

ORIGINAL ARTICLE

Consistency of GINA criteria and childhood asthma control test on the determination of asthma control

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Abstract

Background: Reliable assessment of asthma control is essential for effective treatment. Although several methods are used to assess asthma control, it is still suboptimal all over the world. Childhood asthma control test (C-ACT) is a widely used complementary test in determining the level of asthma control in conjunction with GINA guidelines.

Objective: To evaluate the consistency between the childhood asthma control test (C-ACT) and the Global Initiative for Asthma (GINA) guideline-based asthma control measure in children with asthma and, if present, to investigate the reasons for any discrepancy.

Methods: Patients and their caregivers filled a C-ACT and a socioeconomic status survey before the physician visit. Asthma control level was also assessed according to GINA criteria by a pediatric allergist who was blinded to C-ACT scores.

Results: The mean age of the total 314 patients was 9.0 ± 1.9 yr, ranging between 4.3 and 11.8 yr, of whom 56.1% ($n = 176$) were men. Regarding the study group, 54.8% of patients were controlled according to GINA, and 51.0% of patients were controlled according to C-ACT (score ≥ 20). There was inconsistency between GINA and C-ACT in 26.7% (84/314) of the study group when the patients were evaluated individually ($\kappa = 0.464$). There was not any significant variable that could predict the consistency and inconsistency between these methods.

Conclusion: Consistency between GINA and C-ACT is not as to be expected. Using only one method for determining the control level of asthma does not seem to be reliable and accurate.

For managing patients with asthma, recent asthma guidelines such as GINA focus on the control of asthma rather than on its severity. Determining the control level of the disease is considered to be a better approach to help the patients achieve and maintain fewer symptoms, no asthma exacerbations, normal activity levels, normal pulmonary functions, and minimal adverse effects of asthma medications (1–4).

Several validated tools have been developed to determine the asthma control status of the children and to guide the asthma management decisions (5–8). Asthma control test (ACT) is one of the methods used to determine the control level of asthma in adults and children older than 12 yr old. More recently, a childhood ACT (C-ACT) has been validated for children between 4 and 11 yr of age and has been used

extensively in clinical trials (7). ACT and C-ACT scores and GINA seem to be compatible with each other, for assessing asthma control levels. But, when patients are evaluated individually, there are discrepancies between GINA guideline-based control decisions of the physicians and the patients' assessment of control based on ACT or C-ACT (3, 9–12).

The C-ACT was used in daily practice as a supplementary measure to the physician's assessment, but it had not been validated as a predictor of GINA guideline-defined asthma control. There are only a few studies conducted to compare C-ACT and GINA criteria, to determine the level of asthma control in children (13, 14). In this study, we planned to assess the compatibility of asthma control levels according to GINA and C-ACT in children under 12 yr old.

Methods

Study population and study design

Between January and June 2010, the patients with asthma, aged 4–12 yr, were recruited continuously at the outpatient clinic of the Pediatric Allergy Department. Patients were given the C-ACT and the socioeconomic status survey before the visit. Thereafter, a brief medical history was obtained, and following the physical examination, pulmonary function tests were performed on patients who were able to carry them out. Their control level of asthma according to GINA was determined by a pediatric allergist who was blinded to C-ACT scores. Patients with a history of any other chronic pulmonary or systemic diseases were excluded from the study.

Demographic characteristics, diagnostic features, and previously used treatment modalities were provided from the regular medical records of the patients. The diagnosis of asthma was made according to Global Initiative for Asthma (GINA) guidelines (2). Severity of asthma which was determined retrospectively according to GINA guideline ranged from mild-intermittent to severe persistent.

Epidermal prick tests were carried out on the volar aspect of the forearm with common airborne allergens, including animal danders, house dust mite, mixed tree and mixed grass pollen, and molds, and evaluated after 20 min. The test was considered positive if the diameter of the wheal was at least 3 mm larger than the negative control test (15). The patients who had sensitization for any of the allergens in the epidermal prick test were considered to have allergic sensitization. And the patients whose parents had a history of asthma and/or allergic rhinitis diagnosed by a physician were regarded as having family history of atopy. Spirometry was performed (Spirolab 2, Rome, Italy) and analyzed in accordance with published recommendations (16, 17).

C-ACT survey

The childhood asthma control test is a worldwide validated and accepted tool to help assess the control level of asthma, consisting of two parts and total of seven questions. The first part is to be answered by the patient and the second by the parents (7). Children and their caregivers answered the respective part of the validated Turkish version of C-ACT (18). The final C-ACT score is made up of the sum of the scores of the two parts, ranging from 0 (poorest asthma control) to 27 (optimal asthma control). A cutoff point of ≥ 20 was accepted as 'controlled' asthma (7).

Assessment of asthma control based on GINA

The control status of asthma was determined by the pediatric allergist in a way blinded to C-ACT scores – according to GINA criteria including the frequency of the present symptoms, nocturnal symptoms, use of rescue bronchodilators, degree of limitation in daily activities, and lung functions (2). Initially, patients were grouped as 'controlled', 'partly con-

trolled', and 'uncontrolled' based on the GINA criteria. After the enrollment was completed, patients with 'partly controlled' and 'uncontrolled' asthma were grouped as 'not well controlled', similarly the 'controlled' group redefined as 'well controlled', to obtain a binary split of the patients regarding the control level.

Grouping the patients as 'compatible' and 'not-compatible'

Patients are classified into two groups regarding the assessment of control level as determined by GINA and C-ACT: (i) the patients whose assessment of control level is the same: the 'compatible' group, (ii) the patients whose assessment of control level is different: the 'not-compatible' group.

Socioeconomic status survey

To determine the socioeconomic status of the patients' families, a socioeconomic status survey which is used by Demographic and Health Research of Turkey 2008 (TNSA 2008) was given to the parents after C-ACT survey. The questions asked in this survey mainly relate to the educational status of the parents, family income, and living conditions. The patients were divided into five wealth index quintiles such as lowest, second, middle, fourth, and highest, based on the Turkish census tool to investigate the effect of socioeconomic status on any discrepancy between GINA and C-ACT (19). Then, to obtain statistically acceptable results, these five groups were transformed into three groups. The lowest and second groups were amalgamated into 'lowest', middle left as 'middle', and the fourth and highest were amalgamated into 'highest'.

Ethical issues

The study was approved by Institutional Review Board. The ethical procedures for the study protocol included informed consent of all patients and their caregivers for scientific reporting of research findings based on the survey used.

Statistical analysis

Results were expressed as absolute numbers (percentile), mean and standard deviation (s.d.) or median, and interquartile range. We carried out a ROC analysis to define the cutoff c-ACT score level, which had the highest sensitivity and specificity in total for the compatibility between GINA and C-ACT. Then, different C-ACT cutoff levels were used to find the highest compatibility between two tools. To compare different variables, Student *t*-test, Mann–Whitney *U* test, and chi-square tests were used with the help of SPSS version 15.0 (SPSS Inc., Chicago, IL, USA). The rate of consistency of the two methods was evaluated by kappa test.

Results

Out of 348 children, 314 of them were included in the study and 34 children were excluded because of uncompleted

socioeconomic status surveys and C-ACT. The mean age of the patients were 9.0 ± 1.9 yr, ranging between 4.3 and 11.8 yr of whom 61.0% were men. Only 23 of the patients were under 6 yr old and 277 of them were able to perform spirometry. When we briefly looked at the patient population, patients who were able to perform spirometry had a history of multiple episodes of wheezing with at least a 12% improvement in forced expiratory volume in 1 s following bronchodilator therapy during their follow-up, whereas patients who were not able to perform spirometry had a history of recurrent respiratory symptoms; a strong family history of asthma in first-degree relatives; and/or atopy presenting as atopic dermatitis, food allergy, and/or allergic rhinitis. Most of the patients ($n = 164$, 52.2%) had mild persistent asthma. One hundred and fifty-four (49.0%) of all patients were considered to have 'uncontrolled' asthma according to a C-ACT score < 20 . General characteristics of patients are listed in Table 1.

The differences between the C-ACT scores of patients classified as 'controlled', 'partially controlled' and 'uncontrolled' based on the criteria of GINA were found to be statistically significant ($p < 0.001$; Fig. 1).

There were some discrepancies between the control levels according to C-ACT and GINA. After ROC analysis, we

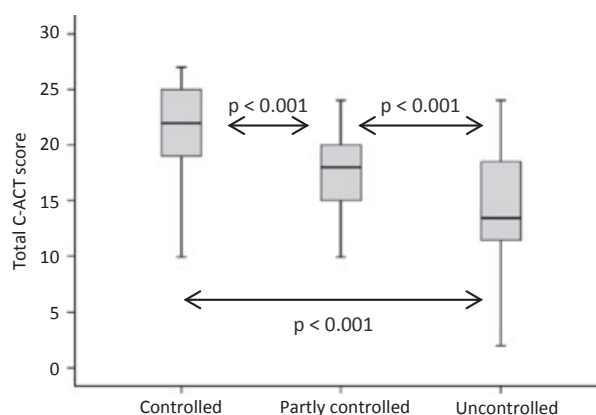


Figure 1 C-ACT scores of the patient groups classified by GINA guideline.

found that cutoff level of 19.5 has the highest sensitivity and specificity (0.721 and 0.746, respectively) for the compatibility between GINA and C-ACT. Then, we analyzed different cutoff levels (18–22), which showed that 20 is the cutoff level that results in the highest compatibility between GINA and C-ACT (Table 2). Among the patients classified as 'well controlled' according to GINA guidelines, 27.9% (48/172) of them were 'not well controlled' with a C-ACT score of < 20 . And also, 25.4% (36/142) of the patients were assessed to have 'not well-controlled' asthma based on GINA, overestimated their asthma status as having 'well-controlled' asthma with a C-ACT score of ≥ 20 . Totally, 26.7% (84/314) of the whole patient group had differing assessments of control levels according to these two methods. As a result, the control decision based on GINA and C-ACT (indicating the control assessment of the physician and the patient, respectively) is not consistent with each other when the control decisions of the method compared patients individually ($\kappa = 0.464$; Table 2).

'Compatible' and 'not-compatible' groups of patients are compared for different parameters to find a variable predicting the discrepancy of the methods. There was not any significant parameter such as gender, age, disease severity, FEV-1, duration of asthma, allergic sensitization, concomitant allergic disease, family history of atopy, parental education, or socioeconomic status that could foresee the discrepancy before between the assessments of the patient (Table 3). We also made logistic regression analysis to find the possible risk factors listed previously that may affect the compatibility between GINA and C-ACT, but we could not find any (data not shown).

Discussion

In our study, 54.8% of patients were controlled according to GINA, and 51.0% of all patients had C-ACT score ≥ 20 . The median C-ACT scores of the patients classified regarding the GINA-based control level of asthma are significantly different from each other (Fig. 1). When the patients were

Table 1 General characteristics of patients ($n = 314$)

Variable	n (%)
Male	176 (56.1)
Age in years (mean $\pm$ s.d.)	9.0 ± 1.9
Age at diagnose in years (mean $\pm$ s.d.)	6.4 ± 2.6
Duration of follow-up period in years (mean $\pm$ s.d.)	2.6 ± 2.0
Patients with allergic sensitization	172 (54.8)
Concomitant allergic rhinitis	146 (47.1)
Family history of atopy	122 (38.9)
Asthma severity	
Mild intermittent	110 (35.0)
Mild persistent	164 (52.2)
Moderate persistent	34 (10.8)
Severe persistent	6 (1.9)
Total C-ACT score *	20 (15–23)
'Well controlled' according to GINA	172 (54.8)
'Well controlled' according to C-ACT	160 (51.0)
FEV1 %	92.4 ± 1.1
Maternal education	
Illiterate	20 (6.4)
Elementary education	202 (64.5)
High School/University	92 (29.1)
Paternal education	
Illiterate	5 (1.6)
Elementary education	180 (57.4)
High school/University	129 (41.0)
Monthly income	
<750 \$	192 (61.2)
≥ 750 \$	122 (38.8)

mean $\pm$ s.d.: mean $\pm$ standard deviation.

*Median (interquartile range).

Table 2 The comparison between GINA and c-ACT according to different cutoff levels used for control decision in C-ACT

Cutoff levels	C-ACT		Non-compatibility between GINA and C-ACT N (%)	κ
	Controlled N (%)	Uncontrolled N (%)		
18	204 (65.0)	110 (35.0)	96 (30.6)	0.350
19	184 (58.6)	130 (41.4)	86 (27.4)	0.429
20	160 (51.0)	154 (49.0)	84 (26.7)	0.464
21	140 (44.6)	174 (55.4)	92 (29.3)	0.455
22	118 (37.6)	196 (62.4)	90 (28.7)	0.461

Table 3 Comparison of the characteristics of two groups (compatible and non-compatible) to investigate the reasons of discrepancy between GINA- and C-ACT-based control

Variable	Compatible group* n = 230 (%)	Not compatible group n = 84 (%)	p
Male	140 (60.7)	46 (54.3)	0.314
Age in year (mean $\pm$ s.d.)†	8.9 $\pm$ 1.7	9.0 $\pm$ 2.0	0.551
Age at diagnose in years (mean $\pm$ s.d.)†	6.0 $\pm$ 2.4	6.5 $\pm$ 2.6	0.135
Duration of follow-up in years (mean $\pm$ s.d.)†	2.8 $\pm$ 2.0	2.5 $\pm$ 2.0	0.180
FEV1 (% predicted; mean $\pm$ s.d.)†	94.4 $\pm$ 13.2	91.2 $\pm$ 12.9	0.062
Patients with atopy	128 (56.0)	46 (54.6)	0.829
Concomitant allergic rhinitis	100 (43.4)	41 (48.5)	0.427
Family history of atopy	97 (42.2)	32 (38.3)	0.540
Asthma severity			
Intermittent	85 (36.9)	29 (34.3)	0.674
Persistent	145 (63.1)	55 (65.7)	
Maternal education			
Illiterate	16 (7.1)	5 (6.1)	0.835
Elementary education	142 (61.9)	55 (65.5)	
High school/University	71 (31.0)	24 (28.4)	
Paternal education			
Illiterate	3 (1.2)	1 (1.7)	0.743
Elementary education	137 (59.8)	47 (56.5)	
High school/University	90 (39.0)	35 (41.7)	
Monthly income			
<750 \$	132 (57.3)	53 (62.6)	0.400
$\geq$ 750 \$	98 (42.7)	31 (37.4)	
Socioeconomic status			
Lowest	96 (41.7)	36 (42.6)	0.819
Middle	38 (16.7)	16 (19.1)	
Highest	32 (38.3)	96 (41.7)	

mean $\pm$ s.d.: mean $\pm$ standard deviation.

*The 'compatible' group is consisting of patients whose control level of C-ACT- and GINA-based measurement of control are compatible with each other.

†analysis made by student *t*-test, the rest of were analysed with chi-square test.

evaluated for the control level of asthma individually, the control decisions of GINA and C-ACT were not consistent with each other. And we could not find any variable that

would allow us to predict the consistency and inconsistency between GINA and ACT.

Asthma is a heterogeneous disease with symptoms, such as airway hyper-reactivity and inflammation, so no single outcome measure could be found to assess asthma control adequately. To define control levels of asthma, different methods like patient surveys, symptom diaries, and inflammatory markers have been tried, but none of these tools are able to determine the control level precisely. It has been reported that there is a difference between the expectations of physicians and patients about the control level of asthma and the benefit of treatment (9–11, 20, 21). This may lead to an overestimation of control level and inadequate treatment causing increased frequency of exacerbations and diminished quality of life, or an underestimation of the control level causing overtreatment with increased financial burden of the disease and adverse effects of stepped-up therapy.

There is no approved and validated gold standard for measuring asthma control; even the GINA classification is described as a 'working scheme based on current opinion and has not been formally validated' (4). The GINA classification does not have an exact time limitation, and it is recommended to take notice of the last week for the symptoms and the last year for the exacerbations when determining the control level of asthma. By using GINA criteria, physicians try to provide a long-term evaluation of asthma control while C-ACT gives the opportunity to regard the symptoms only up to the last 4 wk by the questions directed to the parents. Additionally, regarding the symptom definitions, GINA only categorizes them as daytime or nighttime and focuses on the frequency of the symptoms as less than or more than twice a week. However, C-ACT and ACT not only ask about the frequency of the symptoms in more details, but also the severity of the present symptoms.

As Holgate et al. (22) pointed out in their review of asthma surveys, patients' perception of disease control and frequency of symptoms were often mismatched, namely patients often understate their symptoms and tolerate poor disease control. Besides this, it was reported that even when parents reported prolonged or severe symptoms, a substantial proportion of symptomatic children did not take appropriate treatment (23). These findings suggest that undertreatment and overtreatment of asthma in children were common. These may also be correct for the 'not-compatible' group in

our study which comprises of more than one-fourth of the study population.

There are some studies that found discrepancies between GINA criteria and ACT/C-ACT, which show a gap between physicians' and patients' assessment of control level of asthma. Thomas et al. who emphasized these points in their multinational study found an overall discrepancy rate of 66% between GINA and ACT. The kappa variable changed between 0.29 and 0.52 among European countries and the United States. This was the rate of the patients who had an ACT score ≥ 20 but were assessed as 'partly controlled asthmatics' according to GINA because of either an old exacerbation or isolated symptoms, especially nocturnal awakening (24).

There are only two studies comparing the asthma control level determined according to C-ACT and GINA criteria, and their study groups are relatively small for a full statistical analysis. In one of these studies conducted in a group of 63 asthmatic children, Yu et al. (13), reported that C-ACT scores were found to be higher in the controlled group than in the partially controlled and uncontrolled groups defined according to GINA criteria. In agreement with their results, the C-ACT scores of the control groups were also significantly different in our study but in the study by Yu et al., a comparison to reveal whether C-ACT and GINA code an individual patient into the same control group or not was not assessed. Interestingly, the mean C-ACT score of uncontrolled patients was over 20, which shows the overestimation of the C-ACT in asthma control. In the second study including 84 children under 12 yr, Koolen et al. (14) showed that, for a cut off point < 19 to define uncontrolled asthma, C-ACT had a sensitivity of 33% and a specificity of 100%. Their data reveal that although C-ACT correlated well with GINA criteria in predicting uncontrolled asthma, when we use only C-ACT, we can miss two-thirds of patients who were defined as 'uncontrolled' according to GINA criteria. Our study was conducted among a larger group of patients in our outpatient clinic with a diagnosis of asthma. We have revealed an inconsistency for 26.7% (84/314) of the study group between C-ACT and GINA decision of control level in our study, which is similar to the studies conducted in adult asthmatics and the studies among children mentioned earlier.

In our study, there was a considerable inconsistency between GINA and C-ACT, and no variable could be found to predict the discrepancy (Table 2). The main cause of this discrepancy is considered to be the fact that GINA and C-ACT are different measurement tools, and control criteria of GINA are based on the frequency of symptoms and pulmonary function tests, whereas the C-ACT is directly related to the severity of symptoms. Besides, GINA is a three-step tool which we turned it into two steps and mainly represents the last week, whereas C-ACT is a two-step tool that gives information regarding a period of 4 wk. Also, because of the episodic nature of the childhood wheeze, it is difficult to assess the control especially in preschool ages. Despite these important differences between the two tools, they are the methods that are mainly used to assess the control level of asthma

during childhood, and the main goal of the physicians is to determine the control level as accurately as possible. So we think that it is important to assess the efficacy and compatibility of these tools that are used to decide the level of control. In addition, the disease perceptions of the patient, the parents, and the physicians seem to be different to each other. So, this result confirms the hypothesis of a 'gap' and the fact that a substantial proportion of patients with asthma are not optimally controlled, despite the availability of guidelines (9, 10, 12, 13, 20).

Demographic features, spirometric tests, concomitant allergic sensitization and allergic diseases, asthma severity, follow-up year and age at diagnosis, family history of atopy and also the degree of education, monthly income and socioeconomic status of the parents did not differ between the 'compatible' and 'not compatible' groups. Recently, it has been reported that low parental education and their beliefs about the necessity of medication were associated with uncontrolled asthma and another study showed that children from highly educated parents are protected from non-atopic respiratory symptoms (25, 26). But, we could not find any criteria, including parental education, to predict for which patient group the C-ACT can be more appropriate and reliable and why there is discrepancy between the control decisions of the physicians and the patients. For socioeconomic status, no difference could be found between 'compatible' and 'not compatible' groups. Currently, it has been demonstrated that disparities in asthma control among children from families of different socioeconomic strata persist, even with adjustment for utilization of medical care and use of controller therapies (27). This can be related to our study because ours is a single center experience, subsequently the patients enrolled to the study were mostly living at the same location of the city. As a result, there is no real difference between our two groups for socioeconomic status, even if the method for analyzing socioeconomic status is statistically accurate.

According to these results, we suggest that reliance on a C-ACT alone may result in the potential for overtreatment or undertreatment, because patients' recall of asthma symptoms decreases over time, and a questionnaire can only serve as complementary tool for clinicians, and they should be assessed in conjunction with a thorough medical history and clinical judgment.

Achieving closer alignment between the perspectives of patients and physicians is an important aim of asthma management (20). The possibility that there can be a discrepancy between the control decisions of patients and physicians and that the type of discrepancy can differ from patient to patient should always be kept in mind.

In conclusion, there is a significant discrepancy rate between C-ACT and GINA guidelines that could not be ignored when assessing the patient with asthma and tailoring the therapy. The control determination can change from patient to patient within the same method. New methods for the assessment of the control level of asthma can be developed for different societies or the validated, and reliable assessment methods can be modified for different societies to

determine the control level of asthma more accurately and conveniently. Using more than one method while assessing the required control level will better help patients control their asthma.

Conflict of interest

All of the authors have no conflicts of interest in the manuscript.

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