

Validation of Persian Version of Asthma Control Test Based on new Global Initiative for Asthma Guidelines

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Background: Asthma is a serious global health problem. The lack of a clinical gold standard for evaluation of asthma control, as well as inadequate recognition of uncontrolled asthma by patients and clinicians may contribute to this situation. The Asthma Control Test is an easy and reliable test. The aim of this study was to validate the Persian version of this test with regard to GINA2009 guidelines based on a specialist's rating of asthma control.

Materials and Methods: Patients (n = 150) completed the Asthma Control Test. Pulmonary function was measured. A chest specialist rated asthma control in line with the Global Initiative for Asthma 2009 guidelines. Patients were divided into well controlled, partly controlled and uncontrolled groups in order to evaluate the reliability and validity of the ACT.

Results: The mean age was 41.68 years. The internal consistency reliability of 5-item ACT survey was 0.89%. There were no significant differences in ACT scores between different age, gender, educational status and inhabitancy groups. Between the groups with different GINA-based control levels, a significant difference in ACT score was noted in favor of an ACT-based discrimination of different states of asthma control (F = 305.3, P<0.001). Patient group with poorer lung function (FEV₁) scored significantly lower on the ACT than groups with better lung function (F=6.82, P<0.001). Differences in ACT score between treatment recommendation groups were significant (F=50.54, P<0.001). Statistically significant correlations were observed between ACT scores and GINA-based values of asthma control rating by a specialist (r = 0.86, p<0.001) and treatment recommendations (r=0.54, p<0.001). Correlation between ACT score and percentage of FEV₁ predicted was moderate (r=0.39, P<0.001).

Conclusion: The Persian version of Asthma Control Test is a valid and reliable test for asthma control assessment.

Key words: Asthma, Asthma control test, Guideline

INTRODUCTION

Asthma is a serious global health problem with an estimated 300 million affected individuals and a significant burden in terms of health care costs (1). International guidelines indicate that the primary goal of asthma treatment is to obtain optimal control and reduce the risk

of exacerbations (2) but in spite of recent advances in the diagnosis and treatment of the disease, asthma remains poorly controlled in many patients (3,4). The multifaceted nature of asthma, the lack of a clinical gold standard for determining asthma control, as well as inadequate

recognition of uncontrolled asthma by patients and clinicians, may contribute to this situation (3,5).

The fact that the level of asthma control is often overestimated by both patients and physicians indicates that asthma treatment guidelines alone are not enough for assessment of asthma control and tools are needed to reflect the multi-dimensional nature of asthma control. They should be easily and quickly administered and interpreted in clinical practice (6,7).

There is no consensus regarding a tool for assessing asthma control. There are, however, several published questionnaires that may be useful for assessing asthma control. The Asthma Quality of Life Questionnaire (AQLQ) was developed to measure the functional problems that are most troublesome for adults [17-70] with asthma (2). This tool is a complex test with 32 questions. The Asthma Control Questionnaire (ACQ) is another tool to measure the adequacy of asthma control. It has 7 questions out of which 5 are about asthma symptoms, 1 about daily rescue bronchodilator use and 1 regarding FEV₁ predicted value (2). The Asthma Therapy Assessment Questionnaire (ATAQ) was developed to assist clinicians and health providers to identify asthmatic patients at risk for adverse outcome of asthma (8).

In 2004 Nathan et al. (7) developed an easy test for assessment of asthma control. The Asthma Control Test (ACT) contains five items: the effect of asthma on daily activities, daytime and nocturnal symptoms, use of rescue inhaler medications and self assessment of asthma control, and dealing with asthma control during the previous 4 weeks. Each question has a 5 point scale and the ACT score is the sum of the 5 scores (9). The ACT provides a more simplified assessment of control by not requiring FEV₁ and by providing an easy to use scoring system, which is simpler than the ACQ and more comprehensive than the ATAQ for evaluating the range of asthma control. In the previous studies, a score of 20 or higher was found to be the most discriminating cutoff to separate well controlled asthma from poorly controlled asthma (6,7,9). However, optimal validation of a new questionnaire test is a process

that requires data to be obtained in different settings and variety of populations and languages.

ACT has been translated and validated in different languages (10-13). The Persian version was translated by the Mapi Research Institute In 2006. Based on our knowledge, the Persian version of the test has not been validated so far. The aim of this study was to validate the Persian version of ACT with regard to GINA2009 guidelines based on a specialist's rating of asthma control and FEV₁.

MATERIALS AND METHODS

This was a prospective, cross sectional study, performed from February 2010 to January 2011 in Kurdistan University of Medical Sciences.

Patients 12 years of age or older from two chest clinics were eligible if they were literate in Persian and had a diagnosis of asthma based on clinical history and Beta 2 agonist reversibility of Forced Expiratory Volume in one second (FEV₁) of more than 12% and 200 ml (1), unless they were experiencing current acute exacerbations, had concomitant other lung problems or severe hepatic, renal or cardiac co-morbidities. Pregnant patients and smokers and those who could not cooperate in the conduction of lung function test or were participating in other clinical studies were excluded from the study.

The age of patients, gender, age of asthma onset, place of residence and their level of literacy were recorded.

The ACT was administered to the subjects. After completion of the test, the patients underwent spirometry and an investigator recorded the pre bronchodilator measurement of FEV₁. The method of known groups validity compares mean ACT scores across groups of patients known to differ on a relevant clinical measure. In this study three measures were used. The first was the rating of asthma control by a specialist based on new GINA guidelines, which was categorized into 3 categories: 1) well controlled; 2) partly controlled; and 3) uncontrolled asthma (1). The second measure consisted of specialist's treatment recommendations for asthma 1) step up in

therapy; 2) no change; 3) step down in therapy. The third measure was based on FEV₁ predicted values: 1) FEV₁ less than 60%; 2) 60 to 79%; 3) 80% to 100%; and greater than 100% (7). For each of the above mentioned groups, mean ACT scores were computed and compared among patient groups to evaluate the discriminating validity of ACT. Criterion validity of ACT was evaluated by computing correlations between ACT scores and GINA-based rating of asthma control by a specialist. Correlations were also computed between ACT and FEV₁ values and treatment adjustment.

The study was approved by the ethics committee of Kurdistan University of Medical Sciences and a written approval for using the Persian version of ACT was obtained from GSK (<http://www.asthmacontroltest.com>). All patients or their parents provided written informed consent.

Statistical analysis: SPSS statistical software version 18 was employed for data analysis. The internal consistency reliability of the items on ACT was estimated using the Cronbach's alpha coefficient. The subgroups were defined as: men and women, rural or urban inhabitants, educational level less than high school diploma, high school diploma or post graduate education, and age younger than 30, between 30 and 60 and older than 60 years. One way ANOVA or t-test was used to test the significance of differences between mean ACT scores among the groups and among groups of patients who differ in terms of specialist's rating of asthma control, treatment adjustment, and FEV₁ predicted. Nonparametric Spearman's correlation coefficient was used for differences between ACT scores and specialist's rating, treatment modification and FEV₁. P values less than 0.05 were considered statistically significant.

RESULTS

A total of 150 patients participated in this study. The mean age was 41.68 years (range 12 to 72 years). There were 67 males (44.7%) and 83 females (55.5%). The mean age of

onset of asthma was 32.94 years. A total of 105 patients were urban inhabitants and others were rural residents.

The internal consistency reliability of 5-item ACT survey was 0.89% in the total sample indicating high consistency of answers.

There were no significant differences in ACT scores between age, gender, educational status and inhabitancy groups (Table 1).

Table1. Demographic characteristics of patients and relationship with ACT scores

| | No.(%) in sample | Mean(SD) ACT score | P* |
|-------------------------------|------------------|--------------------|--------------------|
| Sex | | | |
| Male | 67 (44.7%) | 14.4(± 6.08) | 0.33 |
| Female | 83 (55.3%) | 15.06(± 5.36) | |
| Inhabitancy | | | |
| Urban area | 105(70%) | 15.06(±5.97) | 0.17 |
| Rural area | 45(30%) | 13.68(±5.64) | |
| Age | | | |
| ≤ 30 years | 28(18.6%) | 14.35(±5.80) | 0.92 (F= 0.075) |
| 30 – 60 years | 112(74.7%) | 14.75(±5.69) | |
| > 60 years | 10(6.7) | 14.30(±5.96) | |
| Educational status | | | |
| Less than high school diploma | 112(74.7%) | 14.17(±5.8) | 0.21 (F = 1.56) |
| High school diploma | 20(13.3%) | 16.20(±5.25) | |
| College or university degree | 18(12%) | 15.88(±5.24) | |

* P: t. test for 2 samples, ANOVA for more than 2 samples

Based on GINA asthma control guidelines, specialists rated asthma control as well-controlled in 21(14%) patients, partly controlled in 53(35.3%) and uncontrolled in 76 (50.7%) patients. Between the groups with different GINA-based states of asthma control, a significant difference in ACT score was noted in favor of an ACT-based discrimination of different asthma control states (F = 305.3, P<0.001). The mean percentage of FEV₁ predicted value was 60.69% (range, 15% to 138%). The FEV₁ was less than 60% in 50% of patients, between 60% and 79% in 28%, 80% to 100% in 18% and more than 100% in 4% of patients. Patient group with poorer lung function (FEV₁) scored significantly

lower on the ACT than groups with better lung function ($F=6.82$, $P<0.001$). Differences in ACT score between treatment recommendation groups were significant ($F= 50.54$, $P<0.001$) (Table 2).

Table 2 .Discriminative validity tests based on mean ACT scores.

| | Mean (SD) ACT score | F | P |
|--|------------------------|--------|--------|
| Specialist's rating (GINA based) | | | |
| Uncontrolled asthma (n = 76) | 9.29 (± 2.51) | 305.33 | <0.001 |
| Partly control asthma (n = 53) | 18.96 (± 2.65) | | |
| Well controlled asthma (n = 21) | 21.71 (± 2.19) | | |
| Percentage of FEV ₁ predicted | | | |
| < 60% (n = 75) | 13.02 (± 5.18) | 6.825 | <0.001 |
| 60 – 79% (n = 43) | 15.24 (± 5.85) | | |
| 80 – 100% (n = 27) | 16.92 (± 5.55) | | |
| > 100% (n = 5) | 21.6 (± 1.81) | | |
| Treatment adjustment | | | |
| Step up (n = 91) | 11.58 (± 4.34) | 50.54 | <0.001 |
| No change (n = 44) | 18 (± 4.65) | | |
| Step down (n = 15) | 21.80 (± 4.1) | | |

Statistically significant correlations were observed between ACT scores and GINA-based ratings of asthma control by a specialist ($r=0.86$, $p<0.001$) and treatment recommendations ($r = 0.54$, $p<0.001$). Correlation between ACT score and FEV₁ predicted value was moderate and significant ($r=0.39$, $P<0.001$).

DISCUSSION

The cornerstone of GINA guidelines for managing asthma is the assessment of asthma control and monitoring to keep it under control. Data suggests that asthma control is often overestimated by the patients and their physicians (14) and this overestimation can result in asthma disabilities. Lai et al. showed that poorer asthma control was associated with a higher requirement for hospitalization over the previous year (15).

Validated tools have been developed to measure asthma control, such as asthma control questionnaire (ACQ) (16), asthma therapy assessment questionnaire (ATQQ) (8), asthma control scoring system (17), and

asthma control test (ACT) (7). ACT is rapidly completed by the patients and is an easy test to use. Because the translation of ACT questionnaires into other languages may affect the results of survey, revalidation of Persian version of ACT is crucial for its utilization. There is no universal gold standard for asthma control assessment, thus, as in the original study (7) we decided to use a chest specialist's assessment of asthma control based on GINA guidelines as the gold standard (7).

The main finding of this study is the similarity in the results of validation between the original work for the development of ACT and our work, indicating a strong validation of the Persian version of the ACT. There is good correlation between ACT scores and the GINA-based level of asthma control. We observed a moderate correlation between ACT scores and FEV₁, which is consistent with the findings observed in other studies (7,8,12,16).

In addition to using a variety of measures and settings to optimally validate a patient reported tool, different populations must be assessed to confirm generalizability. A related issue is to assess that to what degree the validity of the tool depends on educational level or other demographic characteristics of a population. In this study we found that there are no significant differences in ACT scores between different educational groups, rural and urban populations, gender or age groups. This finding confirms the usefulness of ACT as a valid test in different populations.

In many developing countries, physicians are seeing a higher volume of patients in a limited period of time; in such situations, an accurate, reliable, and easy control tool might be essential for the management of asthmatic patients. ACT provides a more simplified assessment of control by not requiring FEV₁ values, which might not always be available.

In conclusion, the result of this study shows that the Persian version of ACT is reliable and valid for asthma control and is an easy administrated survey that accurately measures asthma control compared with specialist's rating and lung function test.

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