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Asthma Control Test™ in Assessment of Clinical Asthma Control

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Abstract

Background. The goal of asthma treatment is to achieve and maintain control of the disease.

Objective. To assess validity and reliability of Asthma Control Test™ (ACT) as a patient-based tool for quantifying the control of the disease in the subjects with persistent asthma.

Methods. A cross-sectional study including 396 subjects with persistent asthma drown from a population of treated patients was performed. Evaluation of the examined subjects included completion of the ACT, spirometry, and asthma specialist rating of control.

Results. The mean derived ACT score in all study subjects was 19.2±3.3. Prevalence of the study subjects with totally controlled (TC), well-controlled (WC) and not well-controlled (NWC) asthma by derived ACT score was 9.1%, 43.2% and 47.7%, respectively. Results from the spirometry showed that in 45% of the study subjects FEV1 value was less than 80%. Prevalence of the study subjects with TC, WC and NWC asthma by asthma specialist rating was 8.1%, 41.1% and 50.7%, respectively. A strong correlation between the derived ACT scores and asthma specialist rating of control was observed (r = 0.51, P = 0.000).

Conclusion. Our data confirm the usefulness of the ACT as a valid and reliable screening tool for asthma control.

Introduction

According to the actual Global Initiative for Asthma (GINA) guidelines, the goal of asthma treatment is to achieve and maintain clinical control and it can be reached in a majority of patients with a pharmacological intervention strategy developed in partnership between the patient/family and the doctor. Each patient is assigned to one of five "treatment steps" depending on their current level of control and treatment is adjusted in a continuous cycle driven by changes in their asthma control status which involves assessing of asthma control, treating to reach control and monitoring to maintain control (1).

Despite the existence of the treatment guidelines and the availability of asthma medication that could effectively treat the disease, actual studies indicate that many patients with asthma continue to be not well-controlled and are at risk for acute exacerbation resulting in missed work or school, increased use of health care services, and reduced quality of life (2). Furthermore, many studies indicate that the level of asthma control is often overestimated by both patients and physicians suggesting that asthma treatment guidelines alone are not enough to ensure the proper assessment of asthma control (3, 4).

The control of asthma is a complex construct in which many factors play a role. The assessment of individual asthma end points alone, such is lung

function, usually overestimates the level of control achieved (4). Furthermore, such limited end points may not reflect what is important to the patient, whose quality of life is more dependent on the overall impact of the disease rather than on a single measure. Recently, several investigators developed patient-based tools that quantify clinical asthma control, such as Asthma Control Test™ (ACT), Asthma Control Questionnaire (ACQ), and Asthma Therapy Assessment Questionnaire (ATAQ) (2, 5, 6). Asthma Control Scoring System (ACSS) (7) is a tool for quantifying the asthma control that assesses clinical, physiological, and inflammatory parameters and provides a total percentage score as an average of the three component scores.

In the present study we assessed the validity and reliability of the ACT as a patient-based tool for quantifying the asthma control by comparison of its results with results of the asthma specialist rating of the disease control.

Methods

Study design

A cross-sectional study was carried out at the Institute for Occupational Health of R. Macedonia, Skopje-WHO Collaborative Center and GA²LEN Collaborating Center from March 2008 to January 2009.

Inclusion criteria were diagnosis of persistent asthma, age over 18 years, no asthma exacerbation and no respiratory comorbidities. Evaluation of the examined subjects included completion of a questionnaire, lung function testing, and asthma specialist rating of control.

Sample

Examined group included 396 subjects with persistent asthma, 177 males and 219 females, aged 19 to 64 years, mean age 38.4 ± 13.8 years. All subjects were drown from a population of treated patients with diagnosed asthma for at least 1 year. Classification of the disease severity in the patients was determined according to the actual GINA recommendations (1). All participants gave their consent before entering the study.

Questionnaire

The ACT was used in the study with permission and under conditions of GlaxoSmithKLine, Respiratory Centre of Excellence. All patients completed the questionnaire which consisted 5 original ACT items (2) translated in Macedonian:

Q1 In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or home?

Q2 During the past 4 weeks, how often have you had shortness of breath?

Q3 During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake up at night earlier than usual in the morning?

Q4 During the past 4 weeks, have you used your rescue inhaler or nebulizer medication (such as salbutamol)?

Q5 How would you rate your asthma control during the past 4 weeks?

Each question had score ranging from 1 to 5. The patients had to circle the appropriate score for each question. ACT score was derived as a sum of the scores for each response. According to the derived ACT score the level of asthma control was categorized as not well-controlled (ACT score less than 20), well-controlled (ACT score 20-24) and totally (or completely) controlled (ACT score 25). In addition, not-well controlled asthma should be subdivided into partly controlled (ACT score 18-19) and uncontrolled asthma (ACT score equal or less than 17).

A month of totally controlled asthma is defined as none of the following: limited activities at work, school or home, daytime shortness of breath, night-time or earlier in the morning awakenings caused by asthma symptoms, use of rescue medication (such as salbutamol) and any level of disease control by the patient's opinion except completely controlled . To have a month of well-controlled asthma, a patient has to meet at least one of the following criteria: limited work, school or home activities for a little of the time, shortness of breath once or twice a week, asthma symptoms interfering with sleep once or twice a week, use of rescue medication once a week or less and well controlled disease by patient's opinion. Patients whose asthma does not meet the criteria for well-controlled asthma are considered to have not well-controlled asthma.

Lung function testing

Spirometry, including measures of forced vital capacity (FVC), forced expiratory volume in one second

(FEV_1), FEV_1/FVC ratio, maximal expiratory flow at 75%, 50 %, 25%, and 25-75% of FVC (MEF_{75}, MEF_{50}, MEF_{25} and MEF_{25-75}, respectively), was performed in all patients using spirometer Ganshorn SanoScope LF8 (Ganshorn Medizin Electronic GmbH, Germany) with recording the best result from three measurements the values of FEV1 of which were within 5% of each other. The results were expressed as percentages of the predicted values, according to the European Community for Coal and Steel (ECCS) norms (8). According to the actual FEV_1 value, the patients were categorized into 4 groups (FEV_1 value equal or less than 59%, 60-79%, 80-99%, and equal or more than 100%).

Asthma specialist work-up

After questionnaire completion and lung function testing, each patient was interviewed by asthma specialist who was blinded to the results of the ACT. The level of asthma control was rated on a 3-point scale ranging from "not well-controlled", "well-controlled" to "totally controlled". The specialist rating was based on how well the goals of asthma management were being met, as outlined in the GINA guidelines and as determined from patient history, physical examination and FEV_1 value.

Statistical analysis

Continuous variables were expressed as mean values with standard deviation (SD), whereas the nominal variables as numbers and percentages. Chi-square test was used for testing association between the derived ACT scores and the asthma specialist ratings of control and sex, age, and smoking status. Pearson correlation coefficients were calculated between ACT scores and asthma specialist ratings. A *P*-value less than 0.05 was considered as statistically significant. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 11.0 for Windows.

Table 1: Demographics of the study subjects.

Variable	Subjects (n = 396)
Females	219 (55.4)
Age (years)	38.4 ± 13.8
Mean duration of diagnosed asthma (years)	6.3 ± 4.3
Active smokers	93 (23.4)
Pack-years smoked	13.9 ± 6.7
Ex-smokers	43 (10.8)
Passive smokers	74 (18.7)

Data are presented as n, mean ± SD, or n (%).

Results

Demographic characteristics of the study subjects are given in Table1.

The mean derived ACT score in all study subjects was 19.5 ± 3.3, ranging from 12 to 25. Distribution of the study subjects by derived ACT score is shown Figure 1.

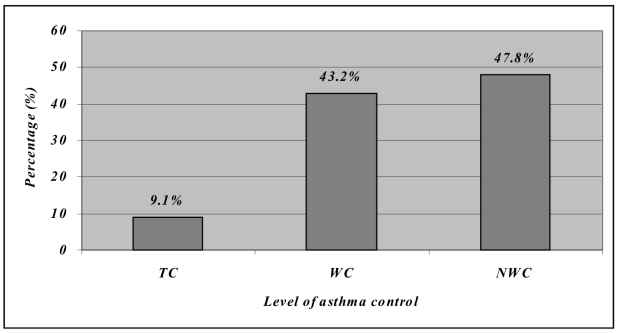

Figure 1: Distribution of the study subjects by level of the asthma control: totally controlled (TC, ACT score 25) 9.1%; well-controlled (WC, ACT score 20-24) 43.2%; not well-controlled (NWC, ACT score less than 20) 47.8%.

Derived ACT score indicating partly controlled asthma was obtained in 54.3% of the study subjects with not well-controlled asthma (25.7% of the whole study population), whereas the prevalence of uncontrolled asthma in the category of not well-controlled asthma was 45.6% (21.9% of the whole study population) (Figure 2).

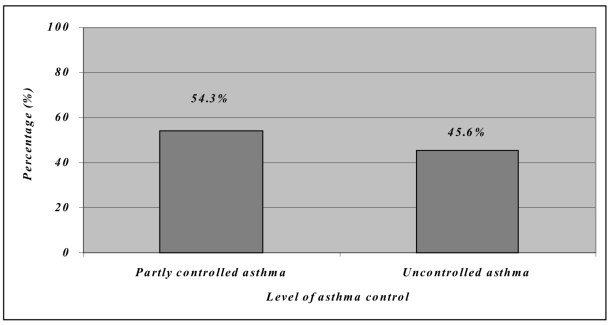

Figure 2: Distribution of the study subjects with not well-controlled asthma: partly controlled asthma (ACT score 18-19) 54.3%; uncontrolled asthma (ACT score equal or less than 17) 45.6%.

The mean scores of appropriate ACT items were similar varying from 3.7 for Q4 to 4.1 for Q5 (Figure 3).

There was no significant association between the derived ACT score and sex, age, duration of the disease or smoking status.

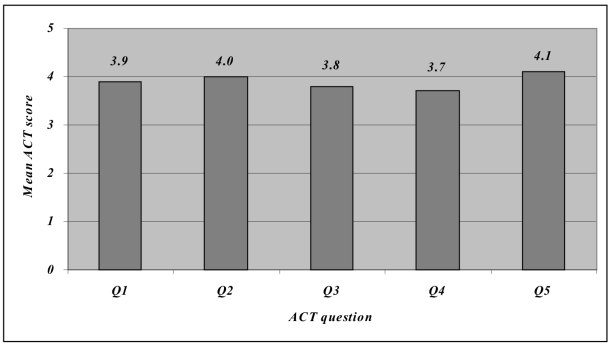

Figure 3: Mean scores of appropriate ACT items: Q1 3.9± 0.5; Q2 4.0 ± 0.4; Q3 3.8 ± 0.5; Q4 3.7 ± 0.6; Q5 4.1 ± 0.4. Q: question.

Results from the lung function measurements showed that in 45% of the study subjects FEV_1 value was less than 80%, whereas in around 14% it was less than 60% (Figure 4).

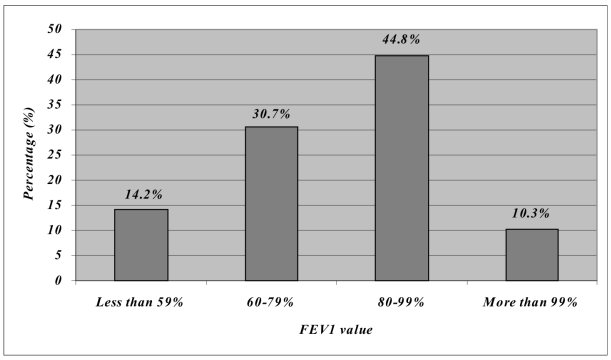

Figure 4: Distribution of the patients by FEV_1 value: FEV_1 value less than 59% was measured in 14.2%, FEV_1 value 60-79% in 30.7%, FEV_1 value 80-99% in 44.8%, and FEV_1 value more than 99% in 10.3% of the study subjects. FEV_1: forced expiratory volume in 1 second.

Distribution of the study subjects by asthma specialist rating is shown Figure 5.

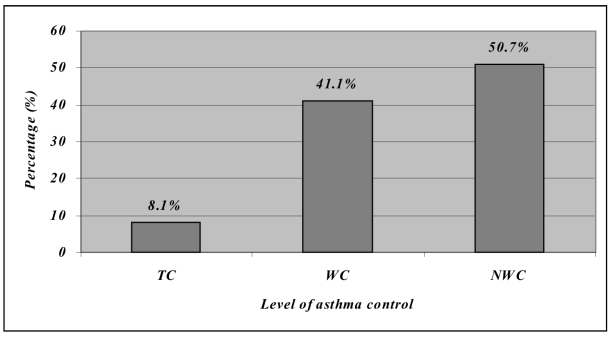

Figure 5: Distribution of the study subjects by asthma specialist rating of control: totally controlled (TC) 8.1%; well-controlled (WC) 41.1%; not well-controlled (NWC) 50.7%.

There was no significant association between the asthma specialist rate of control and sex, age, duration of the disease or smoking status.

The correlation observed between the derived ACT scores and asthma specialist rating of control was strong (r = 0.51, P = 0.000).

Discussion

Asthma is a common life-long chronic inflammatory disorder of the airways that affects children and adults of all ages with an increasing prevalence in many countries in the world. The prevalence of asthma in Western Europe ranges from 3.9% in Germany to 10.9% in the UK (9). The substantial morbidity is associated with a large economic burden that is particularly substantial in developing countries with limited healthcare resources and consecutive difficulties in implementation of the new healthcare initiatives (10). The results from the survey carried out in R. Macedonia in 2003 showed asthma prevalence of 5.4%, which translated to approximately 100,000 affected subjects. The monthly cost for chronic treatment of asthma in adults and children aged over 5 years ranged from € 30 to € 110 per patient, the sum which was partly covered by the Health Insurance Fund (11). This is a serious socioeconomic problem, taking into account that average monthly net-wage paid per employee in R. Macedonia in August 2006 was approximately € 225, whereas the unemployment rate was 36.1% (12).

The largest contributors to healthcare costs associated with asthma are prescription medications (28-68% of costs) and hospitalizations (8-48%) (13, 14). Results of many studies indicate considerable increase of the healthcare costs if the disease is poorly controlled (15-17). According from the Sullivan et al (18), uncontrolled patients incur more than double the healthcare and associated costs than those who are controlled. Actual epidemiologic evidence shows that six of seven European asthmatic adults using inhaled corticosteroids in the past year did not achieve good disease control (19). On the other hand, Calfee et al., 2006 (20) report that patients with asthma who feel in control of the condition show improved asthma-related health, less severe attacks, and are less likely to be hospitalized for asthma. Furthermore, results from the Gaining Optimal Asthma controL (GOAL) study (21) show that most patients achieving guideline-defined control can maintain at least a similar level of control with regular, stable dosing, with little likelihood of losing control.

In the present study we evaluated validity and reliability of ACT in assessment of the clinical asthma control. Examined group included subjects with persistent asthma drown from a population with diagnosed asthma for at least 1 year. Assessment of the disease control in the examined group included self-assessment by completion of the ACT and asthma specialist rating of control. The demographic data of the examined subjects showed a large proportion of daily smokers and a low proportion of ex-smokers that was similar to the results of our previous study (11).

According to the derived ACT score, approximately a half of the sample had asthma that was not well-controlled. In a survey assessing the level of asthma control by ACT among subjects with treated asthma in five European countries, Desfougeres et al., 2007 (22) reported similar prevalence of subjects with not well-controlled asthma in whole study population (55%) ranging from 45% in the subjects with asthma in the United Kingdom and Spain to 72% in the subjects with asthma in Germany. They concluded that despite the level of asthma control had improved since earlier studies, e.g. Asthma Insights and Reality in Europe (AIRE) survey, the majority of patients still remain not well-controlled. High percentage of subjects with not well-controlled asthma was reported by Vervloet et al., 2006 (23) in the study that assessed asthma control in a large study sample of subjects with asthma from seven European countries. The findings from this study indicated that the prevalence of patients with derived ACT score > 20 was higher among patients with mild persistent asthma than in the patients with moderate and severe persistent asthma. On the other hand, Shirai et al., 2008 (24) reported a high percentage of subjects with total control of asthma (42.8%) in the study that assessed the level of asthma control by ACT in a small study sample of Japanese subjects with asthma. According to the asthma specialist rating, approximately a half of the study subjects had asthma that was not well-controlled. We observed strong degree of concordance between the derived ACT scores and asthma specialist rating of control, which is consistent with the findings observed in other studies (25-28). Our findings confirm that ACT provides a more simplified assessment of control by not requiring FEV_1 (taking into account that many patients are managed in settings in which FEV_1 is not available) and by providing a meaningful and easy to use scoring method.

There were some limitations in our study, which should be taken into account when interpreting the results. First, as it was done in several cited studies, the defined levels of control, although based on the goals of treatment of GINA guidelines, are not identical to the categories of "controlled", "partly controlled" and "uncontrolled" subsequently presented in the actual version of the guidelines. However, the categories are similar and the quantitative differences in observations between the three control levels observed in present study support the validity of such classification. The second limitation of the study is a relatively small size of the examined group compared to similar studies that could have certain implications on the data obtained and its interpretation.

In summary, our findings confirm that the ACT is a valid, reliable and practicable tool for assessment of clinical asthma control. We also emphasis the need of wide use of the ACT among the patients with asthma in R. Macedonia in order to identify the subjects with poor disease control and to implement measures for its improvement.

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