Longitudinal Validation of a Tool for Asthma Self-Monitoring

WHAT’S KNOWN ON THIS SUBJECT: To prevent asthma exacerbations, asthma guidelines recommend ongoing monitoring of patients’ asthma symptoms to promote timely adjustments of therapy to achieve and maintain optimal control. Existing tools, validated for ongoing monitoring, have significant limitations in children.

WHAT THIS STUDY ADDS: Our study established longitudinal validation of the Asthma Symptom Tracker, a novel tool designed for use by children or their parents to facilitate ongoing monitoring of patients’ asthma symptoms and proactive medical decision-making to prevent acute exacerbations.

abstract

OBJECTIVES: To establish longitudinal validation of a new tool, the Asthma Symptom Tracker (AST). AST combines weekly use of the Asthma Control Test with a color-coded graph for visual trending.

METHODS: Prospective cohort study of children age 2 to 18 years admitted for asthma. Parents or children (n = 210) completed baseline AST assessments during hospitalization, then over 6 months after discharge. Concurrent with the first 5 AST assessments, the Asthma Control Questionnaire (ACQ) was administered for comparison.

RESULTS: Test–retest reliability (intraclass correlation) was moderate, with a small longitudinal variation of AST measurements within subjects during follow-ups. Internal consistency was strong at baseline (Cronbach’s $\alpha$ 0.70) and during follow-ups (Cronbach’s $\alpha$ 0.82–0.90). Criterion validity demonstrated a significant correlation between AST and ACQ scores at baseline ($r = -0.80$, $P < .01$) and during follow-ups ($r = -0.64$, $-0.72$, $-0.63$, and $-0.69$). The AST was responsive to change over time; an increased ACQ score by 1 point was associated with a decreased AST score by 2.65 points ($P < .01$) at baseline and 3.11 points ($P < .01$) during follow-ups. Discriminant validity demonstrated a strong association between decreased AST scores and increased oral corticosteroid use (odds ratio 1.13, 95% confidence interval, 1.10–1.16, $P < .01$) and increased unscheduled acute asthma visits (odds ratio 1.23, 95% confidence interval, 1.18–1.28, $P < .01$).

CONCLUSIONS: The AST is reliable, valid, and responsive to change over time, and can facilitate ongoing monitoring of asthma control and proactive medical decision-making in children. Pediatrics 2013;132:e1554–e1561

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ABBREVIATIONS

ACQ—Asthma Control Questionnaire
ACT—Asthma Control Test
AST—Asthma Symptom Tracker
CI—confidence interval
ED—emergency department
ICC—intraclass correlation
OR—odds ratio
PCMC—Primary Children’s Medical Center
PCP—primary care provider
ROC—receiver operating characteristic

Dr Nkoy conceptualized and designed the study and drafted the initial manuscript; Drs Stone, Fassl, Uchida, and Ms Koopmeiners participated in conceptualizing and designing the study, interpreting the data, and revising the manuscript; Ms Halbern, Ms Eun H. Kim, and Ms Wilcox coordinated and supervised data collection and critically reviewed the manuscript. Mr Jian Ying and Dr Greene carried out the analyses and reviewed and revised the manuscript. Drs Mosen and Schatz participated in conceptualizing and designing the study and revising the manuscript; Dr Maloney participated in conceptualizing and designing the study, interpreting the data, and revising the manuscript; and all authors approved the final manuscript as submitted.

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Asthma is the most common pediatric chronic illness, with a lifetime prevalence of 13.8% in the United States1 and a significant impact on the child’s and family’s quality of life and on health care costs.2 In 2009, ~7.1 million children under age 18 years had asthma, and 4.1 million had an asthma exacerbation.2 The total costs for pediatric asthma in the United States are estimated at $15.9 billion annually.3,4 Asthma is one of the most preventable conditions necessitating frequent use of acute care services, including emergency department (ED) and hospital admissions in children.5–8 Overall, use of acute care services in children accounts for 54% of the direct asthma medical expenditures,9 and the major reason is poor asthma control in the ambulatory setting.10–13 Poor control leads to recurrent asthma exacerbations, poor quality of life, increased school absenteeism, and increased ED and hospital admissions.14–16 To prevent asthma exacerbations, the National Asthma Education and Prevention Program Expert Panel Report 37 guidelines recommend ongoing monitoring of patients’ asthma symptoms to promote timely adjustments of controller therapy to achieve and maintain optimal control. Yet engaging children and their parents in ongoing monitoring of asthma symptoms remains challenging.17–19 Parents often underestimate their child’s risk for exacerbations and lack effective tools to help them monitor their child’s asthma.19,20 Similarly, primary care providers (PCPs) often lack the tools, incentives, time, and resources to adequately monitor their patients outside clinical encounters.21 Several tools for assessing asthma control have been developed, but few have been validated for ongoing monitoring, and studies have reported significant limitations in children.22–27 We have developed a new tool, the Asthma Symptom Tracker (AST) or Asthma Tracker, a paper-based, patient-centered tool designed to facilitate ongoing monitoring of asthma control through weekly assessments of asthma symptoms. The objective of this article is to establish longitudinal validation of the AST for use by children and their parents.

METHODS
Setting
The study took place at Primary Children’s Medical Center (PCMC), an academic children’s hospital in Salt Lake City, Utah affiliated with the Department of Pediatrics at the University of Utah School of Medicine. PCMC has 289 licensed beds and is owned and operated by Intermountain Healthcare.28

Description of the AST
The AST was developed by a multidisciplinary pediatric care team, including physicians, nurses, health services researchers, graphic designers, and experts in quality improvement from the University of Utah and Intermountain Healthcare, with input from a national expert (M.S.) and children with asthma and their parents. The AST was designed for use at home by older children (age ≥11 years), with or without initial assistance from their parents, or by parents of younger children (age <11 years). The AST is printed on 17 × 11” format card-stock paper (Fig 1) that can be placed on a family’s refrigerator as a reminder for regular use. The tool has 4 sections: user instructions, a questionnaire, a color-coded graphic display, and color-coded decision support.

The user instruction section includes a modified Asthma Control Test (ACT) questionnaire,27 which was adapted for weekly use by changing the survey question header to “During the past week” rather than “During the past month,” as in the standard ACT.

The graphic display section provides space for plotting weekly scores (or AST scores) over time with color-coded zones (green indicates well controlled, yellow indicates not well controlled, and red indicates poorly controlled) using the standard ACT cutoff points previously validated for monthly assessments.27

The decision support section includes 3 color-coded boxes that congratulate and encourage the patient or parent when asthma control scores fall within the green zone or prompt the patient or parent to schedule a follow-up PCP visit and bring the AST with them to that visit if the scores are in the yellow zone for 2 consecutive weeks or in the red zone once.

Study Design and Population
This was a prospective cohort study from March 2011 through May 2012 of children 2 to 18 years old admitted to PCMC with a primary diagnosis of asthma.

Patient Identification
An electronic system29 automatically generated a daily list of eligible patients and e-mailed the list to study coordinators, who then enrolled assenting or consenting patients into the study.

Study Procedures and Data Collection
After assent or consent was signed and instructions given on use of the AST, the study coordinator assisted patients and parents in completing the baseline assessment to determine the patient’s asthma control level during the week before hospitalization. To test for reliability of the AST, the study coordinator concurrently determined the patient’s asthma control level by using a validated tool for weekly assessment, the
Asthma Control Questionnaire (ACQ).26 Subsequent AST assessments were com-
plicated at home by patients or parents, and the information was mailed weekly
to the research team; concurrent ACQ assessments were completed over the
phone30,31 by the study coordinator be-
cause the tool was designed for use by
a trained person.26

As part of the validation testing, at each
assessment patients or parents com-
plicated 5 additional questions assessing
how many days in the previous week
they used controller medications or
oral corticosteroids; whether they used
any nonprescription drugs to ease
symptoms; whether the child had any
unscheduled acute clinic, ED, or hos-
pital visits; and who (patient or parent)
completed the questionnaire.

To facilitate data collection, patients and
parents were provided a package to take
home including the AST with questions
on 26 detachable preaddressed post-
cards for completing and mailing their
responses to the study coordinator on
a weekly basis. During a patient’s first
month in the study, after a postcard was
returned, the study coordinator phoned
the family the same or next day to obtain
a concurrent ACQ score for that week.
Overall, we obtained 5 paired AST and
ACQ scores during the first month, 1
during hospitalization (baseline) and 4
weekly assessments after hospital dis-
charge. Patients or parents then com-
plicated weekly AST assessments alone
until the end of the 6-month study pe-
riod and mailed scores to the study
coordinator. Patients received $40 in
compensation for their participation.
The PCMC privacy board and the Uni-
versity of Utah Institutional Review
Board approved the study.

**Statistical Analysis**

Statistical analyses consisted of test–
retest reliability and longitudinal variation,
internal consistency, criterion validity,
responsiveness, and discriminant validity
of the AST scores. The Supplemental
Information provides additional inform-
ation.

Test–retest reliability was assessed by
estimating the intraclass correlation
(ICC) of the AST scores on a subset of
patients whose asthma control was
stable between the baseline and first
follow-up ACQ assessment and be-
tween the baseline and first similar
ACQ score obtained during the first 4
follow-up assessments. Stable patients
included those for whom a subsequent
follow-up ACQ score was within 0.25
points of the baseline ACQ score, be-
cause this was below the minimal im-
portant difference value necessary to
detect clinical changes in asthma con-
rol status.26 For estimation of the ICC, 1
assessment with an outlier AST score
was excluded from the analysis be-
cause the patient incorrectly reversed
the response scale.

Internal consistency among all 5 items
of the AST was quantified by using
Cronbach’s α. Because there is a
known learning curve with AST use,
Cronbach’s α values were computed
separately at baseline and each of the 4
follow-up weeks.

Criterion validity was assessed by
cross-sectional correlations between
paired AST and ACQ scores at baseline
and at the first 4 follow-up assessments.

We applied a mixed effects model to
separately estimate a baseline regres-
sion coefficient to represent the cross-
sectional association between AST and
ACQ scores at baseline and a pooled
regression coefficient to characterize
the cross-sectional association between
AST and ACQ scores across the first 4
follow-ups. Lastly, in pooled analyses
across the first 4 follow-up assessments,
we produced receiver operating char-
acteristic (ROC) curves to assess the
capability of the AST to diagnose in-
adquate asthma control by using the
ACQ as the gold standard, with inadequate
control defined as an ACQ score ≥1.

We assessed responsiveness of the AST
by characterizing the association be-
tween changes in AST and ACQ scores
over the baseline and first 4 follow-up
assessments. We used a mixed effects
model to relate changes in AST scores
class dependent variable to contempora-
neous changes in the ACQ scores. We
first evaluated changes from baseline
to the 4 follow-up assessments; sub-
sequently, we repeated the analysis
after excluding the baseline to evaluate
changes in AST scores between the first
follow-up and the second to fourth
follow-up assessments.

Discriminant validity was characterized
by the association between change in
AST scores (both as a continuous var-
iable and dichotomized as poor control
[<15] or better control [≥15]) and the
use of oral corticosteroids and un-
scheduled acute care visits reported
by patients over the full study period.
Use of oral corticosteroids and un-
scheduled visits were selected as sur-
rrogate measures for inadequate asthma
control. We used separate mixed effects
logistic regression analyses with ran-
dom individual effects to relate the oc-
currence of unscheduled visits and the
use of oral corticosteroids to AST scores
over the full study period.

**RESULTS**

**Study Population**

Overall, 210 children with asthma (60%
males) with a median age of 5.0 years
(interquartile range 3.0–8.5 years) were
enrolled in the study. Among patients,
2912 individual AST assessments were
completed over the 6-month study period,
with a total of 911 paired AST and ACQ
assessments obtained during the first
month. Of the individual AST assess-
ments, 6.5% (188/2912) were completed by
children alone, and 73.9% (2154/2912) were
completed by parents. In 19.6% (570/
2912) of assessments, no information
was provided about who completed the
form. Overall, frequency of AST use per
week decreased over time. Participant attrition, including the percentage of patients remaining in the study at each assessment interval, is reported in the Supplemental Information.

**Test–Retest Reliability**

The ICC of AST scores for the subset of patients with stable asthma control was .65 between the first and the second ACQ follow-up assessment (n = 36) and .50 between the first and any subsequent ACQ assessment obtained in the second and fourth follow-up (n = 58). Among assessments categorized as well-controlled asthma by ACQ < 1 (n = 152), the within-subject SD of the AST was 2.4 points (scale, 5–25) during follow-ups.

**Internal Consistency**

Internal consistency of AST scores was strong at baseline, with a Cronbach’s α value of 0.70, and increased (to 0.82, 0.83, 0.85, and 0.90, respectively) during follow-ups. We also found consistency among items of the AST through a direct association of the AST subscores q1 to q4 with improvement in overall patient’s self-perception of asthma control (q5) (see Supplemental Information).

**Criterion Validity**

The cross-sectional correlation between AST and ACQ scores was strong at baseline ($R = -0.80, P < .01$) and remained strong ($R = -0.64, -0.72, -0.63$, and $-0.69, with P < .01$), although to a lesser degree, during follow-ups. In the cross-sectional mixed effects analysis (Table 1), a 1-point higher ACQ at baseline was associated with a 2.65 (95% confidence interval [CI], 2.24–2.89, $P < .0001$) lower mean baseline AST score, and a 1-point higher ACQ during follow-up was associated with a 3.11 (95% CI, 2.88–3.34, $P < .0001$) lower mean follow-up AST score. The ROC curve (Fig 2) depicts a strong relationship between AST and ACQ scores over the first 4 follow-up assessments. The area under the curve of the relationship between AST and ACQ scores at baseline was 0.96 and remained high (0.86, 0.86, 0.75, and 0.90) during each follow-up.

**Responsiveness**

We found a significantly strong association between changes in AST scores and changes in ACQ scores (Fig 3). In the longitudinal analysis relating change in AST to change in ACQ scores from baseline to follow-up assessments (Table 1), an increase in ACQ score by 1 point was associated with a decrease in AST score by 2.53 (95% CI, 2.26–2.80, $P < .001$). During follow-ups, a 1-point increase in the ACQ was associated with a 2.08 (95% CI, 1.64–2.52, $P < .001$) decrease in the AST.

**Discriminant Validity**

A decrease in AST scores was significantly associated with an increase in the use of oral steroids (odds ratio [OR] 1.13 per 1-point decrease in the AST, 95%
CI, 1.10–1.16, \( P < .001 \) and an increase in frequency of unscheduled acute care visits (OR 1.23 per 1-point decrease in the AST, 95% CI, 1.18–1.28, \( P < .001 \)) over the full study period. Poor AST control (AST score, \( 15 \) or red zone) was associated with an increase in the risk of unscheduled hospital visits (OR 10.8, 95% CI, 6.5–18.0, \( P < .001 \)) and an increase in the use of oral steroids (OR 2.6, 95% CI, 1.8–3.8, \( P < .001 \)).

**DISCUSSION**

Our study validates use of the AST as a tool for weekly monitoring of asthma control in children. We found a moderate test–retest reliability, small longitudinal variation, high internal consistency, and good criterion validity of the AST. We also found an improvement in the participant learning curve over time, as demonstrated by an increasing trend in internal consistency from baseline to follow-up assessments. The AST was very responsive to changes in asthma status, as reflected by a significant increase in AST scores as patients’ ACQ scores decreased. Furthermore, the AST had clear discriminant validity; decreases in AST scores were significantly associated with increased use of oral corticosteroids and unscheduled acute care visits.

Most asthma exacerbations are preventable because they rarely occur without warning. Specifically, patients with asthma often have warning signs or evidence of declining asthma control that occurs days to weeks before an asthma exacerbation.\(^{32}\) The AST allows frequent (weekly) assessments and effective monitoring to facilitate a fast recognition and rapid response to warning signs of asthma control deteriorations. The AST also provides patients or parents (and PCPs) with easy visualization of changes in asthma control status over time to facilitate appropriate and timely response to deteriorations. Ongoing monitoring with the AST can provide objective data to determine the effectiveness of controller therapy and facilitate timely adjustments of therapy to achieve and maintain optimal asthma control.\(^{17}\)

Several symptom-based short questionnaires have been validated for assessing and monitoring asthma control, but studies have reported significant limitations in children.\(^{22–27}\) For instance, the ACQ has been validated with and without the inclusion of peak flow and has been used for weekly assessment of asthma control.\(^{25,26}\) The ACT is also a short, easy-to-complete questionnaire and is the most commonly used symptom-based tool to assess asthma control.\(^{27}\) Both the ACQ and ACT are responsive to change, but a recent study found that the ACT was preferable to the ACQ in clinical practice.\(^{32}\) Yet weekly use of the ACT has never been validated, and no evidence exists to support its use by

![Figure 2](http://pediatrics.aappublications.org/)ROC curve at baseline. The ROC curve relates the proportion of true-positive and false-positive inadequate asthma control cases for difference cutoff points of the AST score. An ACQ score $\geq 1$ was used as the reference standard for defining inadequate asthma control. Black diamonds indicate the cutoff points of the AST score.
proxies (parents acting for their young children). Through the AST and by extension, our study provides evidence of the ACT’s reliability, validity, and responsiveness as a weekly tool and its use by parents. Other symptom-based questionnaires have been validated for use in various settings, but longitudinal validation has not been evaluated, or studies included only brief follow-up periods of 2 or 3 different assessments. Although the AST was useful in engaging patients and parents in ongoing monitoring, there were several limitations. First, our ICC values were moderate, somewhat lower than previously reported. This may be a result of the longer time interval between test and retest in some patients and a smaller between-subject variation in our sample. Yet we found a small within-subject SD in the well-controlled subjects, demonstrating the longitudinal stability of repeated AST measurements. Second, the attrition rate over time was high, with approximately half (52%) of patients still providing assessments at 10 weeks. Third, criterion validity was assessed against the ACQ rather than an objective assessment of patients’ level of asthma control. Fourth, parents often completed the ASTs, particularly for young children who lacked the cognitive capacity to answer the questionnaire independently. Studies have reported that using parents as proxies can introduce bias because they tend to underestimate their children’s asthma symptoms. We believe that because the AST focuses on tracking trends in asthma control, even if bias is introduced by a proxy, as long as the bias remains constant by having the same parent complete all assessments, the AST can provide valuable information about changes in the child’s asthma control status that can be used for decision-making. Fifth, we did not analyze separately assessments made by children and parents because most assessments were completed by parents, and only 6.5% were completed by children alone. Sixth, we were unable to assess the tool’s utility for children independent of parental oversight, although independent use did occur successfully in some children ≥11 years of age. Although our results show that changes in AST scores were associated with changes in surrogate measures of asthma control, it is still necessary to evaluate whether using the AST will reduce asthma exacerbations. Lastly, the AST is a paper-based tool and has its own limitations, including lack of active prompt to patients or parents. Patients or parents had to interpret results themselves, based on preset recommendations. After completing an assessment, patients and parents had to send their responses back to the research team on a postcard. This process often delayed identification of asthma control deteriorations early to provide active feedback. Another limitation was the lack of patient or parent incentives for sustained AST use. This may explain the high degree of attrition, which may be related to improved asthma control or a child with intermittent asthma. Our future plan includes assessing the AST’s effectiveness in improving asthma outcomes, understanding and addressing critical barriers of long-term AST use by patients and parents, developing

FIGURE 3
Relationship between changes in AST and changes in ACQ scores. Each symbol and number represent an assessment schedule (eg, 1, baseline; 2, first follow-up assessment; 3, second follow-up assessment etc).
and implementing an electronic AST to address several limitations of the paper AST, and creating an incentive mechanism to increase patient and parent engagement in long-term use.

**CONCLUSIONS**

Our study demonstrates that the AST is a reliable, valid, and responsive tool for weekly, ongoing monitoring of asthma control. We hope that use of the AST can facilitate care continuity and shift asthma care from the current reactive, acute model to a preventive, proactive model where assessments are made weekly and treatment decisions are tailored to patients’ individual needs.

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