Customized Asthma Control Test with Reflection on Sociocultural Differences

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INTRODUCTION

Asthma control cannot be accurately assessed by any single testing parameter (1, 2). For example, the pulmonary function test reveals the status of a patient at only a single point in time and does not reflect real-life conditions (3, 4). The assessment of asthma control based solely on patient symptoms is also inaccurate. Rabe et al. (5) reported that 32-49% of patients with severe asthma symptoms, and 39-70% of patients with moderate asthma symptoms, perceived their asthma as well controlled. The fact that patients are likely to overestimate their level of control may cause physicians to underestimate their patients’ symptoms, and therefore under-treat their asthma (6). Exact assessments of patient asthma control levels are required for proper treatment (7).

We evaluated the utility and feasibility of customizing Asthma Control Test (ACT) items to generate a Korean Asthma Control Test (KACT) specific for Korean patients. We surveyed 392 asthma patients with 19 items, selected to reflect the Korean sociocultural context. Guideline ratings were integrated with the evaluations of specialists (i.e., using both guide base rating together with specialist’s rating), and items with the greatest discriminating validity were identified. Stepwise regression methods were used to select items. KACT scale scores showed significant differences between the asthma control ratings generated by integrating ratings \( r=0.77, P<0.001 \), by specialist’s evaluations \( r=0.54, P<0.001 \), or by \( \text{FEV}_1 \) percent predicted \( r=0.39, P<0.001 \). Specialist’s and guideline ratings detected 56% and 48.6% of patients with well-controlled asthma, respectively. However, the integrated ratings indicated that only 34.3% of the patients in the test sample were well controlled. The overall agreement between KACT and the integrated rating ranged from 45% to 78%, depending on the cut-off points used. It is possible to formulate a valid, useful country-specific diagnostic tool for the assessment of asthma patients based on the original ACT that reflect differences in sociocultural context.

Key Words: Asthma; Control; Epidemiology; Korea; Questionnaires

Multidimensional assessment using various factors is necessary for precise assessment of asthma control. However, it is difficult for primary care physicians to practice multidimensional assessment in real-life clinical settings, especially in many Asian countries, because of time constraints and shortages of resources, such as spirometry and trained nurses. Several years ago, an easy-to-use, patient-based five-item Asthma Control Test (ACT; QualityMetric, Lincoln RI, USA) was developed (8). In a longitudinal study on asthma patients who were not under the care of asthma specialists, ACT was demonstrated to be a reliable, valid and responsive tool for assessing changes in patients’ asthma control (9).

Asthma symptoms and aggravating factors vary among countries (10). More importantly, the same symptoms may be described differently, according to culture (11), level of medical
knowledge and education (12-14), patient age (15) and social recognition of asthma (16). Therefore, customization of the ACT items might accomplish more precise assessment of asthma control. Kwon et al. (17) reported that Korean version of the ACT was a reliable and valid tool for measuring asthma control, but they looked at just correlation between ACT and health-related quality of life (HRQL) only. A patients’ HRQL is not fully accounted for by objective measures, so there is possibility that Korean version of ACT may not be strongly validated (18).

Because of objective criteria for evaluating asthma symptoms are lacking, asthma specialists mainly assess asthma control according to their clinical experience. Therefore, using both guideline-based ratings together with specialist’s ratings (i.e., integrating rating), might be a reasonable way to assess the level of asthma control. An integrated rating system may help in the selection of more accurate ACT items with higher discrimination and validity. The objective of this study was to find items that would be more useful for assessing the level of asthma control in Korean asthma patients based on original ACT items.

### MATERIALS AND METHODS

In this cross-sectional study, a working group of eight leading asthma specialists was convened to select and develop customized items for a Korean Asthma Control Test (KACT), starting with the original ACT items (8). Because Koreans tend to have especially sensitive emotional responses to medications, the working group decided to add items related to drug efficacy. In total, 19 items were selected based on original ACT items to reflect a Korean cultural context (19) (Table 1).

### Study subjects

We selected study subjects from patients population of the eight asthma specialists who formed the working group of this study. All participants were older than 16 yr of age and had no other respiratory diseases. Diagnosis of asthma was confirmed by pulmonary function test (e.g. positive bronchodilator or methacholine challenge test). During a routine, previously scheduled visit, participants completed a questionnaire with the 19 selected items.

| Question | Abbreviated text | Responses* |
|----------|-----------------|------------|
| Q 1 | How often have you had wheezing | F |
| Q 2 | How often have you had tightness in your chest | F1 |
| Q 3 | How often have you had coughing | F1 |
| Q 4 | How often have you had shortness of breath | F |
| Q 5 | How often did you have an asthma episode | G |
| Q 6 | Asthma symptoms wake you up at night or earlier than usual | G |
| Q 7 | Unscheduled visit to physician or visit to an emergency room because of asthma | H |
| Q 8 | Asthma restricts you in performing your usual daily activities | C |
| Q 9 | Asthma limits your usual activities and enjoyment of everyday life | A |
| Q 10 | Asthma limits your ability to exercise | D1 |
| Q 11 | Asthma keeps you from socializing | D |
| Q 12 | Missed any time from work or school because of asthma | H |
| Q 13 | Asthma keeps you from getting much work done at work or home | B |
| Q 14 | How many number did asthma keep you at home for more than a day | H |
| Q 15 | Felt fed up or frustrated because of your asthma | B |
| Q 16 | Used your rescue inhaler or nebulizer medication | I1 |
| Q 17 | Felt the efficacy of the drug was lowered | D |
| Q 18 | Felt the efficacy of inhaler was lowered than before | D |
| Q 19 | Rate your asthma control | E |

*Key to response options

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| A | not at all | a little | moderately | quite a lot | extremely |
| B | none of the time | a little of the time | some of the time | most of the time | all the time |
| C | not at all | very little | somewhat | often | quite often |
| D | never | rarely | sometimes | often | quite often |
| E | not controlled at all | poorly controlled | somewhat controlled | well controlled | completely controlled |
| F | not at all | once or twice a week | 3 to 6 times a week | once a day | more than once a day |
| G | not at all | once or twice | once a week | 2 to 3 nights a week | 4 or more nights a week |
| H | Report of the frequency of days in last month | | | | |
| I | not at all | once a week or less | less than 1 times per day | 1 or 2 times per day | 3 or more times a day |

Cut points for sum of counts scoring option determined based on face validity: Q4, Q6, Q13, Q16: count=1 for controlled response options 1, 2; count=0 for poorly controlled response options 3, 4, 5; Q19: count=1 for controlled response options 4, 5; count=0 for poorly controlled response options 1, 2, 3.
and answered questions about their asthma control status over the previous four weeks. After completing the questionnaire, pre-bronchodilator measurements of FEV₁ were recorded. Asthma specialists interviewed the participants without knowledge of the participants’ responses to the questionnaire. After the interview, asthma specialists rated the level of asthma control on a three-point scale of “poorly controlled,” “less-controlled” and “well controlled.”

This study was approved by each asthma specialist’s university Institutional Review Board (R-0603-40-172 in Seoul National University Hospital).

**Methods for item selection**

A stepwise logistic regression method was used to identify items with the greatest validity in discriminating participants’ status. The identifying items were done under the integrated rating system that combined specialist and guideline-based evaluation. To make an integrated rating, a dichotomous variable with a value of 0 (controlled) and 1 (uncontrolled) was used, where a specialist’s rating of “poorly controlled”/“less controlled” was determined as “uncontrolled” and a specialist’s rating of “well-controlled” was determined as “controlled.” As in the global initiative for asthma (GINA) guideline’s levels of asthma control (20), guideline ratings were considered “controlled” when six components of levels of asthma control were “controlled.” If at least one component showed “partly controlled,” the rating was considered “uncontrolled.” Thus, integrated ratings of asthma control were scored as “controlled (level of 0)” when both the specialist’s rating was “controlled” and the level of asthma control of all six components of the GINA guideline rating were “controlled.”

All 19 items were entered as independent variables and the integrated rating was entered as a dependent variable. Items were entered into the model in a forward stepwise fashion. Items with a statistical significance level of *P*<0.05 were selected for inclusion in the final survey.

**Reliability and screening accuracy**

After the items to be included in the KACT were finalized, reliability was evaluated using the internal consistency reliability method and Cronbach’s alpha. In scoring the items, higher scores indicated better asthma control. Two scoring options were used. In the first, the score was the sum of each item from a five-point scale with scores after summation ranging from four to 20. In the second, the score was the sum of dichotomous variables for each item, with 0 indicating “uncontrolled” and 1 indicating “controlled.” These ranged from 0 for “uncontrolled” to 4 for “totally controlled.” Pearson correlation coefficients were computed between KACT scores, the integrated rating, and FEV₁. ANOVA was used to evaluate the ability of KACT scores to discriminate between the groups based on two criteria. The first criterion was based on the integrated rating. Patients were divided into three groups according to asthma control based on the specialist’s rating and the guideline rating. When there was a difference between the specialist’s and guideline based ratings, the lower rating was used. The second criterion was based on percent predicted FEV₁ value, with ≤60% for Group 1, >60%–<80% for Group 2, and ≥80%–100% for Group 3.

Receiver operating characteristic (ROC) analysis was conducted to compare the two scoring options and the KACT evaluation in their ability to identify patients with asthma control problems. Odds ratio, sensitivity, specificity, positive and negative predictive values, and the percent correctly classified were calculated at each scoring level or “cut-off point” for both KACT scoring options.

**RESULTS**

**Sample**

Of a total of 392 patients who completed the survey questionnaire, 305 answered all items with a possible guideline rating. The mean and SD of age of respondents was 56.1±18.5 yr. Of them 49.9% were males range 16-87. The duration of asthma treatment was 4.4±5.6 yr.

According to the specialist’s ratings of asthma control, 56.3% of respondents were evaluated to have well-controlled asthma. According to the guideline ratings for asthma control, 48.6% had controlled levels of asthma control. Approximately 34.3% showed had well-controlled scores by the integrated rating that considered both the specialist’s and guideline ratings. According to spirometry, 60% of the patients had showed a percent predicted FEV₁ value of more than 80%.

**Selected items**

Four items were identified as significant by forward stepwise logistic regression analyses (Table 2). Use of rescue medication was selected as the most predictive item, followed by tightness or pain in chest, coughing, and limited ability to exercise.

**Reliability and screening accuracy**

The internal consistency of the four-item KACT survey was 0.60 for the total sample of 305 participants. The internal consistency of the 4-item KACT survey was 0.52 for the 198 participants.

| Item | Description | Odds ratio (CI) | *P* value |
|------|-------------|----------------|-----------|
| Q16  | Use of rescue medication | 3.74 (1.99,7.02) | <0.001 |
| Q2   | Tightness or pain in chest | 2.00 (1.15, 3.49) | <0.001 |
| Q3   | Coughing | 1.52 (1.17, 1.97) | <0.001 |
| Q10  | Limit your ability to exercise | 1.67 (1.05, 2.68) | 0.023 |

KACT, Korean Asthma Control Test; CI, Confidence interval.
categorized as uncontrolled according to the integrated rating. The integrated rating showed the highest correlation with KACT scale scores ($r=0.77$, $P<0.001$). The correlation between KACT scores and specialist’s ratings alone was also high ($r=0.54$, $P<0.001$), while the correlation between KACT scores and percent predicted FEV$_1$ values was moderate ($r=0.39$, $P<0.001$).

The results of empirical validation test of KACT are presented in Table 3 in discriminating groups with different levels of asthma control. KACT scores for both of 2 scoring options showed significant difference in the level of asthma control between the integrated rating and the percent predicted FEV$_1$ values.

The ROC curve for the sum of total scores was 0.817 and for the sum of dichotomous variables was 0.799 (Figs. 1, 2). Table 4 presents the performance of the sum of total scores option for screening for control problems. Each score level represents a cutoff point that could discriminate controlled from uncontrolled asthma.

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**Table 3.** Comparison of mean (SDs) KACT scores across groups differing in asthma control

| Integrated rating of control | % Predicted FEV$_1$ values |
|-----------------------------|---------------------------|
| Poorly controlled (n=156)    | ≤60% (n=51)               |
| KACT sum scoring            | 14.5 (3.9)                |
| KACT sum of count           | 2.5 (1.3)                 |
| Less controlled (n=21)       | 16.1 (2.6)                |
| KACT sum scoring            | 16.1 (2.6)                |
| KACT sum of count           | 2.9 (0.8)                 |
| Well controlled (n=128)      | 18.3 (2.3)                |
| KACT sum scoring            | 18.3 (2.3)                |
| KACT sum of count           | 3.7 (0.5)                 |
| F                            | 36.4                      |
| $P$ value                    | ≤0.001                    |
| ≤60-80% (n=66)              | 14.1 (4.3)                |
| KACT sum scoring            | 2.3 (1.3)                 |
| KACT sum of count           | 2.6 (1.3)                 |
| ≤80-100% (n=187)            | 17.3 (2.6)                |
| KACT sum scoring            | 3.4 (0.8)                 |
| KACT sum of count           | 20.8                      |
| $P$ value                    | ≤0.001                    |

*P<0.05; †P<0.01.

KACT sum scoring and KACT sum of count are significantly different among each subgroup of integrated rating of control and % predicted FEV$_1$ values, respectively.

KACT, Korean Asthma Control Test; FEV$_1$, Forced Expiratory Volume at one second.

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**Table 4.** Summary of the performance of simple sum scoring at various cut-off points in screening for uncontrolled asthma (N=305)

| Cut-off point | Odds ratio (CI, lower, upper) | Sensitivity (%) | Specificity (%) | Positive predictive value (%) | Negative predictive value (%) | % Correctly classified | Kappa |
|---------------|--------------------------------|-----------------|-----------------|------------------------------|-------------------------------|------------------------|-------|
| ≤11           | 25.2 (3.4, 186.1)              | 19.2            | 99.1            | 97.4                         | 39.8                         | 47.2                   | 13.6  |
| ≤12           | 34.9 (4.7, 256.4)              | 24.7            | 99.1            | 98.0                         | 41.6                         | 50.8                   | 18.1  |
| ≤13           | 53.0 (7.2, 388.2)              | 33.3            | 99.1            | 98.5                         | 44.5                         | 56.4                   | 25.3  |
| ≤14           | 34.1 (8.2, 142.3)              | 39.4            | 98.1            | 97.5                         | 46.7                         | 60.0                   | 29.9  |
| ≤15           | 11.9 (5.5, 25.7)               | 49.0            | 92.5            | 92.4                         | 49.5                         | 64.3                   | 34.6  |
| ≤16           | 8.8 (4.8, 16.0)                | 60.6            | 85.0            | 88.2                         | 53.8                         | 69.2                   | 40.3  |
| ≤17           | 10.5 (6.0, 18.4)               | 74.2            | 78.5            | 86.5                         | 62.2                         | 75.7                   | 49.8  |
| ≤18           | 11.1 (6.4, 19.3)               | 84.3            | 67.3            | 82.7                         | 69.9                         | 78.4                   | 52.1  |
| ≤19           | 5.6 (3.2, 9.9)                 | 87.4            | 44.9            | 74.6                         | 65.8                         | 72.5                   | 34.8  |

CI, Confidence interval.
Since many Korean asthma patients do not pay sufficient attention to their symptoms, they tend to overestimate their asthma control levels, resulting in undertreatment, similar to other Asian countries (23, 24). Primary care physicians must treat a relatively large number of patients in a limited time, so their assessment of asthma control is neither as reliable nor as accurate as it should be. Given these situations, the customized KACT, which reflects Korean conditions, might be able to help asthma control assessment in actual clinical practice. In many cases, asthma can be well-controlled and even completely controlled (25), so KACT might help asthma patients achieve better control by promoting communication between patients and primary care physicians in clinical settings.

In this study we used a guideline-based rating as well as specialist’s ratings in assessing asthma control. Because of the lack of objective criteria for evaluating asthma symptoms, Korean asthma specialists tend to assess asthma control largely on the basis of clinical experience. Thus, it is reasonable to use both guideline-based ratings and an individual specialist’s rating to assess asthma control. The specialist’s ratings and guideline ratings identified well-controlled asthma in 56% and 48.6%, respectively, of study participants. However, only 34.3% were well considered controlled when both specialist’s and guideline ratings were considered. Furthermore, integrated rating showed the highest correlation with KACT scale scores ($r=0.77$) compared to specialist’s ratings alone ($r=0.54$) and percent predicted FEV1 values ($r=0.39$), respectively. Using this integrated tool, we may be able to select more stringent KACT items.

This study has several limitations. The original ACT, without modification of the original items, has proven to be a useful tool for routine evaluation of asthma control by primary care physicians in Asian countries such as China (26) and Korea (17). But there is another report that a culturally targeted asthma intervention program in adult is effective in improving quality of life of asthma patients (27). Another limitation is that our modified KACT yields relatively lower reliability scores compared to the original ACT (0.83 in Nathan et al. compared to 0.52 in this study). To overcome these limitations, large prospective studies are needed to validate the KACT in clinical situations. Finally, we did not control smoking status and some COPD patients who might be enrolled in our current research.

The main purpose of this study was to identify a suitable set of questionnaire items based on the original ACT items. We concluded that it was possible to formulate a valid, useful country-specific diagnostic tool for the assessment of asthma patients based on the original ACT that reflect sociocultural differences. We need further studies to validate these KACT items.

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