine the relationship between C-ACT and those parameters. Tests were considered significant if $P < 0.05$.

RESULTS

Table 1 shows the characteristics of the study group. The mean age of the 107 children (77 boys, 30 girls) was 12.0 years ± 2.9 SD; 49 children were younger than 12 years. According to GINA 66% of our patients did not have controlled asthma (partly controlled n = 56, uncontrolled n = 15), whereas only 18% were uncontrolled according to C-ACT^{M}. Mean C-ACT^{M} score was 22.5 (±4.7 SD), mean FEV1% predicted was 91.3 (±12.6 SD).

Sixty-eight patients received regular asthma treatment with inhaled steroids, 29 patients inhaled steroids plus a long-acting beta-2 agonist, and 18 patients were treated with a leukotriene modifier. All children received rapid-acting beta-2 agonists as needed.

Regarding lung function, 20 children had FEV1 <80% predicted, 35 children had FEV1/FVC <80%, 49 children had MEF50 <65% predicted. A positive bronchodilator test was documented in 29 patients, with a mean increase in FEV1 of 20% (SD ± 8.7). All but five children had evidence of atopic sensitization in either radioallergosorbent test (specific IgE antibodies >0.35 kU/L) or skin prick test (mean wheal diameter 3 mm greater than the negative control) using a standardized panel of five common allergens (dust mite, grasses, trees, molds, animals). FeNO (mean 44.3, SD ± 42) was elevated to >20 ppb in 70 of our patients.

Complete C-ACT^{M} scores (children's and parents' parts) are available for 85 patients. Twenty children were not accompanied by their parents, and one parent and one child had missing answers in the C-ACT^{M} questionnaire. Ten children with controlled asthma (C-ACT^{M} score >19) did not have normal lung function, nine children had normal lung function but a C-ACT^{M} score ≤19, and six children had both a low C-ACT^{M} score and poor lung function.

Table 2 shows a comparison of the C-ACT^{M} scores grouped by sex, age, FEV1, and GINA level of asthma control. Children with low FEV1 and children with partly or uncontrolled asthma according to GINA had significantly lower C-ACT^{M} scores. Main complaints reported by the children were cough (C-ACT^{children} 66%, VAS^{children} 60%) and exercise-induced limitations (C-ACT^{children} 50%, VAS^{children} 65%).

Spearman's rank correlation coefficients revealed significant correlation within all symptom scores (C-ACT^{children}/C-ACT^{Mparents} r = 0.46; VAS^{children}/C-ACT^{children} r = 0.78; VAS^{children}/C-ACT^{Mparents} r = 0.60; $P < 0.000$), and also a significant correlation between C-ACT^{M}, VAS^{children}, and FEV1 (r = 0.28; $P = 0.011$, respectively, r = 0.36; $P < 0.000$). No correlation was seen between the symptom scores and FeNO.

When tested with multiple linear regression adjusted for age, gender, FEV1 and FeNO the significant relationship between C-ACT^{M}, VAS^{children}, and FEV1 persisted ($P = 0.003$, respectively, $P < 0.000$).

DISCUSSION

The English-language version of the C-ACT is a validated and reliable tool for assessing the level of asthma control in children and is intended to complement lung

TABLE 2— Comparison of C-ACT^{M} (Mean; ± SD) Scores by Subgroups

Grouping variable	Group	n	C-ACT^{M} score mean	±SD	*P*-value*
Sex	Female	23	21.0	5.3	0.057
	Male	62	23.0	4.4	
Age	<12 years	45	22.7	4.5	0.790
	≥12 years	40	22.3	5.1	
FEV1% predicted	FEV1 < 80%	16	19.9	6.3	0.049
	FEV1 ≥ 80%	69	23.1	4.1	
Asthma control GINA	GINA^{controlled}	30	25.4	1.8	0.000
	GINA$^{partly-/uncontrolled}$	55	16.1	3.6	

*Mann–Whitney Test.

function evaluation.[5] The German-language version of C-ACT, easily available on the Internet, is increasingly used in clinical practice, but also in research. The present study was performed to determine whether the German-language version of C-ACT^{M} is valid, provides information consistent with the literature and correlates with GINA levels of asthma control and objective parameters such as lung function and FeNO. In agreement with Liu et al., mean C-ACT^{M} scores differed significantly across groups with regard to lung function and GINA levels of asthma control.[5] C-ACT^{M} scores in children with FEV1 $\geq$80% predicted were higher than in children with FEV1 $<$80% (23.1 $\pm$ 6.3 SD vs. 19.9 $\pm$ 4.1 SD) and were also higher in children with controlled versus uncontrolled asthma according to GINA guidelines (25.4 $\pm$ 1.8 SD vs. 16.1 $\pm$ 3.6 SD). Nevertheless, the original article by Liu et al. reported that only FEV1 $<$60% was associated with a mean C-ACT score $<$19. Lenoir et al. investigated asthma control in the general population and found 43% of the subjects to have not well controlled asthma (ACT $\leq$19 and/or FEV1 $<$ 80%), but only 10% of the study group had both.[12] These data are in agreement with our observations and show that symptom scores and lung function are important complementary tools for assessing asthma control.

Of our patients 66% had partly controlled or uncontrolled asthma according to GINA guidelines, whereas only 18% were uncontrolled when using the C-ACT^{M}. A recent publication by Koolen et al. found similar numbers, with only 14% of their children having controlled asthma according to GINA guidelines.[13] Does C-ACT^{M} overestimate asthma control? For asthma to be controlled according to GINA, lung function must be normal and there must be no limitation on activity. The main reason for partly controlled or uncontrolled asthma in our subjects was exercise-induced symptoms. Ten children failed to have normal lung function despite a high C-ACT^{M} score—a problem of symptom perception? A further critical tool is adherence to asthma treatment, which is commonly found to be poor.[14,15] Poor adherence might have contributed to not well controlled asthma in some of our patients; however, we have no data on this issue. Taken together, in comparison to the GINA levels for asthma control C-ACT^{M} allows more symptoms and does not include lung function in the scoring. Therefore, concordance between C-ACT^{M} and GINA is moderate.

Several instruments are available for assessing symptoms and disease control, i.e., the Likert scale, the VAS (with either numeric or line response options), the BORG scale. It is important to choose the right instrument, in particular when working with children.[16–18] Van Laerhoven et al. examined whether the simple VAS (line response option), the numeric VAS (numeric response option) or the Likert scale (verbal categorical response options) is preferred in 120 children of different age groups (6–12 years and 13–18 years). Both younger and older children preferred the Likert scale over the numeric VAS and the simple VAS and found it easiest to complete. The response options correlated strongly with each other and were therefore considered comparable with respect to reliability.[19] In our study both C-ACT^{children} and VAS^{children} were well accepted by younger and older children and correlation between the two questionnaires was highly significant. Recently a web-based version of the ACT and C-ACT was validated. The data provided good agreement between the web-based version with the paper based version in children with normal lung function and 86% of patients preferred the web-based version. The effect on improvement in asthma control has not been addressed in this study and the authors state that the possible benefit for the patient remains to be defined.[20]

Data showing whether ACT and C-ACT correlate with lung function and FeNO values are inconsistent. In adults some investigators observed significant correlations between ACT scores, lung function, and FeNO, whereas others did not.[21–23] This data inconsistency persists in children. We found a correlation between C-ACT^{M} and FEV1, but no correlation between C-ACT^{M} and FeNO. In a Chinese study of 113 young asthmatics, C-ACT and FEV1 differed significantly among patients with different levels of disease control, whereas a Japanese study of 154 children with asthma observed only a weak correlation between C-ACT score and lung function; correlation with FeNO was absent.[24,25] Chan et al. reviewed 45 pediatric patients in an underserved area of San Diego County to determine whether children with an ACT score of $\leq$19 had lower peak expiratory flow than did those with an ACT score $>$19. The ACT scores and peak expiratory flow values were seen to be independent and not correlated, and the investigators concluded that these are distinct parameters for asthma management.[26] However, peak expiratory flow measurement is a relatively insensitive parameter for the assessment of lung function.

Asthma is an inflammatory disease and measurements of fractional exhaled nitric oxide correlate well with measurements of eosinophilic airway inflammation.[27–29] Only few studies have evaluated the correlation between FeNO and C-ACT. One study investigating 100 asthma patients across all ages (6–86 years) found no association between FeNO levels and asthma control when using five different evaluation tools including ACT.[23] A recent publication investigated the relationship between C-ACT and FeNO and lung function in 200 asthmatic children in a more detailed approach. The study population was divided into a group with newly diagnosed asthma and a follow-up

group. In the ''new,'' but not in the ''follow-up'' group significant correlations were observed between C-ACT and FeNO, FEV1 and FEV1/FVC.[30] The authors concluded that C-ACT is not a substitute for other markers of disease control, in particular in children receiving regular controller treatment. In our study no association between C-ACT^{M} and FeNO was observed, but the majority of our patients were on regular asthma controller medication and therefore comparable with the ''follow-up'' patients in the above study. Children who are C-ACT^{M} controlled but show increased FeNO values report few symptoms but have evidence of persistent airway inflammation. Are these patients poor symptom perceivers? Are they at risk for future asthma deterioration or is the measured FeNO closed to their ''personal best''—at least in some of them? As this is a cross-sectional study we will not be able to answer these questions. Long-term data showing whether changes in FeNO are reflected by changes in C-ACT scores in patients on regular controller medication are lacking.

A limitation of our study is the slightly different grading we used for the parents' part of C-ACT, although the original C-ACT and our version clearly mirror increasing symptom frequency. When starting to use the original C-ACT, we learned that asking for symptoms per month/per week/daily is much more practicable than asking for the number of symptom days during the past four weeks. The latter might work when keeping a symptom diary, but not when parents are asked to report these spontaneously in an outpatient setting.

CONCLUSION

The German-language version of C-ACT^{M} is a valid and valuable tool that makes an important contribution to monitoring asthma control in children, along with other tests aimed to follow up lung function and airway inflammation. C-ACT^{M} should not be used as a substitute for lung function measurements in newly diagnosed asthma patients, as this might cause alternative diagnoses to be overlooked.[31] Concordance between C-ACT^{M} and GINA is moderate, because asthma control assessed by C-ACT^{M} allows more symptoms and lung function is not included in the scoring.

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