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RESEARCH PAPER

The Asthma Control Test (ACT) as an alternative tool to Global Initiative for Asthma (GINA) guideline criteria for assessing asthma control in Vietnamese outpatients

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Abstract

Aims: To determine the reliability and validity of the Asthma Control Test (ACT) to detect Global Initiative for Asthma (GINA)-defined uncontrolled or partly controlled asthma, and to determine the agreement between ACT and GINA in classifying asthma control among Vietnamese patients.

Methods: A cross-sectional study was performed in 323 of 360 invited outpatients with asthma in Ho Chi Minh City to compare the ACT and GINA classification for asthma control.

Results: Internal consistency of the ACT (Cronbach's alpha) was 0.83. The kappa coefficient of 0.55, based on the ternary split, represents moderate agreement between the two rating systems with a correctly classified rate of 75%. The area under the receiver operating characteristics curve for the ACT score predicting GINA control was 0.85. To detect GINA-defined 'not controlled asthma', the ACT had a sensitivity of 70%, specificity of 93%, and a positive predictive value of 89%, with a cut-off point of 19. The validity of the ACT with regard to agreement with the GINA classification was consistent across both sexes, but less so in adolescents or younger adults. The ACT score was significantly correlated with the percentage predicted forced expiratory volume in 1 second ($r=0.35$, $p<0.001$) and percentage predicted peak expiratory flow ($r=0.26$, $p<0.001$).

Conclusions: The Vietnamese ACT is useful for identifying outpatients with GINA-defined uncontrolled or partly controlled asthma.

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The full version of this paper, with online appendices, is available online at www.thepcrj.org

Introduction

The prevalence of asthma in Vietnam is estimated to be 5% in adults.[1] Although asthma is not curable it is treatable, and the best way to reduce the burden of disease is to control it. Current Global Initiative for Asthma (GINA) guidelines emphasise the need to evaluate asthma control to guide asthma management decisions.[2] Guideline-defined asthma control can be achieved and maintained for the majority of patients in controlled trial settings.[3–5] In Vietnam, the GINA guidelines were recently used as the main reference source for the national asthma guidelines.[1] A recent study suggested that the level of asthma control in Vietnam is poorer than expected, with less than 1% of patients studied meeting the definition of asthma control.[6] Apart from the lack of preventive medications, limited access to asthma control assessment is another factor responsible for this poor level of asthma control. It is difficult to follow GINA criteria to evaluate asthma control because of the lack of access to lung function assessment. A simple, applicable, and accessible but validated tool to assess asthma control is therefore urgently

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needed for patients with asthma in Vietnam. The Asthma Control Test (ACT) questionnaire – a simple, self-administered, and rapidly completed assessment tool – might be appropriate to meet this demand.[7–9] The ACT has the added advantages that it does not require lung function assessments and can be applied at all levels of healthcare.[7,10] However, this tool has not been validated as a reliable predictor of GINA-defined asthma control in Vietnam. A study was therefore undertaken to validate the Vietnamese version of the ACT.

Methods

This was a prospective study recruiting ambulatory patients aged ≥12 years with asthma at the University Medical Centre, Ho Chi Minh City, Vietnam between January 2008 and January 2009. The objective was to determine the reliability and validity of the ACT as a means of detecting GINA-defined uncontrolled and partly controlled asthma (together labelled 'not-controlled asthma' according to GINA). The study also set out to determine the reliability and validity of the agreement between ACT and GINA in classifying asthma control, as well as to determine the consistency across age, gender, and asthma severity subgroups.

Patients who satisfied the inclusion criteria (≥12 years old, asthma diagnosed according to GINA in the past 6 months, literate in Vietnamese, and able to perform spirometry) were included in the study. Subjects were excluded if they had any of the following exclusion criteria: hospitalised for asthma or had an acute upper or lower respiratory tract infection within 4 weeks prior to study; had a known respiratory disorder other than asthma and/or systemic/thoracic abnormalities that influence normal lung function; or had smoked ≥10 pack-years. All eligible patients had to provide informed consent before being entered into the study.

The questionnaire used was the ACT Vietnamese version for adults, downloaded from www.asthmacontroltest.com with user approval obtained from the authorised owner.

With a presumption based on the literature that the ACT can detect GINA-defined 'not-controlled asthma' with a sensitivity of 70% and a specificity of 75%,[7,8] the calculated sample size was 323 subjects.

Eligible patients answered and submitted the ACT questionnaire to the investigators before physician assessment. Patients then performed spirometry tests followed by interviews with a pulmonologist who evaluated their asthma control and provided treatment modifications as required.

A cognitive debriefing was performed with 20 patients before conducting an official debriefing. The modified questionnaire was re-tested with 10 other asthmatic patients. The final version of the questionnaire was then used for this research.

Data analysis

SPSS Version 16.0 software was used to analyse the data and a p value of <0.05 was considered statistically significant. Cronbach's alpha was used to determine the internal reliability of the five items of the questionnaire.

The validity of the ACT as a means of detecting GINA-defined 'not-controlled asthma' using the GINA binary split criterion as the gold standard ('not-controlled' being combined uncontrolled and partly controlled asthma versus controlled asthma) was determined by sensitivity, specificity, positive and negative predictive values (PPV and NPV), likelihood ratios (LR), the correctly classified rate and area under the ROC curve (AUC). In the ternary split of GINA-defined asthma control, the agreement between GINA rating (uncontrolled, partly controlled and controlled asthma) and ACT rating (ACT score <15, 15–19 and 20–25) in the classification of asthma control was determined using the kappa coefficient of agreement and correctly classified rates.

Subgroup analyses were undertaken based on asthma severity, gender, and age to explore the consistency of the validity of the ACT and its agreement with GINA across the subgroups.

Spearman's coefficient between the ACT and three levels of treatment modifications, as well as ANOVA testing to assess the differences in mean ACT scores among these levels, were applied.

The relationship between ACT and the percentage of forced expiratory volume in 1 second (%FEV_1) compared with the predicted value, and between ACT and the percentage of peak expiratory flow (%PEF) compared with the predicted value, was determined by Pearson correlation coefficients (r).

Results

Revision of the questionnaire

The cognitive debriefing showed that most patients understood four of the five questions. However, the fourth question caused confusion as it asked about rescue medication usage but some patients answered about preventive medication. The question was then revised by rewording as 'rescue medication' and giving a brief explanation of what these medications actually are, citing examples such as salbutamol and Ventolin which are known and commonly used in Vietnam. The revised version questionnaire then underwent further cognitive debriefing, resulting in no residual confusion.

Characteristics of study patients

A total of 360 patients were invited to participate in the study; 323 (90%) of mean age 36 years (range 12–80) agreed to participate. Females comprised 57% of the participants with a mean percentage predicted FEV_1 and PEF of 86% and 88.6%, respectively, and a mean ACT score of 20.5. Other characteristics are described in Table 1, in which GINA stage 3 is prominent (28%), but in general the patients were equally distributed among the four stages. Most of the patients were using preventive medication; the majority had controlled asthma according to both GINA and ACT criteria and were continued on the same treatment after their visit.

Table 1. Characteristics of study patients

	No	%
Asthma severity according GINA		
Stage 1	71	22
Stage 2	82	25
Stage 3	90	28
Stage 4	80	25
Preventive medication use before visit		
No preventive drugs	14	4.3
Inhaled corticosteroid (ICS)	65	20.1
Combination of ICS and long-acting β_2-agonist	244	75.5
Asthma control		
GINA classification		
Uncontrolled	48	14.9
Partly controlled	97	30
Controlled	178	55.1
ACT classification		
Uncontrolled	31	9.6
Partly controlled	84	26
Controlled	208	64.4
Treatment modification		
Maintain current treatment	133	41.2
Step up	72	22.3
Step down	118	36.5

ACT=Asthma Control Test; GINA=Global Initiative for Asthma.

Table 2. Agreement between GINA classification and ACT classification of asthma control

GINA / ACT	GINA-defined control			Total n (%)
	Uncontrolled n (%)	Partly controlled n (%)	Controlled n (%)	
ACT <15 (uncontrolled)	27 (8.4)	4 (1.2)	0 (0)	31 (9.6)
ACT 15–19 (partly controlled)	21 (6.5)	50 (15.5)	13 (4.0)	84 (26.0)
ACT ≥20 (controlled)	0 (0)	43 13.3)	165 (51.1)	208 (64.4)
Total n (%)	48 (14.9)	97 (30.0)	178 (55.1)	323 (100)

Kappa=0.55, p<0.001, correctly classified rate=75%

ACT=Asthma Control Test; GINA=Global Initiative for Asthma.

Table 3. Difference in mean Asthma Control Test (ACT) score across three categories of treatment modification

	Treatment modification			Total (n=323)
	Stepping down (n=118)	Maintaining (n=133)	Stepping up (n=72)	
Mean ACT score	21.6	21.6	16.6	20.5

p<0.001 (ANOVA test)

Reliability and empirical validity of the ACT

Cronbach's alpha was 0.83, indicating a high consistency among the answers to the five questions of the ACT questionnaire.

The cut-off point for the ACT in detecting GINA 'not-controlled asthma' was 19, which yielded the largest AUC of 0.85 with a sensitivity of 70%, specificity of 73%, PPV of 89%, NPV of 79%, positive LR of 9.6, negative LR of 0.3, and a correctly classified rate of 83%. These characteristics indicate a good screening tool. The consistency of these findings was maintained across subgroups of patients based on gender, age, and asthma severity (see Appendix 1 available online at www.thepcrj.org).

Agreement between ACT and GINA in classifying three levels of asthma control

The kappa value was 0.55 (Table 2), indicating a moderate level of agreement beyond chance between the two rating systems (Î=0.4–0.6).[11,12] Both rating systems correctly classified 75% at three levels of asthma control.

In subgroup analyses (see Appendix 2 available online at www.thepcrj.org), the kappa coefficient and correctly classified rates were worse in patients with stage 4 asthma than in those with other stages. These two parameters were, however, similar in patients with mild asthma (stages 1 and 2) and in those with moderate to severe asthma (stages 3 and 4), and in females compared with males. On the other hand, the kappa coefficient indicated only fair agreement in adolescents (0.2<κ=0.39<0.4) with a correctly classified rate of 69%, which is worse than in adults who had a kappa of 0.58 and a correctly classified rate of 76%.

Responsiveness of the ACT to specialist treatment modification

The ACT scores for groups receiving different asthma treatment decisions after medical assessment are shown in Table 3. The mean ACT score was similar for those in whom treatment was either maintained or stepped down (p=0.9) but much lower in those in whom treatment was stepped up. There was a significant correlation between the ACT score and asthma treatment modification (Spearman's r=–0.36, p<0.001).

Relationship between ACT score and %FEV$_1$ and %PEF

The Pearson coefficient between the ACT score and %FEV$_1$ was 0.35 (p<0.001) and between the ACT score and %PEF it was 0.26 (p<0.001).

Discussion

Achieving and maintaining asthma control are fundamental elements of asthma management.[2] Practical tools are needed to assess asthma control in asthma management. Most tools used to evaluate asthma control consider airflow obstruction as a criterion. However, this is often very difficult to perform in developing countries such as Vietnam because spirometers and peak flow meters are not readily available. A tool is required that measures the multidimensional nature of asthma control and that is easy and quick to administer and interpret in order to facilitate the assessment of asthma control in clinical practice. The ACT has proved to be a valid tool for this purpose in other settings.[7–9]

Main findings, and interpretation in relation to previously published work

This is the first evaluation of the ACT undertaken in Vietnam. It was found to be able to predict GINA-defined 'not-controlled asthma' (positive LR 9.6, PPV 89%) with a sensitivity of 70% and a specificity of 93%. The sensitivity is similar to studies from America (69–71%)[7,9] and Hong Kong (70.5%),[13] but lower than figures reported in China (80%)[14] and Korea (85%).[15] The specificity is similar to a study from Korea (93%),[15] and reached a higher level than in some other countries.[7,9,13,14,16] With a cut-off point of ≤19, the ACT correctly predicted GINA-defined 'not-controlled asthma' in 89% of cases while an ACT score of ≥20 predicted GINA-defined controlled asthma in 79% of cases. The area under the ROC curve (AUC) was acceptable at 0.85 (95% CI 0.80 to 0.88) and of similar magnitude to previous findings for the ACT.[7,14,17–20] The ACT has been shown to be a reliable tool by previous authors,[7,8,14–17,21,22] and this is confirmed by this study in a Vietnamese outpatient setting in which Cronbach's alpha reached 0.83, indicating a high consistency among the answers to the five questions.

Most patients in this study population were using preventive medications (Table 1). These numbers are much higher than those in other studies (6–13.6%),[23,24] including a Vietnamese subgroup in an international study.[23] This may explain why the number of patients with severe asthma in this study is higher than in some other studies,[23,25–28] while the rate of patients with controlled asthma in this study is also higher than that in other studies.[23,26,28] This result supports the concept that severity may not be an important index in asthma management.[2] It is clear that 53% of patients in this study had moderate to severe asthma, but their asthma control is good because of their use of preventer therapy. On the other hand, the proportion of patients with moderate to severe asthma in some other studies is low and the rate of asthma control is also quite low,[23,25,27,28] which may be due to lack of appropriate therapy or a poor response to such therapy.

In this study a maximum ACT score of 25 indicates controlled asthma; 94.7% of those with an ACT score of 25 had controlled asthma, 5.3% had partly controlled asthma and none had uncontrolled asthma according to the GINA definition. In addition, patients who responded with the maximum 5 points for the fifth question (indicating their asthma is completely controlled) can be relied upon in our study population. Seventy-three patients in this study responded with 5 points for the fifth question, of whom 83.6% had controlled asthma, 16.4% had partly controlled asthma, and 0% had uncontrolled asthma according to the GINA definition. This suggests that, in patients who rated 5 points for the fifth ACT question or had an ACT total score of 25, none had GINA-defined uncontrolled asthma.

The kappa level of agreement between the two systems was 0.55, representing moderate agreement between the two rating systems,[11] while the correctly classified rate was 75%. Another positive finding in this study was no extreme difference in classification of asthma control between the two rating systems: no patient had an ACT score of ≥20 while having GINA-defined uncontrolled asthma and no patient with GINA-defined controlled asthma had an ACT score of <15 (Table 2).

The subgroup analyses (Appendices 1 and 2) showed that the value of the ACT in detecting GINA-defined 'not-controlled asthma' and the agreement between the ACT and GINA in classifying asthma control was similar in both sexes and groups of patients who had mild asthma (stages 1 and 2) to those who had moderate to severe asthma (stages 3 and 4). The correctly classified rate in assessing asthma control of the two rating systems (GINA and ACT) (both two-level and three-level classification) was worse in patients with stage 4 asthma (75% and 69%, respectively). The validity of the ACT in adolescents is worse than in adults with regard to all test parameters except specificity. The same was found when comparing the younger age group with the older age group. This may be because adolescents and younger adults pay less attention to their health, resulting in recall bias during the completion of the questionnaire. This was confirmed again by the kappa agreement coefficients and the correctly classified rates of adolescents and younger groups, which were poorer than those in older age groups.

Some studies state that the ACT is poorly correlated with FEV_1[17] or suggest that it correlates better with PEF than with FEV_1,[29] but the present study found the opposite. The ACT total score was correlated with $\%FEV_1$ ($r=0.35$, $p<0.001$) and this correlation was better than the correlation between the ACT and %PEF ($r=0.26$, $p<0.001$).

The mean ACT score of those who were stepped up (16.6) was significantly lower than the mean score of those who were stepped down (21.6) and those who were maintained on treatment (21.6) ($p<0.001$, Table 3). This suggests that ACT can usefully predict patients who need increased treatment due to poor asthma control. This is important in clinical practice because these patients need to have their treatment reviewed as well as addressing risk factors for poor asthma control.[30] A study of 382 patients in Hong Kong found that the ACT could predict step-up of asthma therapy in 70.2% of consultations,[13] suggesting that this tool could actually assist doctors' treatment decisions. Indeed, Ko *et al*. found that the ACT correlates better with treatment decisions made by asthma specialists than spirometry, PEF, or fractional exhaled nitric oxide measurements.[13]

Limitations of the study

This study has several limitations, including the possibility of patient selection bias as participants represent a convenience sample from a teaching hospital which may not be representative of the overall population of outpatients with

asthma in Vietnam. Patients' recall of asthma symptoms may not be entirely accurate and we cannot rule out recall bias on the part of participating patients. Another limitation is choosing the GINA 2006 classification of asthma control as the gold standard assessment of asthma control. However, there is no real gold standard for measuring asthma control; even the GINA classifications are described as a 'working scheme based on current opinion which has not been validated'.[2]

In spite of these limitations, the study provides evidence that the Vietnamese ACT is a reliable tool to assess asthma control and, with a cut-off point of 19, it can predict GINA-defined 'not-controlled asthma' with a high PPV and a high positive LR. It appears to be a good tool to predict GINA-defined 'not-controlled asthma' and can predict the step-up decision of doctors.

Conclusions

The ACT is a reliable and simple tool that does not require spirometry measurements. This might be a significant asset in the management of outpatients with asthma in Vietnam. The questionnaire score correlates well with treatment modifications and lung function parameters (FEV_1 and PEF). The ACT is easily and quickly completed by patients and can serve as a useful tool in everyday practice to guide adjustments in asthma therapy.

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Conflicts of interest

The authors declare that they have no conflicts of interest in relation to this article

Contributorship

VNN designed, conducted the study and wrote the paper. NC, LTTL and DP contributed in proposal and paper writing.

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Appendix 1: Sensitivity, specificity, predictive values, likelihood ratios, correctly classified rate and AUC of the ACT in subgroups of patients

	N	%	Cut-off point	Sn	Sp	(+)PV	(-)PV	(+)LR	(-)LR	Correctly classified	AUC
Subgroups of asthma severity											
Stage 1	71	22	19	59	100	100	85	-	0.4	87	0.87
Stage 2	82	25	19	78	90	83	86	7.8	0.2	85	0.84
Stage 3	90	28	19	78	90	91	77	7.8	0.2	83	0.87
Stage 4	80	25	19	61	90	86	67	5.9	0.4	75	0.81
Stages 1&2	153	47	19	70	95	88	85	13.9	0.3	86	0.85
Stages 3&4	170	53	19	70	90	89	72	6.9	0.3	79	0.84
Subgroups of gender											
Female	138	43	19	72	92	89	79	8.9	0.3	83	0.86
Male	185	57	19	67	93	89	80	10.8	0.3	83	0.82
Subgroups of age											
12–18	62	19	19	50	92	81	72	6.0	0.6	74	0.74
19–80	261	81	19	74	93	90	80	10.6	0.3	85	0.87
12–35	164	51	19	62	90	82	77	6.6	0.4	79	0.81
36–80	159	49	19	78	95	94	82	16	0.2	87	0.87

ACT=Asthma Control Test; AUC=area under the curve; LR, likelihood ratio; PV=predictive value; Sn=sensitivity; Sp=specificity.

Appendix 2: Agreement and correctly classified rate of GINA and ACT in classifying asthma control in subgroups of patients

	N	%	kappa	p value	Correctly classified
Subgroups of asthma severity					
Stage 1	71	22	0.57	<0.001	83%
Stage 2	82	25	0.53	<0.001	76%
Stage 3	90	28	0.56	<0.001	73%
Stage 4	80	25	0.48	<0.001	69%
Stages 1 and 2	153	47	0.55	<0.001	79%
Stages 3 and 4	170	53	0.53	<0.001	71%
Subgroups of gender					
Female	138	43	0.56	<0.001	75%
Male	185	57	0.53	<0.001	75%
Subgroups of age					
12–18	62	19	0.39	<0.001	69%
19–80	261	81	0.58	<0.001	76%
12–35	164	51	0.46	<0.001	73%
36–80	159	49	0.61	<0.001	77%

ACT=Asthma Control Test; GINA=Global Initiative for Asthma.