

## VALIDATION OF THE CROATIAN VERSION OF THE ASTHMA CONTROL TEST

Sanja Popović-Grle<sup>1</sup>, Helena Tesari<sup>2</sup>, Vlado Drkulec<sup>2</sup>, Dubravka Pelicarić<sup>1</sup>,  
Davor Plavec<sup>3</sup>

<sup>1</sup>University Hospital Centre Zagreb, Clinical Department for Lung  
Diseases Jordanovac, Zagreb, Croatia;

<sup>2</sup>General County Hospital Požega, Pulmonology Department, Požega, Croatia:

<sup>3</sup>Srebrnjak Children's Hospital, Pulmonology and Allergy Department, Zagreb,  
Croatia

### Summary

Validation of the Croatian version of the Asthma Control Test [ACT] in an adult persons with asthma was the objective of the study. A total of 90 consecutive asthmatic patients were recruited in a prospective observational study. A pulmonologist blinded to the ACT score assessed asthma control according to the Global Initiative for Asthma [GINA] guidelines. Lung function was measured and treatment prescribed until the control visit. Seventy-five patients attended the control visit after three months, according to the same protocol.

Two patients had intermittent asthma, 47 patients mild persistent, 31 moderate persistent and 10 severe persistent asthma. According to the pulmonologist's assessment during the first examination, 12 patients had uncontrolled asthma, 10 poorly controlled, 47 partially controlled, 16 well controlled, and 5 completely controlled under the current treatment. The ACT score was in the range from 5 points to 25 with mean (SD) score 16.3 [5] and Cronbach  $\alpha$  of 0,79 [internal validity). ACT score had the best discriminating power for the pulmonologist's assessment of asthma control ( $F=17.9$ ;  $P<0.0001$ ), significantly discriminating uncontrolled, inadequately controlled and moderately controlled patients, from well controlled and completely controlled patients. In patients attending the control visit, significant correlation was found between the change in ACT score and the change in the level of asthma control assessed by the pulmonologist ( $r^2=0.437$ ;  $P<0.001$ ). The results of our study confirmed the validity of the Croatian version of ACT in the assessment of disease control in patients with asthma, aged 18-85 years.

**Keywords:** asthma; Asthma Control Test; questionnaire; validation.

## INTRODUCTION

Due to a diminished impact of epidemics in our time and better watering with improved living standard, morbidity and mortality has been changed. Many chronic non-communicable diseases step on the health stage. Among them a big part takes chronic airways diseases, among which are asthma, chronic obstructive pulmonary disease (COPD), allergic rhinitis and sleep apnea, with around billion persons affected worldwide [1]. Asthma has been fascinating disease for millenia, yet still not enough recognized and treated. At the end of XX. Century the comprehensive strategy was establish Global Initiative for Asthma (GINA) [2], with the aim to increase awareness about asthma among physicians, health authorities and general population, with the purpose for better prevention, diagnostics and treatment of asthmatics. Each few years a revised document is publish, every time with emphasis on different part of disease management. After more than 10 years of using GINA strategy for classification of asthma severity, the revised GINA in year 2006. stress out asthma control concept. That concept means that the goal of asthma treatment is to achieve and maintain clinical control with least dosage medication [3]. In revised GINA 2012. the partnership doctor-patient was introduced, while in revised GINA strategy 2014. a focus was placed on modifiable risk factors, such as smoking, obesity and anxiety.

Asthma control is assessed by medical history data (incidence of asthma exacerbations), symptoms, lung function, but also assessment of inflammation in airways (exhaled nitric oxide, or induced sputum [4] and biomarkers, what makes asthma assessment complicated, expensive and less available. Physicians need simple clinical tool that measure asthma disease status. Several international and national guidelines have been developed, including the Croatian one [5], most of them recommended usage of questionnaires in the assessment of asthma control. Prevalence of asthma in Croatia, is middle high, around 6.9% in children [6]. Occasionally, a differentiation of inadequate asthma control from asthma exacerbation is complicated and consequently has occupied the attention of scientists for more than a decade [7]. Asthma questionnaires can facilitate decisions about the need for treatment modifications (“step up” or “step down”). Studies show that in adult patients questionnaires can identify patients who are at risk of asthma exacerbation, in need of emergency intervention and hospitalisation [8]. A similar study of a paediatric population was also published [9]. As a prerequisite for the application of a questionnaire in a specific language it is necessary to carry out a validation process. Emphasis has recently been placed on the control of asthma [10] and consequently we were interested in the extent of the correlation of the Asthma Control Test (ACT)

with diagnostic procedures in a specialised pulmonary out-patient department. The object of this study was the validation of the Croatian version of the Asthma Control Test (ACT) in adult persons with asthma.

## MATERIAL AND METHODS

### Study Design and Patients

An observational, prospective, single-centre study was conducted in the University Hospital Centre Zagreb, Clinical Department for Lung Diseases Jordanovac in Zagreb, Croatia. The study was carried out from September 1<sup>st</sup>, up until December 31<sup>st</sup>. Consecutive patients attending a routine check-up visit at the Outpatients department were recruited. Ninety asthmatic patients, aged from 18 to 85 years (mean 45.3, SD 17.4 years, 50 women (55.6%) were enrolled in the study. All patients were required to attend two (physician office) visits, baseline and a scheduled follow-up (control) visit after three months. During the first visit patients completed the ACT and were subject to an interview and clinical examination. In all patients the usual measurements of lung function [11] were conducted using forced spirometry testing with the flow-volume curve and reversibility testing with salbutamol [12]. Spirometry was conducted using computerized apparatus MasterLab Erich Jaeger, Wurzburg, Germany, and performed in accordance with the ATS/ERS Guidelines [13]. All spirometry measurements were compared with reference values published by the European Community for Coal and Steel [14] and expressed as a percentage of the predicted values. For reversibility testing, a standardized dose of salbutamol was used [4] puffs of 100 mcg with a total administered dose of 400 mcg [15]. Spirometry was repeated at a time when at least 75% of maximal bronchodilator activity is expected, after 15 to 30 minutes. A single pulmonologist, with long standing experience in asthma management, blinded for the ACT responses, rated asthma control on a scale from 1 to 5 and asthma severity according to GINA guidelines at both visits. Optimal therapy according to GINA guidelines was prescribed according to the rated level of control, using “step up” or “step down” approach. Seventy-five patients (83.0%) attended the control visit after three months and underwent a similar procedure as during the baseline visit, with the exclusion of reversibility testing (interview and clinical examination by the pulmonologist, lung function measurement and ACT).

Validation of the ACT was assessed according to internal consistency, test-retest reliability, discrimination validity and responsiveness as evidence of change in the ACT scores compared to changes in asthma control. The protocol was approved by the Local Ethic Committee of the University Hospital for Lung Diseases Jordanovac.

All patients provided their written informed consent before being included in the study.

### Statistical analysis

Statistical analysis was performed using STATISTICA ver. 6 (StatSoft Inc., Tulsa, USA) and MedCalc ver. 9.2.0.1 (MedCalc Software, Mariakerke, Belgium).  $P=0.05$  was used as statistically significant for all tests. Mean and SD were used to characterize continuous variables and number and percentage (%) for categorical ones. Internal consistency of the ACT was assessed using Cronbach  $\alpha$ . Test-retest reliability was assessed in patients with no change in the level of asthma control (according to the pulmonologist's assessment between the baseline and control visit, using intraclass correlation coefficient (ICC). ANOVA was used to compare continuous variables between subgroups according to asthma severity and asthma control. Chi-square test was used to compare categorical variables between subgroups. Linear regression analysis and Spearman rank order correlation were used to calculate the level of association between variables. Discriminant analysis and receiver operating characteristic (ROC) curve analysis was used to calculate the area under the ROC curve, cut-off value, sensitivity, specificity, positive and negative likelihood ratios (+LR, -LR) and diagnostic odds (DO) for ACT in predicting asthma control.

### RESULTS

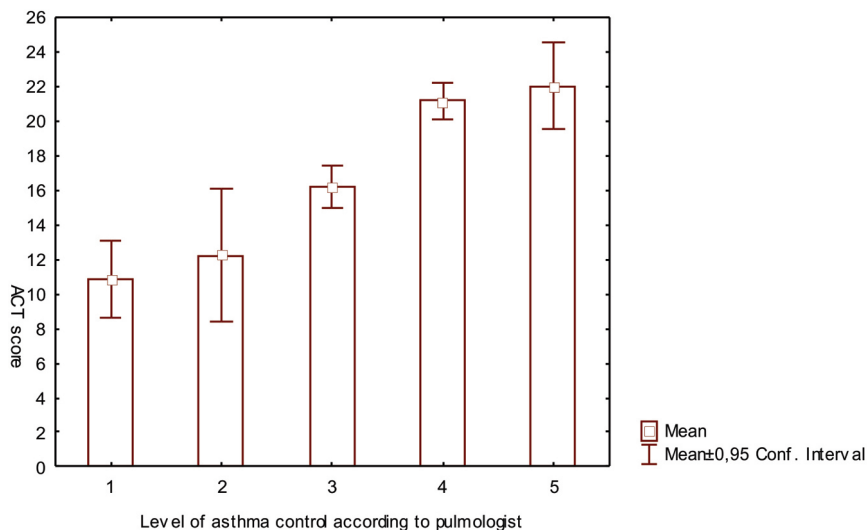
Table 1 shows a description of baseline values for the socio-demographic and clinical characteristics of patients recruited in the study. Two (2.2%) patients had intermittent, 47 (52.2%) mild persistent, 31 (34.4%) moderate persistent and 10 (11.1%) severe persistent asthma. At baseline visit, 12 (13.3%) patients were not controlled, 10 (11.1%) were poorly controlled, 47 (52.2%) were partially controlled, while 16 (17.8%) were well controlled and five (5.5%) were completely controlled. Forty-nine (54.4%) patients used inhaled corticosteroids in monotherapy, 26 (28.9%) used inhaled corticosteroids + long-acting  $\beta_2$ -agonists; 18 (20.0%) used leukotriene receptor antagonists, 4 (4.4%) of them used leukotriene receptor antagonists + inhaled corticosteroids 5 (5.5%) leukotriene receptor antagonists + inhaled corticosteroids + long-acting  $\beta_2$ -agonists and 1 (1.1%) leukotriene receptor antagonists + inhaled corticosteroids + theophyllin; 6 (6.7%) used just theophyllin; 1 (1.1%) used oral corticosteroid therapy and 58 (64.4%) short-acting  $\beta_2$ -agonists as needed. The average (SD) forced expiratory volume in the first second (FEV<sub>1</sub>) as a percentage of the predicted value was 79.0% (21.1%) and the average reversibility to salbutamol was 16.0% (11.8%, range 1.4-64.0%) with a statistically significant inverse correlation to FEV<sub>1</sub>(%) ( $r=-0.487$ ;

$P < 0.001$ ). ACT score rated from 5 points to 25, with a mean [SD] value of 16.3 (5.1) points with Cronbach  $\alpha = 0.796$  (internal validity) showing high internal consistency. The only lung function parameter significantly associated with ACT score was peak expiratory flow (PEF) (Spearman  $R = 0.224$ ,  $P = 0.037$ ). ACT showed the best discriminant capacity for the pulmonologist's asthma control assessment ( $F = 23.07$ ;  $P < 0.0001$ ; Figure 1) significantly differentiating patients who were not controlled, poorly controlled and partially controlled (non-controlled asthma), from patients who were well and completely controlled (controlled asthma) with the area under the ROC curve of 0.921 (95% CI, 0.868-0.957;  $P < 0.001$ ), sensitivity of 84.3% (95% CI, 74.7-91.4%), specificity of 85.0% (95% CI, 75.3-92.0%), +LR 5.62, -LR 0.18 and DO 31.22 for the ACT value  $\leq 19$  (Figure 2). The addition of  $FEV_1$  (%) to ACT did not contribute to discriminant capacity for asthma control assessment (area under the ROC curve 0.895, 95% CI 0.818-0.971,  $P > 0.05$ ). Out of 75 patients who attended the control visit 7 (9.3%) were poorly controlled, 12 (16.0%) partially controlled, 32 (42.7%) well controlled and 24 (32.0%) completely controlled. Three patients (4.0%) showed two points poorer asthma control than on the baseline visit, five (6.7%) one points poorer, fourteen (18.7%) showed the same level of control, twenty-two (29.3%) one points better, twenty-one (28.0%) two points better, eight (10.7%) three points better and two (2.7) even four points better control. During the control visit  $FEV_1$  (%) was 85.5% (SD 19.9) and

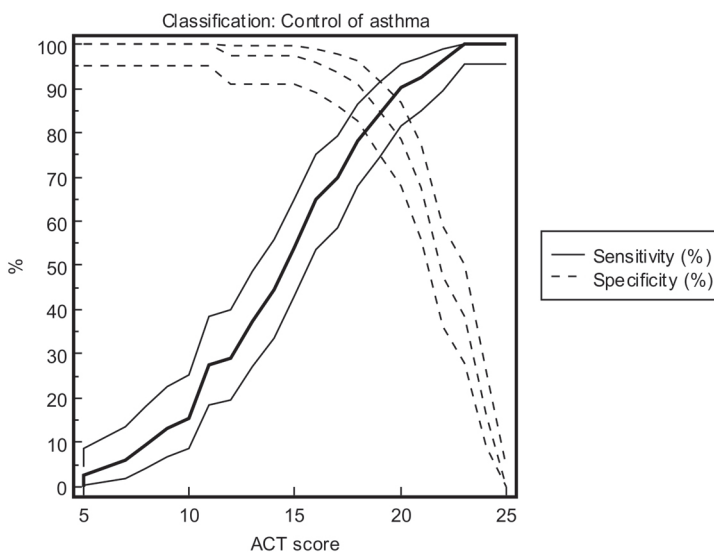
**Table 1.** Demographic and clinical characteristics of the investigated asthma patients sample (N=90)

	Asthma severity according to GINA				Total
	Intermittent (N=2)	Mild persistent (N=47)	Moderate persistent (N=31)	Severe persistent (N=10)	
Gender (%) Male	1 (50.0)	20 (42.6)	15 (48.4)	4 (40.0)	40 (44.4)
Female	1 (50.0)	27 (57.4)	16 (51.6)	6 (60.0)	50 (55.6)
Age, mean (SD), yrs*	24.5 (9.2)	42.2 (16.3)	47.0 (17.1)	58.3 (17.7)	45.3 (17.7)
Duration of asthma, mean (SD), yrs	3.5 (2.1)	10.4 (10.7)	8.7 (10.1)	17.4 (20.0)	10.4 (11.9)
% FVC, mean (SD)*	101.3 (14.1)	98.6 (13.5)	80.1 (20.6)	64.6 (14.7)	88.5 (20.2)
% $FEV_{1r}$ , mean (SD)*	99.9 (24.2)	90.5 (14.4)	70.3 (15.4)	44.4 (15.5)	79.0 (21.1)
% PEF, mean (SD)*	93.1 (3.8)	85.6 (17.3)	69.5 (16.0)	42.9 (11.0)	75.8 (20.9)
% reversibility of $FEV_{1r}$ , mean (SD)	25.0 (12.8)	12.5 (9.8)	15.6 (9.7)	25.2 (22.1)	16.0 (11.8)
Concomitant conditions (%)	2 (100)	32 (68.1)	23 (74.2)	9 (90.0)	66 (73.3)
Exacerbation rate, mean (SD), n/yr	0.50 (0.71)	0.98 (1.04)	1.24 (1.01)	1.61 (0.79)	1.13 (1.01)

\* $p < 0.01$



**Figure 1.** Distribution of ACT scores according to the level of asthma control according to pulmonologist (N=90); 1 - uncontrolled (N=12), 2 - poorly controlled (N=10), 3 - somewhat controlled (N=47), 4 - well controlled (N=16), 5 - completely controlled (N=5).



**Figure 2.** Plot versus criterion value for asthma control and ACT score (N=90); sensitivity and specificity plots with 95% CIs.

the average ACT score was 20.7 points (SD 4.2; range 10-25). In patients who attended the control visit, significant correlation was found between the change in ACT score and the change in asthma control assessed by the pulmonologist (Spearman  $R=0.729$ ;  $P<0,001$ ). In the subgroup of patients in which the same asthma control was assessed by the pulmonologist on both visits ( $N=14$ ) a high level of correspondence of the ACT score ( $ICC=0.864$ ;  $P<0.001$ ) was found.

## DISCUSSION

A person with asthma in good control has no limitation of productivity or physical activity and lead creative life, that why the asthma control is so important. Asthma control has been defined as the degree to which the symptoms and activity limitation have been prevented, and consequently the step of treatment is adjusted according to the level of asthma control achieved [3]. The results of the Asthma Insights and Reality in Europe study (AIRE), Asthma in America study (AIA) and European Community Respiratory Health survey (ECRHS) showed that despite national and international guidelines asthma management is suboptimal worldwide [18]. No gold standard measure for asthma control was universally accepted. A good indicator of asthma control in patients is required usage of rescue medications such as short-acting  $\beta_2$ -agonists. Patients are often well informed that the frequent usage of short-acting  $\beta_2$ -agonists is not recommended, although few of them are aware of the fact that the usage of short-acting  $\beta_2$ -agonists of more than once or twice weekly is a sign of loss of asthma control [3]. Asthma Control Test is a short patient-based 5-question survey which does not include pulmonary function tests and has been shown to accurately predict the degree of asthma control assessed by the pulmonologist on the basis of history, clinical examination and spirometry [10]. We were interested in the ability of the Croatian version of the ACT questionnaire to predict the level of asthma control assessed by the experienced pulmonologist. In patient with asthma whose asthma is uncontrolled or oposite, completely controlled, the physician interview is short, clinical examination typical, and an asthma specialist can easily make a clinical judgement. In our study less than half of patients included in this study, examined in the Outpatients Department, were in these categories: twenty-two (24.4%) were uncontrolled, and 21 (23.3%) patients were well and completely controlled on their regular asthma treatment. On the other hand, there is a great proportion (47/90) of partially controlled asthmatics in whom more time is needed for the clinical interview. It is important to ask the patient about the day- and night-time symptom frequency, impact of asthma on usual daytime activities, such as everyday functioning at school or work, interference with sleep, activity limitations,

usage of medicines, compliance, education, environment control, asthma emergency department visits, hospitalisations and comorbidities, particularly symptoms in the upper respiratory tract [19]. A comprehensive, lengthy and demanding interview is required with most patients in order to precisely estimate asthma control and its specific dimensions. This is time consuming even for an asthma specialist, not to mention less experienced physicians (general practitioners), and it is debated on how to assess control in such a way that it both supports management and simplicity of use. In contrast to this consuming time clinical approach, ACT offers brief, but still comprehensive, insight into asthma control which can help to establish the level of asthma control, together with its specific dimensions in conjunction with the results obtained from other clinical tests. This is also evident from the results of our validation study, showing that ACT has a high and significant association with the pulmonologist's evaluation of asthma control. It has been demonstrated that ACT predicts asthma control as determined by a specialist evaluation better than  $FEV_1$ , which indicates that control cannot be measured by airway function alone [10, 20,21), and confirms that specialist assessments are based on more than lung function measurements. Asthma control is multidimensional in nature, and thus measures of pulmonary function only provide a score in time assessment. In our study the addition of  $FEV_1$  did not contribute significantly to the discriminant ability of ACT, which was consistent with previous reports [21,22), but did contribute marginally in the validation study of the original version [10] showing that, although there was no significant correlation of ACT score with lung function parameters (apart from a very low level with PEF),  $FEV_1$  value did not contribute any additional information about the level of asthma control that was not already present within the ACT score. Almost absent correlation of ACT score with lung function parameters most probably reflects the multifaceted dimension of asthma control which also depends on many other parameters such as underlying inflammation, which is thought to cause poor control [23]. The published validation of a Spanish version of ACT, contrary to our results, indicates the significance of spirometry in the assessment of asthma patients and also emphasises that  $FEV_1$  should not be used on its own to assess asthma control, but in conjunction with clinical assessment [20]. A study in Japan also emphasised the need for multiple measures of control and the significance of measuring peak expiratory flow and fractional exhaled nitric oxide (FeNO) in the assessment of asthma control in patients in which the ACT score showed complete asthma control, because the disappearance of symptoms does not mean that the underlying inflammation is adequately controlled [21]. Our study shows that ACT correlates with complete assessment, including a comprehensive interview by an experienced pulmonologist, physical examination and lung function measurement. One of the



advantages of this quick and simple tool for the assessment of asthma control is the monitoring of patients, so that modulation of treatment is easily recognized.

Our study showed that the Croatian version of ACT was equally accurate in patients with a stable level of control between two consecutive visits and in patients in which control was improved or lost. In this respect it allows precise assessment of therapeutic interventions, compliance and indication of possible co-morbidities. American authors consider that the great value of ACT is in the monitoring of patients after asthma exacerbation [20], as well as predictors of exacerbation and changes in therapy [22].

After translation of the international questionnaires to other languages, validation procedure needs to be conducted. ACT has proved to be very useful in clinical practice, which is confirmed by validation of this questionnaire in Europe (Spain) [18,21] and in the world (Japan, Singapur) [19, 23].

## CONCLUSION

After translation of ACT to the Croatian language we conducted validation of the Croatian version of ACT in adult patients with asthma and demonstrated that the Croatian version of ACT is useful in the assessment of disease control in adult patients with asthma.

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### Sažetak

#### Validacija hrvatske inačice testa za kontrolu astme (*Asthma Control Test*)

U ovoj prospektivnoj opservacijskoj studiji provedena je validacija hrvatske inačice testa za kontrolu astme [Asthma Control Test (ACT)] u odraslih osoba s astmom. U istraživanje je uključeno 90 susljednih bolesnika s astmom. Pulmolog koji nije znao rezultat ACT testa procjenjivao je kontrolu astme u bolesnika prema globalnim smjernicama za astmu [Global Initiative for Asthma (GINA)]. Izvedeni su testovi plućne funkcije i preporučeno je liječenje do sljedećeg kontrolnog posjeta. U sljedeći kontrolni posjet za tri mjeseca došlo je 75 bolesnika, prema planiranom protokolu.

Dvoje bolesnika imalo je povremenu astmu, 47 bolesnika blagu trajnu astmu, 31 umjereno tešku trajnu astmu, a 10 bolesnika tešku trajnu astmu. Prema procjeni pulmologa na prvom pregledu, 12 bolesnika imalo je nekontroliranu astmu, 10 loše kontroliranu, 47 djelomično kontroliranu, 16 dobro kontroliranu, dok je njih 5 imalo astmu potpuno kontroliranu dotadašnjim načinom liječenja. ACT rezultat kretao se od 5 do 25 bodova sa srednjim [SD] zbrojem 16.3 [5] i Cronbach  $\alpha$  od 0,79 [interna validacija]. ACT rezultat imao je najbolju diskriminirajuću snagu za pulmološku procjenu kontrole astme [F = 17.9; P < 0.0001] te značajno diskriminirajuću za nekontrolirane, djelomično kontrolirane i umjereno kontrolirane bolesnike u odnosu na dobro kontrolirane i potpuno kontrolirane bolesnike s astmom. U bolesnika koji su bili u drugome kontrolnom posjetu značajna korelacija nađena je između promjene ACT rezultata u odnosu na stupanj kontrole astme kako ju je procijenio pulmolog [r<sup>2</sup> = 0.437; P < 0.001]. Rezultati ove studije potvrđuju valjanost hrvatske inačice testa za kontrolu astme ACT u procjeni stupnja kontrole bolesti u bolesnika s astmom u dobi između 18 i 85 godina.

**Ključne riječi:** astma; test za kontrolu astme (Asthma Control Test); upitnik; validacija.