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BRIEF COMMUNICATION

The validation of the Turkish version of Asthma Control Test

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Abstract
Introduction Current guidelines focus more on levels of asthma control than on severity of asthma. The original version of the Asthma Control Test (ACT), a self-administered instrument to determine asthma control levels, was designed for English-speaking patients. More recently, the ACT has been translated into many languages and has been validated for many cultures, but this is the first study to evaluate the Turkish version.
Purpose We aimed to evaluate the reliability, validity, and responsiveness of the Turkish version of the ACT among outpatients with asthma.
Method This multicenter prospective study included 220 asthma patients in outpatient clinics in Turkey. The ACT was completed at admission (Visit 1), after 10 ± 2 days (Visit 2), and at 5 ± 1 weeks (Visit 3). At each visit, physicians assessed patients' asthma control levels.
Results The Turkish version of the ACT showed an internal consistency reliability of 0.84 (Cronbach's alpha). Test–retest reliability was 0.85 in stable patients. There was a significant correlation between the ACT and physicians' assessments at admission ($r = 0.68$, $p < 0.001$). The AUC was 0.91, with a sensitivity of 89.06 % and a specificity of 78.26 % for a score of ≤ 19 for screening "uncontrolled" asthma. A minimally important difference of three points on the ACT was consistent with the GINA physician assessment scores between the baseline and the follow-up visits.
Conclusion The Turkish version of the ACT is a valid and reliable tool for assessing asthma control in patients in outpatient settings. The test may facilitate the designation of asthma patients' symptoms as either controlled or uncontrolled.

Keywords Asthma · Adult Asthma Control Test · Validity · Reliability · Responsiveness

The members of The Turkish Asthma Control Test Study Group are given in Appendix section.

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Introduction

Asthma is a common chronic condition associated with substantial morbidity. The objective of asthma therapy is to

achieve optimal disease control and quality-of-life improvements [1].

Current Global Initiative for Asthma (GINA) guidelines for asthma management decisions focus more on levels of asthma control than on asthma severity and suggest subdividing asthma into three categories: controlled, partly controlled, and uncontrolled [2]. Assessing control is a multidimensional process based on symptoms, changes in pulmonary function, and effects on functional status [2, 3].

The Asthma Control Test [ACT] assesses the patient's perspective of his or her current asthma control level, which physicians can use when evaluating the overall status of asthma control [4, 5]. The original version of the ACT was evaluated in English-speaking patients and found to be internally consistent, reproducible, valid, and responsive to clinical changes. The ACT has subsequently been translated into different languages and has been evaluated in various cultural settings [5–14]. The aim of this study was to evaluate the reliability, validity, and responsiveness of the Turkish version of the ACT.

Methods

Turkish version of the ACT

The ACT is a self-administered questionnaire that includes five items assessing the frequency of shortness of breath, general asthma symptoms, use of rescue medications, impact of asthma on daily functioning, and overall self-assessment of asthma control. Each item includes five response options with values ranging from 1 to 5. Responses for each of the five items are summed to yield a score ranging from 5 (poor control of asthma) to 25 (complete control of asthma). An ACT score of <20 indicates uncontrolled asthma. The Turkish version used in the present study was obtained from GlaxoSmithKline, Turkey, with permission (see www.asthmacontroltest.com) [15]. QualityMetric, Inc., culturally adapted and linguistically validated the Turkish version of the ACT [16, 17].

Study population

Our prospective observational, multicenter study involved 14 tertiary hospitals in different geographic regions of Turkey. Participants were recruited from the outpatient clinics of the centers between February 2011 and April 2011. The response rate was 41 %. The study included a total of 220 asthma patients older than 16 years. Asthma diagnosis was based on patient history and on GINA guidelines. Participants had to have a history of recurrent wheezing, shortness of breath, and cough and had to demonstrate objective signs of reversible airway obstruction with at least a 12 % increase in the forced expiratory volume in 1 s (FEV1) after 15 min of inhalation of 200 mcg of salbutamol. We excluded patients with coexisting pulmonary diseases such as pneumonia, bronchiectasis, or emphysema and those having an asthma attack at the time of enrollment.

Study design

The ACT was administered to the sample patients three times: first at enrollment (Visit 1), then 12 ± 2 days later (Visit 2), and last 5 ± 1 weeks later (Visit 3). Before inclusion in the study, each patient provided written informed consent.

During the first visit, sociodemographic variables such as age, gender, and education were recorded. Using the GINA criteria, a physical examination, and patient history, physicians classified each patient's asthma control status as totally controlled, partly controlled, or uncontrolled.

At the second and third visits, all variables except sociodemographic data were collected again. Pulmonary function tests were administered at every visit. Patients completed the ACT themselves with the help of a nurse or office secretary; afterward, physicians assessed each patient's asthma control status blinded to the ACT outcomes.

All patients received asthma treatment (inhaled corticosteroids with or without long-acting beta agonists and short-acting beta agonists PRN) between Visit 1 and Visit 3.

The study was approved by the Central Ethical Committee (B.10.0.İEG.0.1.00.01).

Statistical analysis

Reliability

Internal consistency and test–retest reliability tests were used to assess reliability. We computed Cronbach's alpha coefficients to estimate the internal consistency reliability of the ACT scores at each visit. We determined the test–retest reliability of the ACT scores by computing the intraclass correlation (ICC) between Visit 1 and Visit 2 in stable patients (those whose control status was the same at Visits 1 and 2).

Validity

We tested the construct validity of the ACT measurements through exploratory factor analysis including Barlett's test of sphericity and the Kaiser–Meyer–Olkin (KMO) procedure. Exploratory factor analysis was conducted through principal axis factoring with an oblimin rotation. We chose

the number of factors to rotate using the eigenvalue greater-than-one rule, the percentage of total explained variance for extracted factors, and the number of factors that conceptually may be explained. The specific criteria for accepting the factor construction included factor loading >0.40 and item communality >0.30 [12].

We tested the *cross-sectional construct validity* through the correlation of the ACT scores with the FEV1% predicted value at Visit 1, using the Pearson correlation coefficient.

We examined *convergent validity* through the correlation of the ACT score with the physician's assessment of the patient's control status at Visit 1, using the Spearman correlation coefficient.

Discriminant validity

We used a one-way ANOVA test to determine known-groups validity by comparing mean ACT scores at admission among patients grouped into three categories according to the physician-administered GINA assessments (controlled, partly controlled, and uncontrolled asthma). The second measure consisted of predicted FEV1% values. Patients were categorized into four groups based on their predicted FEV1% values: <30–59 %, 60–79 %, 80–100 %, and >100 %. This stratification was roughly based on asthma severity, as defined by GINA classification guidelines (one-way ANOVA test) [2].

Screening accuracy

We used receiver operating characteristic (ROC) analysis to examine discriminant validity. The criterion used for the ROC curve analysis was physician assessment of asthma control. We conducted two different ROC curve analyses: one for identifying uncontrolled asthma and one for identifying completely controlled asthma. We calculated sensitivity, specificity, percentage of patients correctly classified, positive predictive value (PPV), and negative predictive values (NPV).

Responsiveness

1. Specialist control rating: Responsiveness was examined through changes in GINA-based physician assessments of asthma control between Visits 1 and 3. We used a Jonckheere–Terpstra test to compare changes in ACT scores across various groups of patients, categorized by their change in level of asthma control as determined by physician assessment (worse, no change, improvement by one level, and improvement by two levels).
2. Predicted FEV1% values: We derived the change in the percentage of predicted FEV1 values by subtracting the Visit 1 predicted FEV1% values from the Visit 3 predicted FEV1% values and dividing by the Visit 1 predicted FEV1% values. We then divided the sample into two groups: patients who improved by 10 % or more from Visit 1 and those who did not [5].
3. Minimally important difference (MID): We grouped patients according to their level of change in asthma control between Visit 1 and Visit 3, as determined by physician assessment (worse, no change, and improvement). We used a one-way ANOVA test to compare the changes in ACT scores across these patient groups. We tested MID as a responsiveness parameter and adopted three points of ACT change according to the GINA criteria, as suggested by Schatz et al. [18].

Results

Our sample comprised 220 patients (28.2 % males) with a mean age of 37 ± 12 years (Table 1). At the baseline visit, specialists rated asthma control as totally controlled in 22.3 % of the 220 patients, partly controlled in 38.6 %, and uncontrolled in 39.1 %. At the baseline, all the GINA (controlled, partly controlled, and uncontrolled) groups conformed to the MID of three points of change on the ACT.

Reliability

The Turkish ACT had an internal consistency of 0.84 at admission. The GINA-based physician assessments had Cronbach's alphas of 0.80 among those with controlled asthma, 0.81 among those with partly controlled asthma, and 0.79 among uncontrolled asthma patients. The test–retest reliability between Visit 1 and Visit 2 showed an ICC of 0.85 (SEM: 0.10, 95 % CI 0.77–0.88) among the 128 stable patients. The Cronbach's alphas were 0.84 and 0.82 at Visit 2 and Visit 3, respectively.

Validity

Construct validity of the ACT

Factor analysis. The value of the Barlett's test of sphericity (367.745, $p < 0.0001$) and the criterion KMO (0.849) was acceptable.

Factor analysis revealed one factor with an eigenvalue of 2.97, explaining 59.50 % of the total variance. This result illustrates the unidimensionality of the ACT. Loadings and item communalities ranged from 0.685 to 0.844 (mean = 0.769) and from 0.469 to 0.712 (mean = 0.595), respectively (Table 2).

Table 1 Sociodemographic and clinical characteristics of the study population

	Study population
N	220
Age, mean ± SD	37 ± 12
Males, %	28.2
Education, %	
Primary, ≤8 years	47.7
Body Mass Index (BMI), mean ± SD	26.45 ± 5.21
FVC, L, mean ± SD	3.48 ± 0.94
FVC, %	95.73 ± 17.23
FEV1, L, mean ± SD	2.75 ± 0.99
FEV1, %	87.40 ± 18.85
% Predicted FEV1 categories, %	
<30–59	6.8
60–79	23.7
80–100	45.9
>100	23.7
PEF, L, mean ± SD	6.47 ± 5.87
PEF, %	75.21 ± 22.82
GINA, %	
Controlled	22.3
Partly controlled	38.6
Uncontrolled	39.1
ACT scores according to GINA classification, mean ± SD	
Controlled	22.65 ± 2.87
Partly controlled	18.32 ± 4.30
Uncontrolled	13.23 ± 4.23
Patient's medications, %	
Short-acting B2 agonists	70
Inhaled corticosteroids alone	33
Combination therapy	69
ACT at baseline, mean ± SD	17.30 ± 5.37

SD standard deviation

Table 2 Loadings and item communalities of the ACT

Items	Item loadings	Item communalities
1	0.786	0.617
2	0.844	0.712
3	0.734	0.539
4	0.685	0.469
5	0.799	0.638

Eigenvalue: 2.97, % of variance 59.505

Cross-sectional construct validity: The correlation of FEV1% with ACT scores at the first visit was fairly poor (r: 0. 27, $p < 0.001$).

Table 3 Discriminant validity tests on mean ACT scores at Visit 1

	Mean ± SD ACT score	Significance
GINA classification		
Controlled	22.65 ± 2.87	$p < 0.001$
Partly controlled	18.32 ± 4.30	
Uncontrolled	13.23 ± 4.23	
FEV1 predicted, %		
<30–59	18.53 ± 5.47	$p < 0.01$
60–79	17.91 ± 4.93	
80–100	15.44 ± 5.05	
>100	14.71 ± 6.09	

Convergent validity: The correlation between ACT scores and physician assessments of asthma control at Visit 1 was satisfactory ($r = 0.69$, $p < 0.001$).

Discriminant validity

ACT scores were significantly different among the three GINA classifications of patients based on physician assessments ($p < 0.001$). Moreover, patients with poorer lung function (predicted FEV1%) scored significantly lower on the ACT than patients with better lung function ($p < 0.01$) (Table 3).

Screening accuracy

The ROC analysis showed a sensitivity and specificity of 89.06 and 78.26 %, respectively. The percentage of patients correctly classified was highest with a cut-off score of 19 (84.5 %). At this cut-off, we obtained the best negative predictive value (83.7 %) and positive predictive value (85.1 %). The area under the ROC curve was 0.91 (95 % CI 0.86–0.93). When we evaluated a cut-off for patients with totally controlled asthma versus partly controlled/uncontrolled asthma, ≤20 yielded the optimal balance in terms of the percentage of correctly classified patients and the PPV and NPV (Tables 4, 5).

Responsiveness

We demonstrated the responsiveness of the ACT by evaluating mean changes in ACT scores across groups of patients who differed in the level of change in the physician's assessment of asthma control, change in predicted FEV1% values, and MID. At Visit 1 and Visit 3, there was a significant difference in mean (SD) score changes among the various groups of patients ($p < 0.001$). We found that the mean change in ACT scores was 5 for those patients who improved by one according to the GINA physician

Table 4 Performance of the ACT at various cut points in screening for uncontrolled asthma (sensitivity, specificity, predictive values, likelihood ratios, and percentage of patients correctly classified by the Asthma Control Test score)

Cut-off point	Sensitivity	Specificity	+PV	−PV	Patients correctly classified
ACT score	%	%	%	%	%
≤11	29.69	98.91	97.4	50.3	41.8
≤12	38.28	98.91	98.0	53.5	63.6
≤13	44.53	97.83	96.6	55.9	66.8
≤14	52.34	96.74	95.7	59.3	70.9
≤15	60.94	96.74	96.3	64.0	75.9
≤16	67.97	93.48	93.5	67.7	78.6
≤17	75.78	88.04	89.8	72.3	80.9
≤18	84.37	81.52	86.4	78.9	83.1
≤19	89.06	78.26	85.1	83.7	84.5
≤20	92.19	72.83	82.5	87.0	84.0
≤21	94.53	59.78	76.6	88.7	80.0
≤22	95.31	48.91	72.2	88.2	75.9
≤23	99.22	33.70	67.6	96.9	71.8
≤24	100.00	20.65	63.7	100.0	66.8
≤25	100.00	0.00	58.2	100.0	41.8

AUC: 0.85 (0.80–0.90, 95 % CI)

+PV positive predictive value

−PV negative predictive value

Table 5 Performance of the ACT at various cut points in screening for uncontrolled (uncontrolled and partly controlled) asthma versus controlled asthma

Cut-off point	Sensitivity	Specificity	+PV	−PV	Patients correctly classified
ACT score	%	%	%	%	%
≤11	22.8	100.0	100.0	27.1	40.0
≤12	28.7	98.0	98.0	28.2	44.1
≤13	33.9	98.0	98.3	29.8	48.2
≤14	40.4	98.0	98.6	32.0	53.2
≤15	46.8	98.0	98.8	34.5	58.2
≤16	52.6	93.9	96.8	36.2	61.8
≤17	61.4	93.9	97.2	41.1	68.6
≤18	70.2	89.8	96.0	46.3	74.5
≤19	74.9	87.8	95.5	50.0	77.7
≤20	78.8	83.7	94.4	53.2	80.0
≤21	84.8	73.5	91.8	58.1	82.3
≤22	88.9	65.3	89.9	62.7	83.6
≤23	95.9	51.0	87.2	78.1	85.9
≤24	98.8	34.7	84.1	89.5	84.5
≤25	100	0	77.7	–	77.0

AUC: 0.88 (0.85–0.91, 95 % CI)

+PV positive predictive value

−PV negative predictive value

assessments and was 9 for those who improved by 2 according to the GINA physician assessments. However, we found that the ACT change was −2 for patients whose physicians classified them as having less well-controlled asthma according to the GINA criteria.

The change in ACT scores was concordant with changes in physician's assessment (Table 6). The MID of three points corresponded with improvement by one or two GINA levels, as previously suggested [18].

Table 6 Mean changes in ACT scores as a function of changes in physician's GINA assessment of asthma control and changes in FEV1 values between Visit 1 and Visit 3

	ACT score (Mean ± SD)	Significance
Worse	−2 ± 2.84	
No change	1 ± 3.67	$p < 0.001$
Improvement by 1	4.11 ± 3.56	
Improvement by 2	9.90 ± 4.77	
FEV1		
<10 % improvement	1.44 ± 4.4	$p < 0.001$
≥10 % improvement	4.13 ± 4.8	

SD standard deviation

Discussion

The results of our study demonstrated that the Turkish version of the ACT is a useful tool for evaluating asthma control in Turkish adult patients.

Reliability results of the Turkish version mirrored those of the original version and those of other language versions in terms of internal consistency, with a Cronbach's alpha of 0.84 (Spanish: 0.84, Chinese: 0.85, Arabic: 0.92, Greek: 0.72, Korean: 0.71) [6–8, 12, 13]. Test–retest reliability (ICC: 0.85) between the first and second visit was comparable to that of the Turkish Childhood ACT (ICC: 0.71) [14] and to versions of the ACT in other languages (Spanish: 0.85, Portuguese: 0.93, Greek: 0.85) [6, 11, 12].

In regard to construct validity, the exploratory factor analysis showed a single-factor ACT model. This analysis adequately explained the total variance and supported the unidimensional structure of the ACT found in previous studies [6, 12].

We found a weak correlation between lung function measures and asthma control. However, as suggested in previous studies, this does not indicate that the ACT has a low validity in our population [5, 19]. We found a strong correlation r:0.69 between GINA physician assessments and ACT scores. As previously reported, ACT scores

correlate better with physician assessments of asthma control than with FEV1 measurements [5, 12].

Patients with an ACT score of 19 or less provided the optimum balance of sensitivity (89 %) and specificity (78 %) for uncontrolled asthma (Table 4). A cut-point score of 19 also yielded the largest AUC (AUC: 0.85). Depending on the specific objectives, other cut points could be considered. If the intent is to improve asthma symptoms or to keep asthma at a minimum well-controlled level with the goal of achieving complete asthma control, then cut-point scores of 20 or more may be appropriate (Table 5).

We found that each of the three groups (controlled, partly controlled, and uncontrolled) conformed to the MID of three points of change on the ACT at the baseline. We also have found that the mean change in ACT scores was 5 for those patients who improved by one level according to the GINA physician assessments and was 9 for patients who improved by two levels. These findings met the MID suggested previously. However, we found that the ACT change was −2 for patients who physicians identified as having worsening asthma symptoms. A one-point increase on the ACT among patients who were stable according to the GINA physician assessments (patients whose GINA scores remained the same between visits) corresponds to a worsening of (−2), which could be regarded as a total worsening score of 3 [18]. We demonstrated that the ACT is useful for screening uncontrolled asthma as well as for monitoring changes in asthma control, as ACT scores were responsive to changes in physician rating and lung function.

Because the ACT is a patient self-administered questionnaire, variable outcomes can be expected depending on the culture and language of the patient population. Previous studies involving different populations have tested the validity and reliability of the Spanish, Chinese, Arabic, Vietnamese, African, and Greek versions of the ACT and have found them to be similar to the original English version [6–8, 12]. We found that the Turkish version had validity and reliability comparable to the original version, too. Despite these similar results, we note that 15 % of the patients in our study were not correctly classified at the cut-off score of 19. This discrepancy could pose a problem for asthma patients previously found to be far from the GINA objectives [2, 21]. The Turkish ACT is a useful tool for evaluating asthma control status; however, it should be supported with a physician's clinical evaluation of the patient.

One of the limitations of the study was the lack of a gold-standard test to determine asthma control. We tried to overcome this by using the widely accepted method of GINA classification.

The other limitation of this study was the selection of patients from outpatient clinics of tertiary hospitals. Patients at such facilities are likely to receive better follow-up care and education on asthma management and thus to have better control outcomes compared to those treated in primary care settings. Previously, however, we have demonstrated that asthma control is inadequate at both the primary and tertiary levels in Turkey [20, 21]. Finally, the multicenter nature of the study and the variability in the physicians evaluating the patients might have led to inter-observer variation. We tried to overcome this issue by using standardized patient records.

In conclusion, the Turkish version of the ACT is a valid, reliable tool for assessing asthma control among adult Turkish patients with asthma. We also found that the ACT is responsive to changes in asthma control status. The ACT tool could improve assessment of asthma control in busy clinical practice settings where physicians are seeing a high number of patients within a limited period of time.

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Conflict of interest The authors have no conflict of interest.

Appendix: The Turkish Asthma Control Test Study Group

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