

ORIGINAL ARTICLE

AIRWAY DISEASES

Asthma control assessment in a pediatric population: comparison between GINA/NAEPP guidelines, Childhood Asthma Control Test (C-ACT), and physician's rating

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Abstract

Background: Guidelines recommend regular assessment of asthma control. The Childhood Asthma Control Test (C-ACT) is a clinically validated tool.

Aim: To evaluate asthma control according to GINA2006, NAEPP, pediatrician's assessment (PA), and C-ACT in asthmatic children visiting their ambulatory pediatrician or tertiary care pediatric pulmonologist.

Methods: Demographic data, treatment, and number of severe exacerbations during the previous year were collected. Control was assessed using (i) strict GINA 2006 criteria, (ii) GINA without taking into account the exacerbation item, (iii) NAEPP criteria, and (iv) PA. Children and parents filled out the C-ACT.

Results: Five hundred and twenty-five children completed the survey (mean age: 7.7 years; 28% $\leq$ 6 years). 78% had a controller treatment. 58% reported $\geq$ 1 severe exacerbation. C-ACT was $\leq$ 19 in 29.5%. Control was not achieved in 76.5%, 55%, 40%, and 34% according to GINA 2006 guidelines, NAEPP guidelines, GINA 2006 without exacerbation criteria, and PA, respectively. C-ACT was significantly lower in children $\leq$ 6 years old ($P = 0.002$) or with severe exacerbations ($P < 0.0001$). According to PA, 89% of patients with a C-ACT > 21 were controlled and 85% of patients with a C-ACT < 17 not controlled.

Conclusion: We observed discrepancies between the different tools applied to assess asthma control in children, and the impact of age and exacerbations. Cutoff point of 19 of C-ACT was not associated with the best performance compared to PA. Assessment of control should take into account symptoms and lung function as suggested by the latest GINA guidelines as well as exacerbation over a long period.

The goal of asthma treatment is to achieve and maintain control (1–3). For Global Initiative for Asthma (GINA) guidelines, controlled asthma was defined by minimal diurnal symptoms and need for β_2 agonists (≤ 2 week), absence of nocturnal symptoms, no limitation of activities, and normal forced expiratory volume in 1 s (FEV1) or peak expiratory flow (PEF). In 2006, the definition included the absence of exacerbation over the past year (1). National Asthma Education and Prevention Program (NAEPP) guidelines (2007)

tolerated the occurrence of one exacerbation (2). Various studies reported that control is not achieved in a large number of children and that exacerbations requiring unscheduled physician's visits, emergency treatment, or hospitalization remained frequent (4, 5).

Asthma control score instruments have been developed and validated for adults and also for children (6–9). The Childhood Asthma Control Test (C-ACT) is designed for children aged 4–11 years (7). Liu et al. have established that

a score ≤ 19 indicates lack of control over the last 4 weeks (7). However, higher cut points have been reported (10–12). C-ACT does not take into account exacerbations.

The present study was performed to assess control according to guidelines (GINA, NAEPP), C-ACT, and physician's evaluation in asthmatic children aged 4–11 years, followed up by pediatric pulmonologists in tertiary centers or by ambulatory pediatricians. We hypothesized that there are differences according to the methods of assessment of control and that taking into account exacerbation strengthens these differences. Part of the results was presented as an abstract form in the meeting of the American Thoracic Society, New Orleans, 2010.

Patients and methods

Study population

This was a prospective study including two populations of asthmatic children aged 4–11 years, conducted between October 2007 and April 2009, one recruited in four tertiary pediatric pulmonology centers (Necker Enfants Malades hospital, Paris; Lille and Grenoble University Hospital, Le Havre hospital) and the other one recruited by general pediatricians in the city of Lille and its region. Diagnosis of asthma was made according to the French guidelines, with the same criteria by general pediatricians and hospital centers. General pediatricians were all participants of a structured network and have participated to an educational program in asthma diagnosis, management, and treatment. They were consequently trained in asthma diagnosis and management. This study was approved by the Committee for Evaluation of Research Protocols of the Société de Pneumologie de Langue Française.

Study protocol

Patients were included during a single visit. Children with a chronic illness other than asthma were excluded. The pediatrician conducting the visit filled a form containing historical data, controller therapy – none, inhaled corticosteroids (ICS), ICS and long-acting bronchodilators (LABA), leukotriene receptor antagonist and immunotherapy, and the number of severe exacerbations defined by systemic corticosteroid use, emergency visits or hospitalization over the past 12 months.

Pulmonary function tests (PFTs) were performed for all patients followed up in hospital. In children ≥ 7 years old, forced vital capacity (FVC), FEV₁, and FEV₁/FVC were measured and airway obstruction was defined by FEV₁/FVC < 0.8 (1–3, 13). In children < 7 years old, respiratory resistances were measured by interrupter technique and airway obstruction was defined by resistances $> 150\%$ of predictive values (PV) (3, 14–16).

All children and their parents filled in a C-ACT questionnaire.

Asthma control assessment

Asthma control was assessed by the pediatrician, blinded to the C-ACT score:

- 1 According to the GINA 2006: diurnal and nocturnal symptoms, short-acting β_2 -agonists use, and activity limitation (past month), lung function if available, and any exacerbations (past year) (GINA strict).
- 2 According to the NAEPP: diurnal and nocturnal symptoms, short-acting β_2 -agonists use, and activity limitation (past month), lung function if available, and exacerbations (past year). The definition of well-controlled asthma tolerated the occurrence of one exacerbation requiring oral systemic corticosteroids during the past year.
- 3 According to the GINA 2006 criteria but without the criterion 'exacerbation' over the past 12 months (GINA symptoms).
A table listing all the criteria of control according to GINA and NAEPP guidelines has been inserted on the form. The assessment was made by the pediatrician during the visit. Two physicians (KEA and SBL) reviewed all the forms and validated the level of control.
- 4 Finally, the pediatricians rated asthma as totally controlled, well controlled, partially controlled, and uncontrolled (physician's assessment). They were instructed to base their ratings on how well the goals of asthma were being met, as determined on the basis of information from the patient history, physical examination, and lung function test if available (3).

For the analysis, patients were divided into two groups, either controlled (totally or well controlled) or not controlled (partially controlled or uncontrolled)

C-ACT measurement

All children and their parents filled in a C-ACT questionnaire. We used the French version, translated by the MAPI-research institute in Lyon, France. The physician did not see or influence the responses. The C-ACT is divided into two parts: four questions for the child on perception of asthma control, limitation of activities, coughing and awakenings at night (four response options), and three questions for the caregiver over the past 4 weeks: daytime complaints, daytime wheezing, and awakenings at night (six response options) (7). C-ACT scores range from 0 to 27.

Statistical analysis

Continuous variables were described with mean and standard deviation. Qualitative variables were analyzed as frequencies and percentages.

To compare the two populations of asthmatic children (tertiary hospitals and general pediatricians) and to compare controlled to not controlled children, chi-square tests or Fisher's exact tests were used for qualitative variables and the Mann–Whitney test for continuous variables because the distribution of the variables was not normal according to Shapiro–Wilk test. The Spearman's coefficient was used to test the correlation between two continuous variables. The coefficient of kappa was used to analyze concordance between control assessed according to GINA, NAEPP, and physician's rating. Analyses by ROC curve were performed

to determine a cutoff point that maximized the sensitivity and specificity according to the different tools of assessment. Accuracy was measured by the area under the ROC curve (AUC). Decision trees were performed using the software SIPINA to identify ACT cutoff points that best allowed classifying controlled and not controlled children (SIPINA software; Research Unit ERIC, Lyon 2 University, France). Statistical analyses were performed by SAS 9.2 software (SAS Institute Inc., Cary, NC). Graphs were made with Excel. A *P* value <0.05 was considered statistically significant.

Results

Five hundred and twenty-five children completed the study, of whom 353 (67%) recruited in tertiary centers (Table 1). The mean age was 7.7 years (SD, 2.2) and 145 (28%) were ≤ 6 years. Children recruited at the hospital were more frequently new patients (24.5% vs 9%, *P* < 0.0001) and older [7.9 years (SD, 2.23) vs 7.2 years (SD, 2.1), *P*: 0.002]. They had used less frequently a controller therapy (75% vs 83.5%, *P*: 0.028) over the past year. At least one severe exacerbation in the past year was reported by 64% of the children with hospital follow-up vs 46% for those with general pediatrician's follow-up (*P* < 0.0001). The rate of exacerbations over the past year was also higher in children with hospital follow-up [2.2 (SD, 3.2) vs 1.1 (SD, 1.83), *P* < 0.0001]. Forty-two per cent of the children had no exacerbation during the past year, while 21% had one and 26% at least three. For the 343 patients who underwent PFTs, there was no airway obstruction in 242 (70.5%). For children aged ≥ 7 years (*n* = 226), the mean FEV₁/FVC was 0.84 (SD, 0.09) and less than 0.8 in 73 (32%).

Evaluation of asthma control according to guidelines and physician's assessment

Both populations were grouped for control analysis. Control was not achieved in 76.5%, 55%, 40%, and 34% of

children according to GINA strict criteria, NAEPP criteria, GINA symptoms criteria, and physician's assessment, respectively. The concordance was poor between GINA strict and GINA symptoms (κ = 0.34) and weak between GINA strict and NAEPP (κ = 0.54). Among children who performed PFTs, asthma was more often not controlled according to GINA symptoms in children with abnormal PFTs (51/101, 50.5%), than in those with normal PFTs (85/242, 35%) (*P* = 0.008), also according to the other tools (GINA strict: *P* < 0.0001, NAEPP: *P* = 0.009 and physician's assessment: *P* = 0.0001).

C-ACT Score

The mean of C-ACT score was 21.1 (SD, 4.3) (Fig. 1). The C-ACT score was ≤ 19 in 155 children (29.5%) and lower in children with hospital follow-up [20.6 (SD, 4.6) vs 22.0 (SD, 3.6), *P* = 0.0023]. A positive correlation was observed between age and C-ACT score (*r* = 0.093; *P* = 0.033), and the mean C-ACT score was significantly lower in children aged ≤ 6 years [20.2 (SD, 4.4)], vs the older [21.5 (SD, 4.3)] (*P* = 0.002). C-ACT score was also significantly lower in case of severe exacerbation during past year [20.2 (SD, 4.6) in case of ≥ 1 exacerbation and 22.3 (SD, 3.6) in the absence of exacerbation (*P* < 0.0001)].

We did not find significant differences in the C-ACT scores according to the treatment. The average C-ACT score was 21.1 (SD, 4.2) in patients without controller treatment (*P* = 0.80 vs the other children), 21.1 (SD, 4.4) for patients treated with ICS (*P* = 0.91) and 21.2 (SD, 4.2) for patients treated with ICS-LABA (*P* = 0.88).

ACT score and guidelines or physician assessment of control

C-ACT scores according to the different modalities are described in Table 2. Whatever the criteria, C-ACT scores were significantly higher in children with controlled asthma (*P* < 0.0001). To detect patients who were not controlled, a cutoff point of ACT ≤ 19 was associated with a sensitivity of 36.5% and a specificity of 92.5% according to GINA strict (AUC = 0.727), 48% and 94% according to NAEPP (AUC = 0.801), 58% and 89.5% according to GINA symptoms (AUC = 0.838), and 62% and 88% according to the physician's assessment (AUC = 0.840), respectively.

The optimal cut point for not controlled asthma was ≤ 21 according to GINA symptoms (sensitivity: 76%, specificity: 81.5%), NAEPP (sensitivity: 81%, specificity: 70%), and physician's assessment (sensitivity: 71.5%, specificity: 83%). This cutoff point was ≤ 22 according to the strict GINA (sensitivity: 71.5%, specificity: 64.5%).

Finally, we analyzed the accuracy of the C-ACT score to correctly classify asthma control (Fig. 2). According to the GINA symptoms, 94% of patients with a C-ACT < 14 were considered to be not controlled, while 86% of patients with C-ACT > 21 were considered to be controlled. According to the physician's assessment, 85% of patients with a C-ACT < 17 were considered not controlled, while 89% of patients with a C-ACT > 21 were found to be controlled.

Table 1 Clinical characteristics of patients

Characteristics	<i>N</i> = 525
Age, years [mean (SD)]	7.7 (2.2)
Boys, <i>n</i> (%)	348 (66)
New patient <i>n</i> (%)	96 (19)
Controller therapy <i>n</i> (%)	
No treatment	116 (22)
ICS only	132 (25.5)
ICS + LABA	226 (43.5)
LTA	36 (7)
Immunotherapy	26 (5)
Severe exacerbation's rate [mean (SD)]	
Past month	0.2 (0.6)
Past 3 months	0.7 (1.2)
Past 12 months	1.8 (2.9)
C-ACT [mean (SD)]	21.1 (4.3)

ICS: inhaled corticosteroids, LABA: long-acting beta 2 agonists, LTA: leukotriene antagonists, C-ACT: Childhood Asthma Control Test.

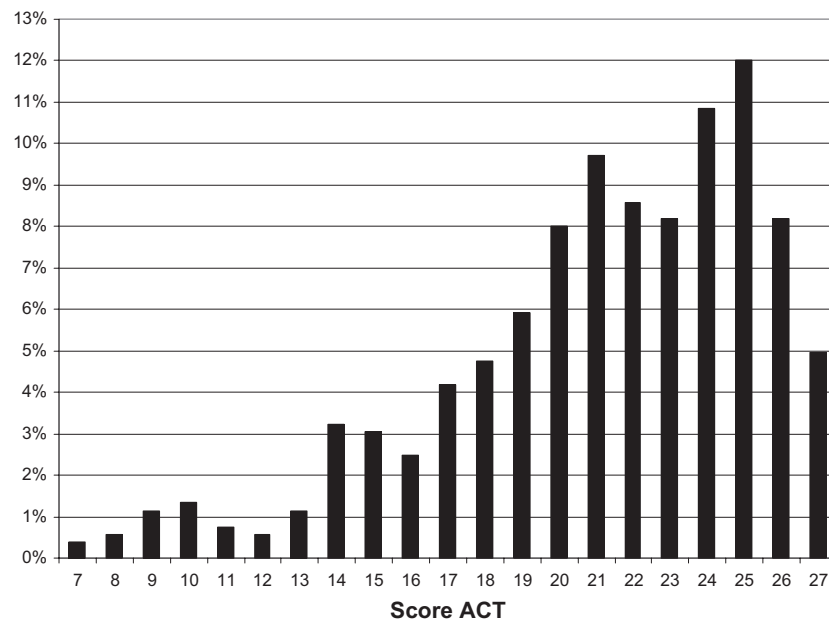


Figure 1 Distribution of C-ACT scores.

Table 2 Control levels according to the different modalities of assessment

	<i>n</i> (%)	ACT [mean (SD)]	<i>P</i> value
GINA strict			
Controlled*	123 (23.5)	23.5 (2.7)	<i>P</i> < 0.0001
Not controlled†	401 (76.5)	20.3 (4.5)	
GINA symptoms			
Controlled*	314 (60)	23.1 (3.08)	<i>P</i> < 0.0001
Not controlled†	211 (40)	18.1 (4.27)	
NAEPP			
Controlled*	234 (45)	23.5 (2.6)	<i>P</i> < 0.0001
Not controlled†	287 (55)	19.1 (4.5)	
Physician's assessment			
Controlled*	336 (66)	22.9 (3.03)	<i>P</i> < 0.0001
Not controlled†	171 (34)	17.8 (4.31)	

*Controlled: totally or well controlled.

†Not controlled: partially controlled or uncontrolled.

Discussion

This study focuses on the assessment of control using different tools in a large population of asthmatic children and confirms the discrepancies between GINA, NAEPP, physician's assessment, and C-ACT score. Young age and exacerbations were associated with the lack of control. We also observed that the reference cutoff of 19 for the C-ACT was not associated with the best performances. However, C-ACT is a good tool to assess asthma control in clinical practice, especially for general practitioner.

Population

The population consisted of children attending tertiary centers but also general pediatric clinics but the criteria of diagnosis and management of asthma were homogeneous among physicians. The population is characterized by the young age ($28\% \leq 6$ years). Most children took a controller therapy (ICS and LABA in 43%), representing a population with more severe asthma compared to the general asthmatic population, which can be explained by the hospital recruitment. The level of control was low and similar to the result of the French study ELIOS performed mainly in general practice (controlled asthma in only 26% of 3483 children aged 4–15 years) (4).

Exacerbations

Exacerbations were frequent and patients with exacerbations in the past year failed to achieve the same level of control compared to children with no recent exacerbation. By tolerating one exacerbation per year as proposed by NAEPP guidelines, 45% of the patients reached good control (2). By separating exacerbation criteria from the others (symptoms, activity limitation, β_2 short-acting agonists use, and lung function), as suggested by recent GINA guidelines, 60% of children were rated as controlled. Severe exacerbations do not concern all children, as illustrated in the CAMP study (30% of patients without any exacerbation) but they are one of the main characteristics of severe asthma (17–20). A past history of exacerbation is a major risk factor for recurrence, as reported by Covar et al. in the PACT study and Wu et al. in the CAMP study (21, 22).

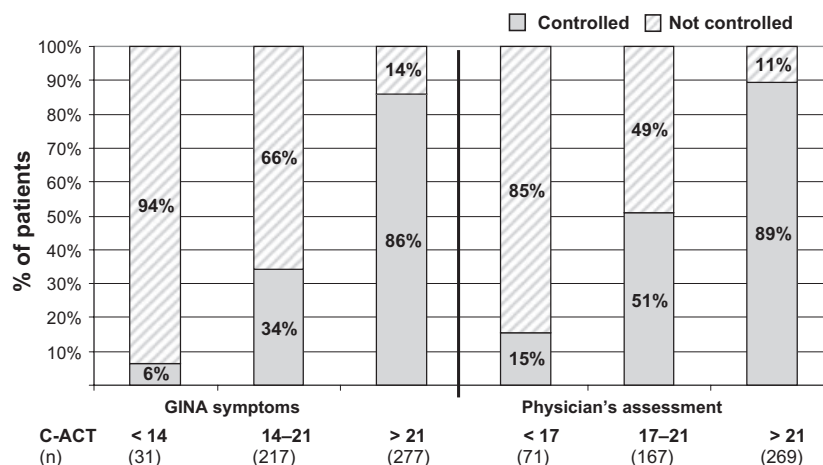


Figure 2 Performance of C-ACT cutoff points for correctly classifying asthma control according to the GINA symptoms criteria and to the physician's assessment.

C-ACT Score

The C-ACT cutoff point of 19 proposed by Liu et al. to identify inadequately controlled asthma was not the best determinant in our study (7). Initially, it was calculated in a population of 343 children followed up in a tertiary center (specificity: 83%, sensitivity: 71.5%, compared to physician's assessment) (7). This cut point has been discussed by several studies conducted in different countries and languages (10–12). Therefore, translation or parents'/children's perception is probably not involved. Indeed, translations of the C-ACT score have been formally validated and the symptoms which are described in the C-ACT score are universal. In a population of 113 Chinese children, among whom 35% were controlled according to GINA criteria, Leung et al. defined a cutoff ≤ 24 , compared to the GINA (sensitivity: 66%; specificity: 63%) (10). Koolen et al. evaluated asthma control in 173 Dutch children (84 aged 4–11 years) (11). Only 17% of them were controlled according to GINA criteria. The C-ACT cutoff point of 19 obtained a sensitivity of 33% and a specificity of 100%, compared to the GINA, and the cut-off point of 22 achieved the best performance (sensitivity: 82%, specificity: 85%). Two other studies were conducted in two groups of Turkish asthmatic children (12, 23). Yavuz et al. determined the role of C-ACT and fractional concentration of exhaled nitric oxide (FeNO) in identifying children whose asthma was not controlled (76 children, aged 6–11 years, mean: 8.7 years) (12). C-ACT score was better than FeNO, and an optimal cutoff point of 22 was also found (sensitivity: 69%; specificity: 77%). In a larger group (314 patients, mean age: 9.0 ± 1.9 years, ranging between 4.3 and 11.8 year), Erkoçoglu et al. evaluated the consistency of GINA criteria and C-ACT on the determination of asthma control (23). In this group, 51% were controlled according to C-ACT and 54.8% according to GINA criteria. If the cutoff point of 20 had the highest compatibility between GINA and C-ACT, there was inconsistency in 26.7% (84/314) of the patients.

In our study, the optimal C-ACT cutoff point that correctly predicted not controlled children was 22 (GINA strict) or 21 (GINA symptoms, NAEPP, physician's assessment). Furthermore, a C-ACT score < 14 (GINA symptoms) or < 17 (physician assessment) improved the accuracy to detect that asthma was not controlled. Liu et al. have also established a second cutoff point < 13 to detect very poorly controlled asthma, associated with poorer outcomes (asthma severity, lung function, level of treatment) (24).

Discrepancies between C-ACT score and GINA can be explained by different approaches toward taking into account asthma manifestations: no details on daily or nocturnal asthma symptoms but strict definition in term of frequency in GINA guidelines, more accurate definition but also more tolerant for the frequency in C-ACT; impact of the criterion 'exacerbation' over the past year in the 2006 GINA guidelines; and a shift toward partial control in case of one exacerbation over the previous 12 months even if good control of symptoms. This strengthens that the tolerance of one exacerbation per year proposed in the NAEPP definition of controlled asthma, and the definition of control without this criterion in the current GINA guidelines, may help to achieve a more accurate definition (1, 2).

We reported age and past history of exacerbations as important features of control level. In a large US study conducted in general pediatricians, which included 2429 asthmatics (4–17 years), the youngest patients had the worse scores, which may reflect poor asthma control and a greater risk of exacerbations, but also highlights the difficulty of measuring the level of control in this population (25). Indeed, data are collected from parents who underestimate asthma burden and impact on the child's life (26). Liu et al. have shown that parents rated asthma as mild in 30% of uncontrolled asthmatics according to C-ACT score (25). C-ACT has the advantage to be easy to administer, even in the early age and to question directly the children, with caregiver assistance. Liu et al. have also showed that 35% of patients consulting

for nonrespiratory-related complaints had a C-ACT score of ≤ 19 , vs 54% of those consulting for a reason related to asthma (25). Thus, assessment of asthma control using a validated instrument should be performed at every visit, regardless of the reason.

The definition of control by GINA includes a functional criterion, FEV_1 or $PEF < \text{or} \geq 80\%$ of predicted value), which is not the case with the C-ACT. In our study, it should be noted that among the patients with an obstruction on PFTs, assessed by FEV_1/FVC ratio or airway resistances, 50% were considered controlled according to GINA symptoms criteria. That emphasizes that the functional criteria used by the GINA are not the best to assess respiratory function in childhood. The FEV_1/FVC or distal airways flows are more accurate parameters in the evaluation of obstruction. In a study including 367 children with mild to moderate persistent asthma, Nair et al. showed that up to 45% had abnormal PFTs and that this result led to step-up treatment in 10–20% of them (27).

In conclusion, C-ACT is a supplementary tool in control assessment and may be useful in daily medical practice, at any time of the management, particularly in the youngest. However, we confirm the discrepancies between the different measurements available to assess asthma control in children and the fact that generally used C-ACT cut-off point might underestimate a part of the children whose asthma is not controlled. Finally, C-ACT does not include lung function, which is recommended on a regular basis. Evaluation of the exacerbations over a longer period is also necessary in order to anticipate and limit the risk.

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Conflicts of interest

A. Deschildre has received honoraria for lectures and expert advises by NOVARTIS, GSK, MSD, TEVA, ALK, travel assistance to attend a conference from GSK, Novartis, Mead Johnson. J. de Blic has received honoraria for lectures and expert advises by ALK, CHIESI, GSK, MSD, Mundi-Pharma, Stallergènes and TEVA, travel assistance to attend a conference from CHIESI, GSK, ALK. The other authors of the paper declare no conflicts of interest.

Author contributions

All the authors had a substantial contribution to the conception and design, acquisition of data, analysis and interpretation of data. They contributed to the draft writing and revised it critically. They finally approved the version to be published.

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