Validation of the Serbian version of the Asthma Control Test

Validacija srpske verzije Testa za kontrolu astme

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Abstract

Background/Aim. Asthma still remains poorly controlled in the majority of patients. The Asthma Control Test (ACT) is a short and useful patient-administered questionnaire for identification of patients with poor asthma control in clinical settings. The aim of this study was to validate a Serbian version of the ACT in the adults with asthma. **Methods.** A total of 250 consecutive adult asthmatic patients were recruited in a prospective observational study. The exclusion criteria were chronic respiratory disease and acute respiratory tract infection in preceding 4 weeks. **Results.** The spirometry and ACT questionnaire were performed on the baseline visit and 6 months later. The ACT test was completed by 98.8% of patients with the mean time of completion of 4.5 minutes. The correlation of ACT score and lung function parameters (forced expiratory volume in 1 second – FEV_1 and forced vital capacity – FVC) was significant ($p = 0.016$ and $p = 0.002$, respectively). A change in the ACT scores between baseline and 6-months visit was not associated with a change in FVC and FEV1. The ACT score had excellent diagnostic accuracy according to the physicians asthma control classification and even outstanding accuracy according to the patients' classification. **Conclusion.** The results of this study confirm the reliability, validity and accuracy of Serbian version of the ACT, contributing to established value of original ACT test and with consistent findings as the previously reported validity of ACT in other languages. Therefore, it should be utilized more in everyday clinical practice as a useful and reliable tool of asthma control assessment.

Key words:
asthma; surveys and questionnaires; serbia.

Apstrakt

Uvod/Cilj. Astma i dalje ostaje slabo kontrolisana kod većine bolesnika. Test za kontrolu astme (*Asthma Control Test* – ACT) je kratak i koristan upitnik za identifikaciju bolesnika sa lošom kontrolom astme. Cilj ove studije je bio da se učini validacija srpske verzije ACT kod odraslih bolesnika sa astmom. **Metode.** Ovom prospektivnom opservacionom studijom je obuhvaćeno 250 odraslih bolesnika sa astmom. Kriterijumi za isključenje su bili postojanje hroničnog respiratornog oboljenja kao i akutna infekcija respiratornog trakta u prethodne četiri nedelje. **Rezultati.** Prilikom prve posete i šest meseci kasnije učinjena je spirometrija i popunjen ACT. ACT je popunilo 98,8% bolesnika sa prosečnim vremenom završetka od 4,5 minuta. Korelacija rezultata ACT i parametara plućne funkcije (forsirani ekspiratorni volumen u prvoj sekundi – FEV1 i forsirani vitalni kapacitet – FVC) bila je značajna ($p = 0,016$ odnosno $p = 0,002$). Promena rezultata ACT između prve posete i nakon šest meseci nije bila povezana sa promenom FVC i FEV1. Rezultat ACT je imao odličnu dijagnostičku tačnost u klasifikaciji kontrole astme prema lekaru i čak izuzetnu tačnost prema klasifikaciji samog bolesnika. **Zaključak.** Rezultati studije su potvrdili su pouzdanost, validnost i tačnost srpske verzije ACT, doprinoseći već utvrđenoj vrednosti originalne verzije ACT. Takođe, ovi rezultati su u skladu sa rezultatima istraživanja validnosti verzija ACT na drugim jezicima. Stoga bi ga, kao korisno i pouzdano sredstvo za procenu kontrole astme, trebalo više koristiti u svakodnevnoj kliničkoj praksi.

Ključne reči:
astma; ankete i upitnici; srbija.

Introduction

Asthma is a heterogeneous disease characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms (wheeze, shortness of breath, chest tightness and cough) that vary over time and in intensity together with a variable expiratory airflow limitation [1]. Asthma is one of the most common chronic diseases worldwide with

the estimated 300 million affected individuals. Prevalence of asthma in Belgrade, Serbia is 6.8% in adults[2]. The developed countries have high health care expenditure on asthma, especially when inadequately controlled[3].

The guidelines on diagnosis and management of asthma were previously focused on the assessment of severity of symptoms, limitation and variability of airflow, but their disharmony suggested that the severity alone, cannot be used for the assessment of therapy and classification[4]. On this basis, the revised Global Initiative for Asthma (GINA) guidelines, in year 2006, proposed a new classification based on the level of control rather than the severity of asthma[5]. Achieving and maintaining an adequate asthma control was defined as the primary goal of asthma management. When asthma is well-controlled, the patients have no night and day symptoms, lead active life, have little, or no need for reliever medication, have normal, or near-normal lung function and no exacerbations. These are the parameters that the doctors usually integrate to assess the asthma control and create adequate treatment plans.

Nevertheless, asthma still remained poorly controlled in a majority of patients[6,7]. These circumstances alarmed the need for the development of tools that are easy and fast to administer in everyday practice, that identify the parameters that accurately assess control, and are simple to manage both by the patients and physicians. The Asthma Control Test (ACT) is a short and useful patient-administered questionnaire for identification of patients with poor asthma control in clinical settings, according to the GINA criteria[8,9]. The ACT score is a valid tool to simply assess the current level of asthma control in terms of symptoms, rescue medication use, and (peak expiratory flow – PEF) variability, and it also correlated better than spirometry with the treatment decisions made by the asthma specialists (PEF and exhaled nitric oxide – NO)[10,11].

Concerning the valuable role of ACT in the asthma control assessment, the aim of this study was to validate a Serbian version of the Asthma Control Test (ACT) in the adults with asthma.

Methods

This was an observational, prospective, multicentric study conducted from January 1st, up to December 31st, 2016, in two health institutions in Belgrade, the Clinic for Pulmonary Diseases, Clinical Center of Serbia and the Institute for Students Health Care. The patients over 18 years of age diagnosed with asthma according to the Global Initiative for Asthma (GINA) classification[1], who attended a routine check-up visit were included in the study. The exclusion criteria were chronic respiratory disease and/or acute respiratory tract infection in preceding 4 weeks. The Global Initiative for Asthma (GINA) classification was performed in order to separate the patients' disease status at the: well-controlled, partially controlled and uncontrolled asthma[1,5].

The ACT consisted of 5 items with 5 response options evaluating different dimensions associated with asthma control in previous 4 weeks; the daily activity limitations due to asthma, the presence of day or night symptoms, the use of rescue medications, and the subjective perception of asthma control (Figure 1). The questions were scored from 1 (worst) to 5 (best). The sum of the scores classified asthma control as: uncontrolled asthma (< 19 points), controlled asthma (20–24 points), and optimal disease control (25 points)[9,10].

The ACT questionnaire was used on two visits, at the baseline visit and 6 months later. During the first visit, asthma control was assessed according to the GINA guidelines[1]: the socio-demographic data (age, gender, educational status) were collected, the asthma diagnosis date recorded and classification of severity of disease according to the GINA criteria was made.

At both visits, the spirometry measurements were performed in accordance with the American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines[12] as well as lung auscultation (breath sound, expiration duration, wheezing). The data about current therapy modality was also collected. The patients' perception and the physicians opinion of asthma control were classified into 5 categories: total control, good, partial, poor, without any control. The patients categorized their asthma control status according to the question 5 in the ACT questionnaire, while the physicians categorization rely on the clinical and spirometry findings. The study protocol was approved by the Ethics Committees of Clinic for Pulmonary Diseases and the Institute for Students Health Care. The patients signed the informed consent, and the whole study was planned according to the ethical guidelines detailed in the Declaration of Helsinki (revised in 1983).

Statistical analysis

A sample size was calculated according to Rosner[13]. To power the study to 80%, 0.05 significance level and standard deviation in the ACT values of 4.0 from the previous pilot study produced the sample size of minimum 220 subjects. Assuming 10% drop-out rate, we finally included 250 subjects in this current validation study. The validity of the ACT was analyzed for its feasibility, reliability, transversal and longitudinal validity and predictive capacity.

Feasibility of the ACT was evaluated by the percentage of missing responses and the time required to complete the questionnaire. A percentage of completed questionnaires of more than 80% and a mean time of completion of less than 5 minutes were expected.

Transversal validity of the ACT questionnaire was assessed through the ACT relationship with the lung function parameters (forced expiratory volume in the first second – FEV1 (L, %), forced vital capacity – FVC (L, %), and auscultation assessment (quality of breath sound, wheezing and expiration quality). The correlation analysis was performed to test relation between the ACT and FEV1 (%), and the FVC (%) expectable correlations were low to moderate. The relation between the ACT scores and asthma symptoms was estimated through the auscultation method (quality of breath sound, wheezes and expiration duration). One way analysis of variance (ANOVA) was used to compare the differences in the sub-groups.

Test o kontroli astme

Ovaj test može pomoći osobama sa astmom da procene stepen kontrole astme.

Molimo Vas da zaokružite odgovarajući broj pored odgovora za svako pitanje. Ukupno ima PET pitanja.

Rezultat ovog testa ćete dobiti sabiranjem brojeva koji odgovaraju svakom Vašem odgovoru. Molimo Vas da prodiskujete rezultate sa Vašim lekarom.

1. U protekle 4 nedelje, koliko često Vas je astma ometala u obavljanju uobičajenih aktivnosti na poslu, u školi ili kući?

Uvek	Vrlo često	Povremeno	Retko	Nikada
1	2	3	4	5

2. U protekle 4 nedelje, koliko često ste imali osećaj nedostatka daha?

Češće od jednom dnevno	Jedanput dnevno	3-6 puta nedeljno	1-2 puta nedeljno	Nikada
1	2	3	4	5

3. U protekle 4 nedelje, koliko često su Vas simptomi astme (šištanje u grudima, gušenje, kašalj, pritisak u grudima) budili noću ili rano ujutru?

4 i više noći nedeljno	2-3 noći nedeljno	Jedanput nedeljno	Jednom ili dva puta	Nikada
1	2	3	4	5

4. U protekle 4 nedelje, koliko često Vam je bila potrebna pumpica za otklanjanje simptoma ili inhalator?

3 i više puta dnevno	1 ili 2 puta dnevno	2 ili 3 puta nedeljno	1 nedeljno ili ređe	Nikada
1	2	3	4	5

5. Kako biste ocenili kontrolu Vaše astme u protekle 4 nedelje?

Uopšte nije kontrolisana	Slabo kontrolisana	Donekle kontrolisana	Dobro kontrolisana	Potpuno kontrolisana
1	2	3	4	5

Fig. 1 – Asthma Control Test (ACT) – Serbian version.

Longitudinal validity was analyzed by testing the mean change in the ACT scores with changes in the clinical variables [FEV1 (%) and FVC (%)], which were categorized into 3 groups: reduction, without change and increase. The change in asthma control as perceived by the physician and patients was analyzed according to 5 categories questions.

Reliability analysis

The ACT questionnaire was estimated in terms of internal consistency and test-retest reliability. Internal consistency was measured by the Cronbach α statistic and test-retest reliability through the interclass correlation coefficient (ICC) [14]. The ICC greater, or equal to 0.70 was expected.

Predictive potential of the ACT score

The predictive potential of the ACT score compared to the clinical item (FEV1) for the asthma control prediction, perceived by the physicians and patients, respectively was performed by using the receiver operating characteristic (ROC) curve analysis. We aimed to test the diagnostic accuracy of FEV1, ACT score and model of integrated FEV1 and the ACT. The model formulated by the binary logistic regression analysis enabled the integration of FEV1 and ACT score and the areas under the receiver operating characteristic (AUC-ROC) curves with 95% confidence interval (CI) and *p* values were calculated.

According to the Hosmer and Lemeshow [15] (H-L) rules for the logistic models, the discriminative abilities of the

models were classified per their AUC values as poor ($0.5 \leq$ AUC < 0.7), acceptable ($0.7 \leq$ AUC < 0.8), excellent ($0.8 \leq$ AUC < 0.9) and outstanding (AUC ≥ 0.9). p value < 0.05 was considered a statistically significant. For all analyses, the SPSS software (IBM®SPSS®version 22.0) was used.

Results

A total of 250 consecutive adult asthmatic patients were recruited in a prospective observational study, but 3 patients did not complete the ACT at the baseline visit (3 participants gave up during the first visit). Table 1 presents the basic patients' data for the whole study group and the sub-groups, according to the GINA recommendations for the asthma status assessment. One hundred and eleven (45%) patients had intermittent, while 109 (44.1%) mild persistent, 19 (7.7%) moderate persistent and 8 (3.2%) severe persistent asthma.

The study sub-groups with different level of asthma control did not differ by gender distribution, age, level of education and asthma control. Our subjects had a minimum of secondary school education. It was obvious that the subject with uncontrolled asthma had the significantly lower pulmo-

nary function parameters (FVC, FEV1 and FEV1/FVC), compared to the subjects with well-controlled disease and for several measures also to partially controlled subjects.

Feasibility

The ACT test was completed by 98.8% of patients with the mean time [standard deviation (SD)] of completion of 4.5 (4.0) minutes.

Reliability

The Cronbach α for the ACT was 0.81 for the whole study group. The test-retest reliability estimated by the ICC was 0.82 (95% CI 0.69–0.95).

Transversal validity

The correlation of ACT score and lung function parameters (FEV1 and FVC) was analyzed for transversal validity. According to the correlation coefficient values the correlation was significant, but low (Figure 2).

Table 1

The basic demographic and clinical data of asthma patients categorized according to the Global Initiative for Asthma (GINA) criteria [5]

Parameter	Whole group n = 247 (100.00%)	Well controlled asthma n = 54 (21.9%)	Partially controlled asthma n = 114 (46.1%)	Uncontrolled asthma n = 79 (32.0%)	p
Gender (male/female), n (%)	98/149 (39.7/60.3)	19/35 (35.2/64.8)	52/62 (45.6/54.4)	27/52 (34.2/65.8)	ns
Age (years), mean ± SD	25.4 ± 8.91	24.4 ± 8.01	25.9 ± 9.22	25.6 ± 9.10	ns
Education, n (%)					
secondary	230 (93.1)	51 (92.7)	104 (92.0)	75 (94.9)	ns
graduated	17 (6.9)	4 (7.3)	9 (8.0)	4 (5.1)	
Asthma duration (years), mean ± SD	12.2 ± 7.72	12.01 ± 7.30	12.09 ± 8.01	12.43 ± 7.66	ns
FVC (L), mean ± SD	4.74 ± 1.22	4.90 ± 1.14	4.88 ± 1.09	4.43 ± 1.11[a.b]	0.012
FVC (%), mean ± SD	106.6 ± 14.78	110.6 ± 16.73	107.2 ± 12.97	102.8 ± 14.75[aa]	0.008
FEV$_1$ (L), mean ± SD	3.71 ± 0.88	3.92 ± 0.82	3.82 ± 0.83	3.41 ± 0.93[aa.bb]	0.001
FEV$_1$ (%), mean ± SD	97.1 ± 17.23	102.9 ± 14.96	98.2 ± 14.19	91.4 ± 20.81[a.b]	< 0.001
FEV$_1$/FVC, mean ± SD	78.3 ± 9.95	80.5 ± 6.99	78.6 ± 9.63	76.4 ± 11.75[a]	0.056

FVC – forced vital capacity; FEV$_1$ – forced expiratory volume in 1st second; SD – standard deviation.
p from the ANOVA (post-hoc Tuckey test) or χ^2 test, where appropriate.
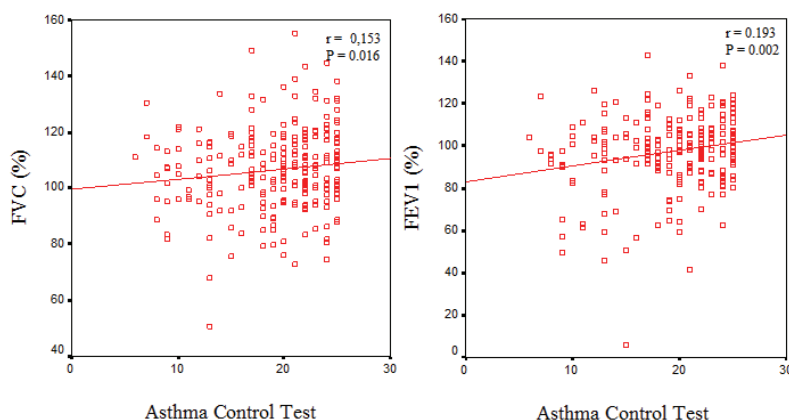

Fig. 2 – Correlation between the Asthma Control Test (ACT) and forced vital capacity (FVC) (%) and forced expiratory volume in 1st second (FEV1) (%) (the Pearson's parametric correlation).

Then we tested the ACT scores values in the sub-groups according to the auscultation measures: breath sound, wheezes and expiration duration. The results are presented in Table 2.

Table 2

The Asthma Control Test (ACT) scores according to lung auscultation (breath sound, wheezing and expiration quality)

Parameters of pulmonary function	mean ± SD	p
Breath sound intensity		
normal	19.3 ± 4.80	0.019
week	15.2 ± 5.67	
Wheezing		
without	20.2 ± 4.24	
low-tone	16.4 ± 5.39*	
high-tone	16.1 ± 6.50*	< 0.001
polyphone	14.4 ± 4.77***	
Expiration duration		
normal	19.7 ± 4.66	< 0.001
prolonged	17.0 ± 5.21	

* $p < 0.05$; *** $p < 0.001$ compared respectively to normal pulmonary function regarding wheezing (without wheezing).

The ACT scores were significantly lower (i.e., the worse disease control) in the patients with the worst lung auscultation findings.

Longitudinal validity

Table 3 presents the results of the mean change of the ACT scores in the subgroups by the level and direction – FVC and FEV1 were categorized as: reduction, without change and increase between two visits. The change in scores between baseline and 6-months visits was not associated with the change in FVC and FEV1 (% predicted).

Figure 3 shows the correlation of ACT score with physician's and patient's assessment of asthma control. According to both patients and physicians opinion, the ACT score was significantly lower in the patients with uncontrolled asthma. The asthma control assessment was equal to the physician's opinion in 145 (58.7%) patients.

Diagnostic accuracy (predictive potential) for the asthma control level

Table 4 presents the results of ROC analysis performed to test diagnostic accuracy of the FEV1 and ACT score, and its integrated Model, for the asthma control classification.

According to the H-L rules, the ACT score had an excellent diagnostic accuracy as stated by the physicians' asthma control classification and even outstanding accuracy according to the patients' classification. FEV1 had lower diagnostic accuracy (poor according to the H-L rules) by both classifications. The model of integrated both examined parameters (ACT and FEV1) did not improve the diagnostic accuracy neither to the physicians' nor to patients' classifications (Figure 4).

Table 3

The mean change in the Asthma Control Test (ACT) scores according to a change in clinical parameters of pulmonary function

Parameter	Reduction	Without change	Increase	p
FVC (%), mean ± SD	0.75 ± 11.62	-2.83 ± 3.37	3.06 ± 9.76	0.436
FEV$_1$ (%), mean ± SD	-1.87 ± 14.51	-10.0 ± 8.62	7.5 ± 23.54	0.163

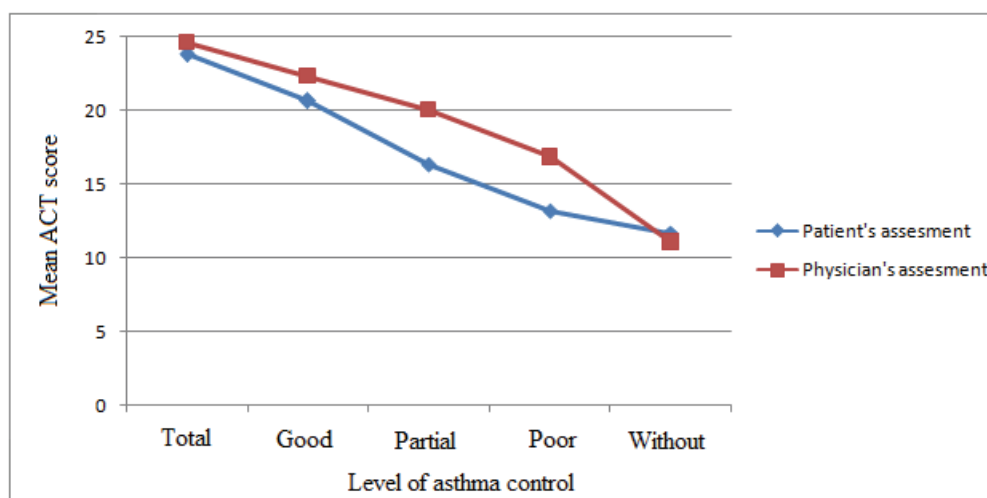**FVC – forced vital capacity; FEV$_1$ – forced expiratory volume in 1st second.**

Fig. 3 – The mean Asthma Control Test (ACT) scores according to the level of asthma control as assessed by the patients and physicians.

Table 4

Diagnostic accuracy of the separate parameters and the Model of the integrated forced expiratory volume in 1st second (FEV_1) (%) and the Asthma Control Test (ACT) score according to the patients' and physicians' criteria for the asthma control classification.

Parameter	Physicians' classification		Patients' classification	
	AUC (SE)	95% CI	AUC (SE)	95% CI
ACT score	0.841 (0,025)	(0.792–0.890)***	0.936 (0.018)	(0.902–0.971)***
FEV_1 (%)	0.654 (0.036)	(0.585–0.725)***	0.627 (0.041)	(0.546–0.707)***
Model of integrated FEV_1(%) and ACT score	0.845 (0,025)	(0.796–0.895)***	0.891 (0.023)	(0.845–0.937)***

AUC – area under the curve, SE – standard error, CI – confidence interval.
***$p < 0.001$ according to the receiver operating curve (ROC) analysis.**
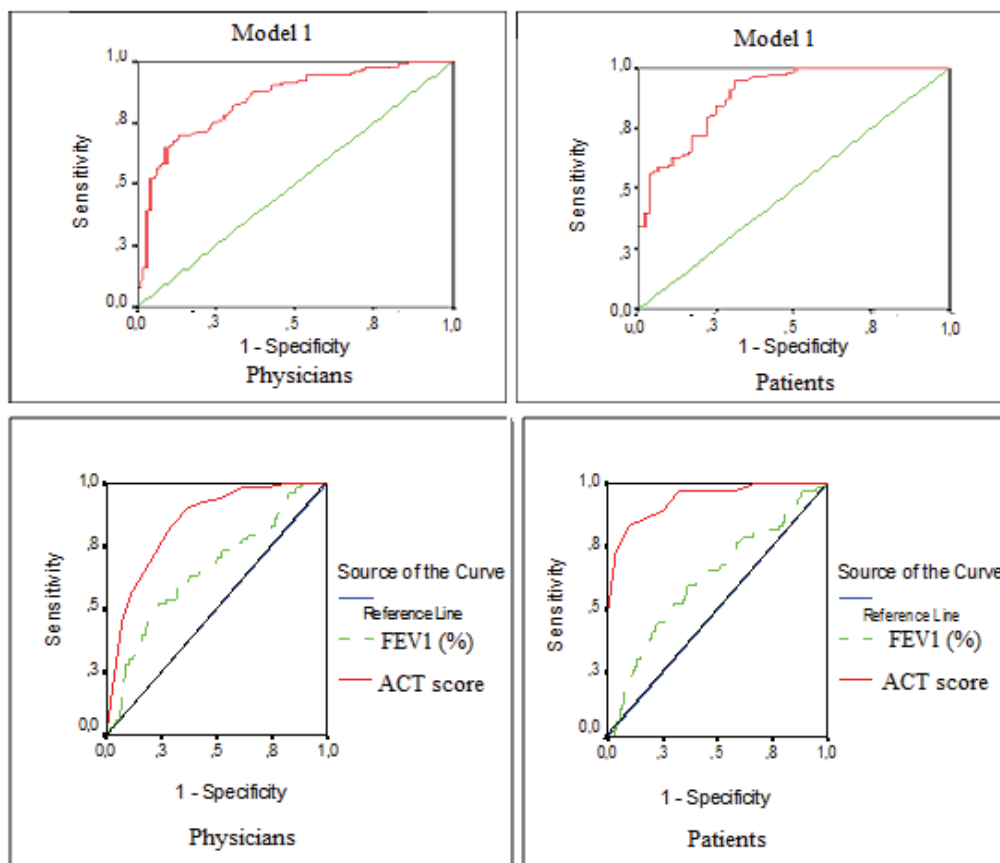

Fig. 4 – Receiver operating characteristic (ROC) analysis of the forced expiratory volume in 1st second (FEV_1), the Asthma Control Test (ACT) score and the Model 1 (integrated FEV1 and the ACT score) in diagnostic capability for the asthma control prediction according to the patients' and physicians' criteria.

Discussion

Asthma, although heterogenic in nature, is a well-defined disease, however, the assessment and therefore the effective management of it is still elusive, so the equal emphasis is put nowadays both to asthma severity and asthma control [1, 5]. The Asthma Control Test has been developed and validated as a test of appropriate assessment of asthma control, responsive to changes in asthma control over time, proven to be useful tool to the clinicians and easy to apply in everyday clinical care [8, 16]. After validation of original ACT questionaire, the validation of ACT questionaire its translations was reported in the last decade [17–22]. Although valida-

tion methodology was different in these studies, the overall findings regarding the translated ACT versions were consistent, confirming its value to assess asthma control. The spirometry testing is, on the other hand, the objective assessment of lung function status, but given the variable nature of asthma, it cannot be used as a sole predictor of disease status and control, and it is recommended to be combined with other tests for better asthma management [23].

In our research, in addition to the spirometric testing, we investigated the lung auscultation findings for transversal validity. Although more subjective parameter as lung function values, it is clinically relevant and performed in everyday practice for the estimation of asthma control. Our results

showed a significant correlation of asthma control assessment with the ACT and auscultation findings. The correlation of ACT score and lung function parameters was significant in our and the studies of Nathan et al. [8] and Gurková and Popelková [21], but not significant in the studies performed by Popovic-Grle et al. [22] and Lababidi et al. [18]. The only lung function parameter that was significantly associated with the ACT score was a peak expiratory flow (PEF) in Popovic-Grle et al. [22]. The correlation between the ACT and FEV1 was different in these studies probably because of the difference in the predicted values of patients FEV1 [8, 16, 17, 22].

For the testing of longitudinal validity, the highest increase in the ACT score was the most evident in the patients with the improved lung function measured by FEV1 and FVC. With the patients where decrease or no change in FEV1 and FVC was recorded, the ACT score was only slightly increased, or even decreased. Those changes were not statistically significant due to the large inter-individual variations of ACT scores. The finding is in accordance to the performed correlation analysis, which showed a significant positive relationship.

The ACT score was significantly positively correlated both in physicians' and patients' assessment of asthma control. We used the same 5-point scale of asthma control perception as in validation of original test (total, good, partial, poor and without control). Different scales were used by other authors [17], but all reports showed the positive and significant correlation of ACT score and the subjective assessment of asthma control. We did not test the difference among physicians' and patients' assessments in this research, the information which could contribute to the overall patient/physician relationship that was stressed out as important

to the asthma management [1], because this important subject was not the aim of this study.

Our results showed an excellent and outstanding diagnostic accuracy of ACT score according to physicians' and patients' classification, and the result remain unchanged after integrating the lung function tests, as reported previously in the studies with the same methodology [17].

The reliability of Serbian translation was very similar to the original test as far as internal consistency was concerned (0.81 to 0.85 respectively), as well as to the version of ACT in other languages which were testing this parameter. The internal reliability of 5 questions in the ACT survey was 0.92 in the Arabic version, 0.87 in Czech's version, 0.85 in the original Nathan version, 0.83 in the Spanish version and 0.796 in Croatian version [8, 17, 18, 21, 22]. The Cronbach's α coefficient was slightly lower in the ACT performed by the North African population and it ranged from 0.58 for the Algerian ACT version to 0.67 for the Moroccan ACT version [19].

Conclusion

Almost 75% of asthma patients included into investigation were either partially controlled, or uncontrolled. This in itself suggest that the efforts for all aspects of asthma management should be continued.

The feasibility result of the Serbian version shows that the ACT test is easily applicable, understandable and not time-consuming. Overall results of our study also confirm that the reliability, validity and accuracy of Serbian translation contribute to the established value of original ACT questionaire and its versions in other languages. Therefore, it should be applied more in everyday clinical practice of respiratory physicians as a useful and reliable tool for the asthma control assessment.

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