

Comparing the Asthma APGAR System and the Asthma Control Test™ in a Multicenter Primary Care Sample

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Abstract

Objective: To compare asthma control assessment using the Asthma APGAR system, a tool developed by primary care clinicians, in a multicenter primary care sample with the Asthma Control Test (ACT™)/Childhood Asthma Control Test (CACT™), a tool developed by asthma specialists.

Patients and Methods: This is a substudy of a multicenter, randomized, controlled pragmatic trial that tests the effectiveness of the Asthma APGAR system in primary care practices. As part of the study, enrolled patients completed both the ACT™/CACT™ and the Asthma APGAR system between March 1, 2011, and December 31, 2011. Kappa and McNemar statistics were used to compare the results of questionnaires.

Results: Of the 468 patients in our sample, 306 (65%) were classified as not controlled by the ACT™/CACT™ or the Asthma APGAR system. The overall agreement was 84.4%, with a kappa value of .68 (substantial agreement) and a McNemar test *P* value of .35 (suggesting no significant difference in the direction of disagreement). Of those with poor control as defined by the Asthma APGAR system, 23.8% (73) had no controller medications and 76.5% (234) were seldom or sometimes able to avoid identified triggers for their asthma. Of those who stated that they had been prescribed controller medications, 116 of 332 (35%) stated that they did not use the controller medication on a daily basis.

Conclusion: The Asthma APGAR system and the ACT™/CACT™ similarly assess asthma control in a multicenter primary care–based sample. The Asthma APGAR system identified an “actionable item” in more than 75% (234) of the individuals with poor asthma control, thus linking an assessment of poor asthma control with a management strategy.

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Asthma is a common burdensome chronic disease with significant costs to individual and society that is chiefly managed by primary care providers.¹ Assessing asthma control and severity is a key tenant of asthma management, and standardized and validated tools can be very helpful in making these assessments.^{2,3} Rapid assessment and decision making about asthma management can be aided by the use of asthma assessment tools such as the Asthma Control Test (ACT™)⁴ or the Asthma Control Questionnaire (ACQ).⁵ However, there may be limitations to the utility of the ACT™ and the ACQ in primary care practices.^{6,7} Scores from the ACT™ and the ACQ allow providers to rapidly determine whether a patient's asthma is not controlled^{4,5}; however, no guidance for next steps to improve asthma control are linked to the ACT™ or ACQ assessments. The clinician is required to refer

back to asthma guidelines that emphasize increases in asthma medications.¹ The ACT™ was designed by specialists⁸ who may not need additional guidance on the next steps of asthma management, while primary care clinicians may benefit from additional tools that link the assessment to management options.

Several studies have tested methods to assist in the translation of asthma guidelines into primary care practices, often with disappointing results.⁹⁻¹⁵ A recent Cochrane Database analysis concluded that there is inconclusive evidence that management in primary care–based asthma clinics is effective,¹⁶ possibly because of the limited number of studies or because of a lack of effective asthma management tools available that are tailored to the needs of primary care providers. Asthma management tools that allow the time spent with patients to be used most efficiently are needed because the current



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time to manage asthma in a primary care practice is insufficient.¹⁷ Recent studies in primary care focusing on improving clinician self-efficacy¹⁸ and using enhanced support via mobile phones¹⁹ have not reported a significant improvement in asthma outcomes. To address the gap in the primary care management of asthma, the Asthma APGAR system was designed.² The Asthma APGAR system, in addition to an assessment of control similar to tools such as the ACTTM and the ACQ, collects information on asthma triggers, adherence to treatment, inhaler technique, and the patient's perception of response to treatment. By including these additional assessment domains, the Asthma APGAR system helps the primary care clinician link the assessment to a plan for managing the patient's asthma.

A large prospective, randomized, multicenter trial using the Asthma APGAR system is underway (clinicaltrials.gov Identifier: NCT01446315), with the primary goal of determining whether use of the Asthma APGAR tool can affect asthma outcomes, such as asthma-specific quality of life, asthma control, and asthma exacerbation rates, in a primary care setting.²⁰ This article compares the level of agreement between the Asthma APGAR system and the ACTTM assessments of "in control" and "not in control." We specifically note areas of disagreement between control assessments in the Asthma APGAR system and the ACTTM and highlight the "actionable items" identified in individuals whose asthma was found to be not in control.

PATIENTS AND METHODS

This is a substudy of a trial funded by the Agency for HealthCare Quality and Research. The parent "Asthma Tools Study" is a randomized controlled pragmatic trial to test the effectiveness of the Asthma APGAR system² in primary care practices. The protocol has been presented in detail previously.²⁰ In brief, 20 primary care practices (members of 2 practice-based research networks) were randomized to either intervention or usual care. Randomization was stratified by whether the practice is part of a family medicine residency program and whether it is a family medicine or general pediatrics practice.

The Asthma APGAR system (Figures 1 and 2) was introduced to the intervention practices. The system consists of both a patient-completed questionnaire and an algorithm to guide the use

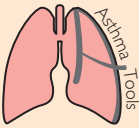
of the patient's answers in next steps in asthma care. This linked system addresses several important factors commonly associated with poor asthma control, including lack of adherence to the prescribed therapy, unrecognized or exposure to known triggers, poor inhaler technique, and misdiagnosed asthma. As part of collecting patient-reported outcomes, enrolled patients completed the Asthma Quality of Life Questionnaire (AQLQ),²¹ the ACTTM,⁴ and the Asthma APGAR patient questionnaire² at the time of enrollment and will complete them every 6 months thereafter for 2 years. The ACTTM and the AQLQ also have versions for children aged 5 to 12 years, the Childhood Asthma Control Test (CACTTM)²² and the Pediatric Asthma Quality of Life Questionnaire (PAQLQ),²³ which were administered to 5- to 12-year-olds. The Asthma APGAR system is designed to be answered by parents and children together, allowing the amount of collaboration to be matched to the individual child's abilities. The baseline questionnaire packet also included demographic data (eg, birth date and sex), which were also used in the analyses. This study uses data only from the baseline enrollment packet of questionnaires.

The enrollment goal for the parent study is 1400 individuals aged 5 to 45 years with physician-diagnosed asthma. The data for this substudy come from the first 468 patients who were enrolled and returned their baseline packets over the first 6 months of enrollment from March 1, 2011, to December 31, 2011. Return rate for these baseline packets was 97%. All questionnaires included in this analysis were machine-scored, with a 10% sample scored twice to assess scoring errors. None were found.

The Asthma APGAR system, the ACTTM/CACTTM, and the AQLQ/PAQLQ were scored according to published instructions for scoring and interpretation.^{2,4,21-23} For the Asthma APGAR system, any score above 2 is considered to be consistent with inadequate asthma control and a score of 2 or less is considered to be consistent with asthma in control.² This scoring is based on the National Asthma Education and Prevention Program 2007 guidelines chart of control assessment.¹ For both the ACTTM and CACTTM, a score of 19 or less is designated as consistent with inadequately controlled asthma.^{4,22} For this study, we used only the distinction of "in control" and "not in control," with the ACTTM/CACTTM cutoff score of 20 or more

Name _____
APGAR PLUS
Date _____

A = Activities
P = Persistent
G = triGGers
A = Asthma medications
R = Response to therapy



P = Asthma Plan
L = Lung function
U = Use of inhaler
S = Steroids

Please circle your answers:

A 1. In the past 2 weeks, how many times did any breathing problems (such as asthma) interfere with your **ACTIVITIES** or activities you wanted to do?

Never 1-2 times 3 or more times

P 2. How many **DAYS** ☀ in the past 2 weeks did you have shortness of breath, wheezing, chest tightness, cough or felt you should use your rescue inhaler?

None 1-2 DAYS 3 or more DAYS

3. How many **NIGHTS** 🌙 in the past 2 weeks did you wake up or have trouble sleeping due to coughing, shortness of breath, wheezing, chest tightness or get up to use your rescue medication?

None 1-2 NIGHTS 3 or more NIGHTS

G 4. Do you know what makes your breathing problems or asthma worse?

Yes No Unsure

- Please circle things that make your breathing problems or asthma worse:

Cigarettes Smoke Cold Air Colds Exercise Dust Dust Mites
 Trees Flowers Cats Dogs Mold Other: _____

- Can you avoid the things that make your breathing problems or asthma worse?

Seldom Sometimes Most of the time

A 5. List or describe medications you've taken for breathing problems or asthma in the past 2 weeks: Remember you may use Nasal, Oral, or Inhaler medications.

| Breathing or Asthma Medication | When taken? | | Reasons for taking medication: | Reasons for not taking medication: |
|--------------------------------|--------------------------------|------------------------------------|--------------------------------|------------------------------------|
| | <input type="checkbox"/> Daily | <input type="checkbox"/> As needed | | |
| | <input type="checkbox"/> Daily | <input type="checkbox"/> As needed | | |
| | <input type="checkbox"/> Daily | <input type="checkbox"/> As needed | | |
| | <input type="checkbox"/> Daily | <input type="checkbox"/> As needed | | |

R 6. When I use my breathing or asthma medicines I feel:

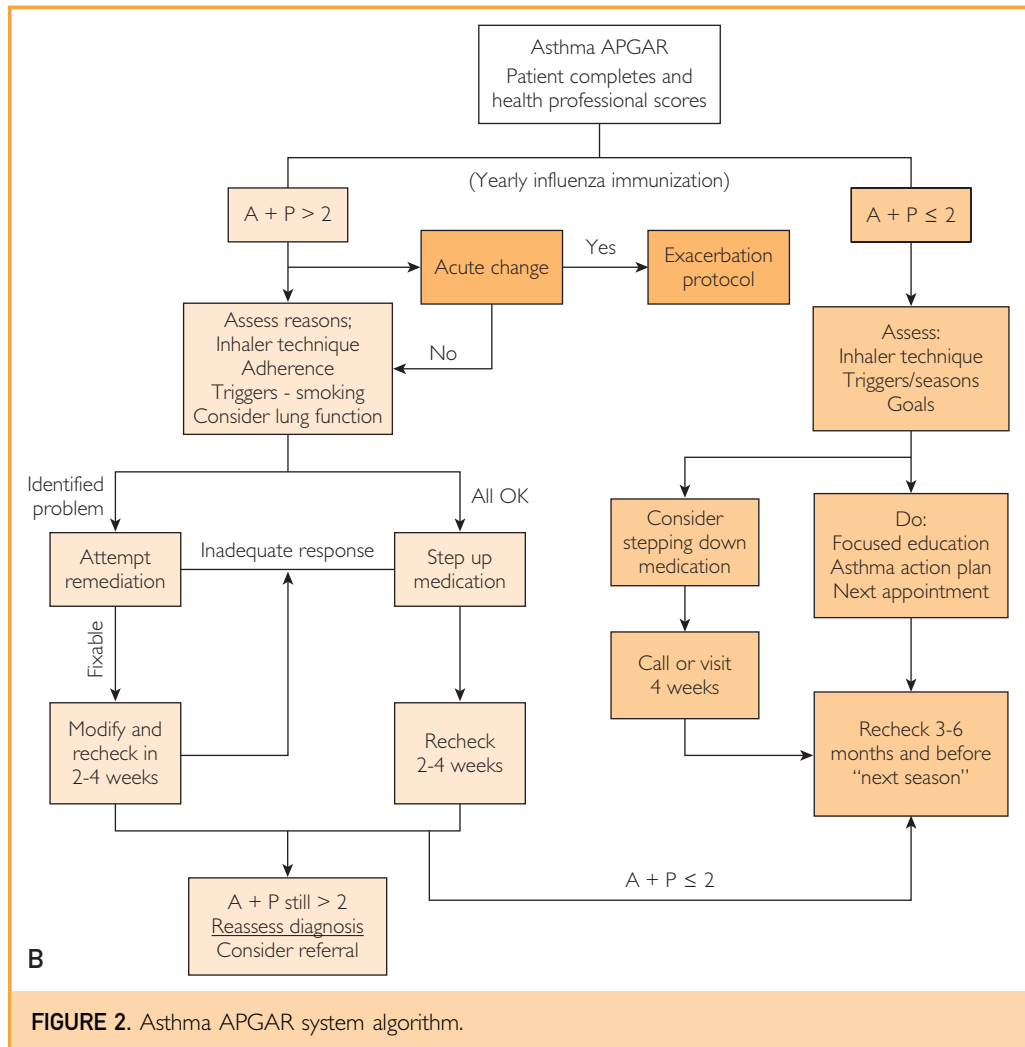
Worse No Different A Little Better A Lot Better

FIGURE 1. Patient Asthma APGAR system form.

being considered in control and anything less than 20 not in control. The AQLQ is a 32-item questionnaire in 4 domains (symptoms, activity limitation, emotional function, and environmental stimuli), each scored on a 7-point scale.²¹ The PAQLQ is a 23-item questionnaire in 3 domains (similar to the AQLQ without

the environmental stimuli domain), also scored on a 7-point scale.²³

This study and the parent Asthma Tools Study were approved by the institutional review boards (IRBs) of all participating sites as well as the IRB of the Olmsted Medical Center and the American Academy of Family Physicians, hosts



of the National Research Network. The National Research Network's IRB served as an IRB for sites not affiliated with any IRB. All enrolled patients 18 years and older signed informed consent. Parents signed consent for all children and adolescents younger than 18 years, with the child's assent required for children ages 5 to 17 years, requiring the child to sign at age 8 to 17 years. Each of the previously validated tools was used with permission.

Data Analysis

Primary analysis was to determine the agreement between the ACTTM/CACTTM and the Asthma APGAR system for each individual. Agreement was assessed with percent agreement and kappa statistics. We also report McNemar statistic *P* values to assess whether

disagreement favors one asthma score over the other. Association with the AQLQ/PAQLQ was assessed using Spearman and Pearson correlation coefficients. Demographic characteristics associated with asthma control status were identified using logistic regression.

RESULTS

The study included a total of 468 patients. The demographic characteristics of the patients and the level of control as measured by the Asthma APGAR system are summarized in Table 1. There was considerable diversity in terms of age, ethnicity, education, and income. The patients who were more likely to be not controlled were those 19 years and older (*P*=.01), females (*P*=.02), blacks (*P*=.002), smokers (*P*=.03), and those exposed to secondhand smoke

($P=.02$). Those in the highest income group were significantly more likely to be in control ($P=.015$).

Figure 3 and Table 2 show comparisons of the degree of control as measured by the ACTTM/CACTTM and the Asthma APGAR system for patients aged 5 to 11 years, 12 to 18 years, older than 19 years, and the entire group. In the age group 5 to 11 years, the CACTTM and the Asthma APGAR system scores were in agreement 85.8% of the time (95% CI, 78.5-91.4%), resulting in substantial agreement ($\kappa=.716$; 95% CI, .060-.84). The McNemar test P value of .48 shows no significant difference in the direction of disagreement using the 2 instruments. In the age group 12 to 18 years, the scores for the 2 instruments were in agreement 81.3% of the time (95% CI, 71.0-89.1%), resulting in substantial agreement ($\kappa=.625$; 95% CI, .45-.80). Again, there was no significant difference in the direction of disagreement as shown by the McNemar test ($P=.61$). In the age group of 19 years and older, there was 84.7% agreement (95% CI, 79.7-88.8%) between the 2 scoring systems, resulting in substantial agreement ($\kappa=.674$; 95% CI, .58-.77; McNemar test $P=.27$).

Of the 468 patients, 306 patients (65%) were classified as not controlled by either the ACTTM (or the CACTTM) or the Asthma APGAR system. Alternatively, 162 patients (35%) were classified as controlled by both the ACTTM/CACTTM and the Asthma APGAR system. Thus, 73 patients (15.6%) were classified differently by the 2 instruments. The overall agreement was 84.4%, with a kappa value of .68 (substantial agreement) and a McNemar test P value of .35.

Of special interest are those who fall just outside the zone of concordance. Twenty-eight patients had an ACTTM score of 19 or less (consistent with not controlled) but an Asthma APGAR system score of 2 or less, suggesting adequate control. Conversely, 29 had an Asthma APGAR system score of 3 or more, suggesting inadequate control, but an ACTTM (CACTTM) score of 20 or more, suggesting good control. The majority (51 of 57=88%) of these discordant scores are within 2 points of the cut point for the ACTTM/CACTTM or 1 point for the Asthma APGAR system.

Comparing the Asthma APGAR system and the ACTTM/CACTTM with the AQLQ/PAQLQ

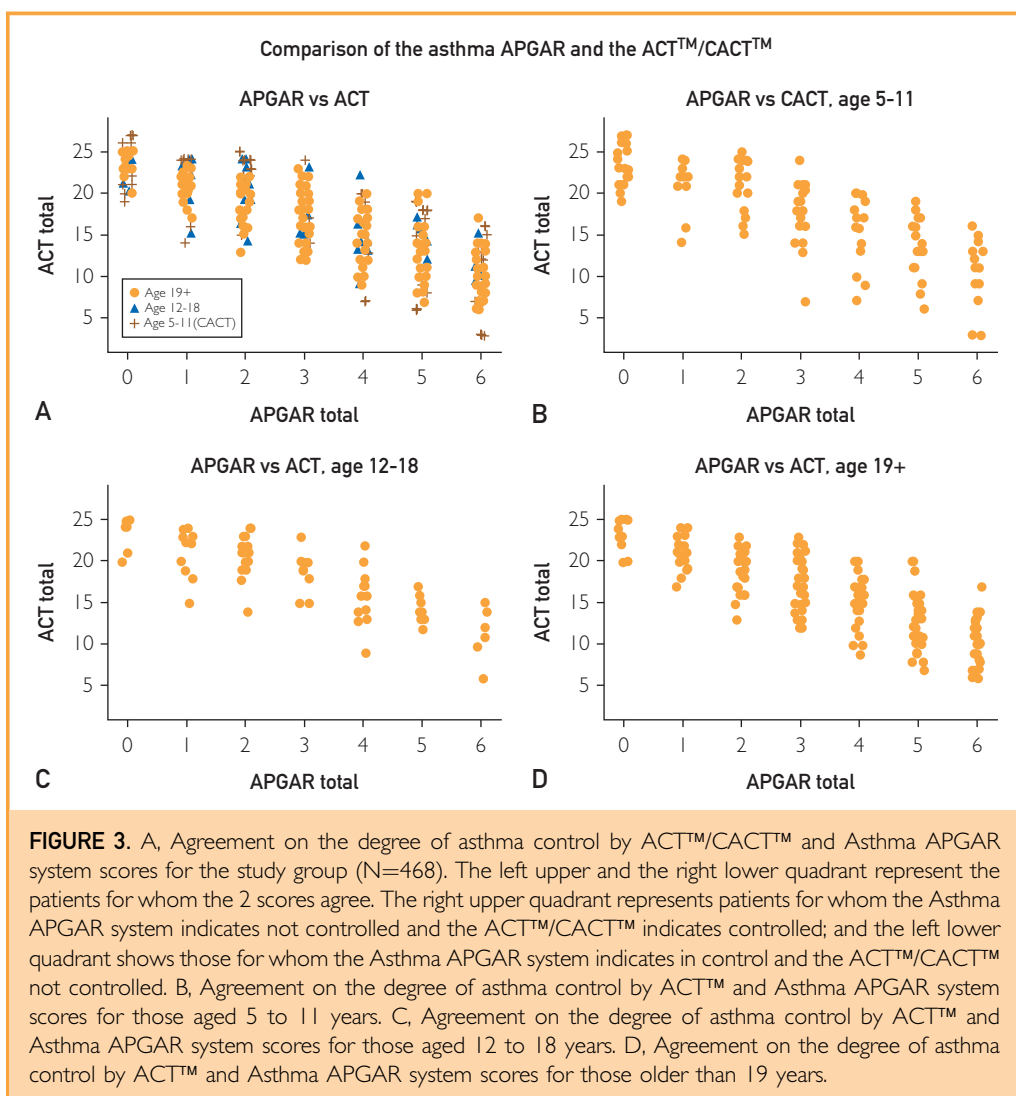
TABLE 1. Demographic Characteristics and Asthma Control Status of Cohort (N=468)

| Characteristic | No. (%) | Control by Asthma APGAR system | |
|---|------------|--------------------------------|------|
| | | No. in control | % |
| Age (y) | | | |
| 5-11 | 128 (27.4) | 58 | 45.3 |
| 12-18 | 81 (17.3) | 44 | 54.3 |
| 19-39 | 130 (27.8) | 44 | 33.8 |
| ≥40 | 129 (27.6) | 47 | 36.4 |
| Sex | | | |
| Male | 183 (39.1) | 88 | 48.1 |
| Female | 285 (60.9) | 105 | 36.8 |
| Race | | | |
| White | 324 (69.2) | 126 | 38.9 |
| Black | 56 (12.0) | 19 | 33.9 |
| Hispanic | 56 (12.0) | 33 | 58.9 |
| Asian | 8 (1.7) | 5 | 62.5 |
| Multiple | 20 (4.3) | 20 | 100 |
| Unknown | 4 (0.9) | 0 | 0 |
| Household income (\$) | | | |
| <10,000 | 126 (26.9) | 50 | 39.7 |
| 10,000-24,999 | 102 (21.8) | 43 | 42.2 |
| 25,000-49,999 | 89 (19.0) | 30 | 33.7 |
| 50,000-74,999 | 89 (19.0) | 35 | 39.3 |
| ≥75,000 | 52 (11.1) | 30 | 57.7 |
| Unknown | 10 (2.1) | 5 | 50.0 |
| Education status ^a | | | |
| High school or less | 132 (28.2) | 52 | 39.4 |
| Post high school | 334 (71.4) | 141 | 42.2 |
| Unknown | 2 (0.4) | 0 | 0 |
| Smoking status | | | |
| Smoker | 49 (10.5) | 9 | 18.4 |
| Nonsmoker but secondhand smoke, current | 102 (21.8) | 35 | 34.3 |
| Nonsmoker but secondhand smoke, ever | 232 (49.6) | 158 | 68.1 |

^aEducational status is of parent if patient is younger than 19 y.

resulted in similar outcomes. The level of control was associated with the level of quality of life measured by the AQLQ/PAQLQ. Using the Spearman test for correlation, the Asthma APGAR system and the AQLQ/PAQLQ statistic is $-.77$ ($P<.001$) and the same ACTTM/CACTTM and the AQLQ/PAQLQ statistic is $.79$ ($P<.001$). The Pearson correlation coefficients are similar: The Asthma APGAR system with the AQLQ/PAQLQ is $-.76$ ($P<.001$) and the ACTTM/CACTTM with the AQLQ/PAQLQ is $.79$ ($P<.001$).

The Asthma APGAR also reports directly "actionable items" related to adherence, triggers, and responsiveness to medications currently prescribed. Of those with poor control based



on Asthma APGAR system score of 3 or more, 73 of 306 (23.8%) had no daily medications and 234 of 306 (76.5%) were seldom or sometimes able to avoid identified triggers for their asthma. Of those who stated that they had been prescribed daily controller medications, 116 of 332 (35%) stated that they did not use the controller medication on a daily basis, instead reporting as-needed use only. Overall, only 3.3% (15) of the individuals completing the Asthma APGAR system stated that they did not feel “a little or a lot better” when using their asthma medications.

DISCUSSION

The analysis from this study suggests that the Asthma APGAR system and the ACT™/CACT™

are similar in the assessment of asthma control in a multicenter primary care sample. Although there are some individuals who would be categorized as not well controlled only by the Asthma APGAR system or the ACT™/CACT™, these individuals are less than 13% (57) of the cohort studied. Another important finding from this study is the high proportion of individuals with asthma that is not in control (65.4%, 306) although only 3.3% (15) felt that their asthma medications were not helpful when used. This difference underscores the need to identify effective tools to help primary care management of apparent reasons for lack of control. Such issues may include assessment of adherence, triggers, and proper inhaler technique that are all part of the Asthma APGAR system

but missing from other control assessments. Following these individuals prospectively during the trial will provide additional information in terms of key asthma outcomes (quality of life, exacerbations, control, etc).

Although the ACT™/CACT™ provided a numerical result for control status, no additional information is provided to guide next steps of care. In contrast, of the 65% of individuals assessed to be out of control on the Asthma APGAR system, most (>75%) of the individuals had “actionable items” identified on this 6-question tool. Thus, the Asthma APGAR system provided primary care physicians and other clinicians with specific information to guide next steps of care. Those steps included addressing adherence, trigger avoidance, and evaluation of inhaler technique before simply stepping up therapy. This support for comprehensive asthma management might prevent potentially ineffective (or unnecessary) stepping up of pharmacotherapy therapy. For example, both poor adherence to prescribed therapy and poor inhaler technique are known to be common.^{24,25} Simply increasing inhaled therapy is unlikely to solve the problems when the medications are not reaching the target area because of poor technique.²⁶ The effect of stepping up therapy in the face of ongoing trigger exposure (eg, cockroach allergy and cigarette smoking) is not clear; although this strategy may be effective, it will be more likely to be effective if coupled with education on trigger avoidance.²⁷ Using the Asthma APGAR tool and its built-in efficiency to identify key aspects of asthma management and common reasons for lack of asthma control in primary care practices could avoid unnecessary prescription of asthma medications while providing reminders to the primary care staff to address issues the Asthma APGAR system identifies for them (Figure 4).

Tools for measuring asthma control have been assessed using criterion standards and against each other. The ACT™ and the CACT™ were validated using specialist assessment of asthma control as a criterion standard.^{4,22} In the initial validation studies, the ACT™ and the CACT™ were reported to have high overall levels of agreement with asthma specialists’ assessments of control (71%-78%), with the area under the receiver operating characteristic curve of .77.^{4,22} The ACT™ has been compared with other assessments of asthma control including

TABLE 2. Level of Agreement Between the Asthma APGAR System and the ACT™/CACT™

| Age (y) | Agreement (%) (95% CI) | κ statistic (95% CI) | McNemar test | |
|----------|------------------------|-----------------------------|--------------|--|
| | | | P value | |
| 5-11 | 85.8 (78.5-91.4) | .716 (.60-.84) | .48 | |
| 12-18 | 81.3 (71.0-89.1) | .625 (.45-.80) | .61 | |
| ≥19 | 84.7 (79.7-88.8) | .674 (.58-.77) | .27 | |
| All ages | 84.4 (80.8-87.6) | .681 (.61-.75) | .35 | |

ACT™ = Asthma Control Test; CACT™ = Childhood Asthma Control Test.

the ACQ,⁵ the Asthma Therapy Assessment Questionnaire,⁷ and the Global Initiative for Asthma (GINA) assessment of control.²⁸ Using the GINA assessment as the criterion standard, the ACT™ correctly predicted uncontrolled asthma in 80.7% of the cases (adults only) whereas the ACQ predicted GINA uncontrolled asthma in 71.3% of the cases.²⁸ Comparing assessment with ACT™ to GINA for both in and not in control, the ACT was found to have a kappa value of .511.²⁹ The low levels of disagreement we measured in our study between ACT™/CACT™ and the Asthma APGAR system are, therefore, similar to disagreement levels previously reported for the ACT™/CACT™ and other validated asthma control tools.

The comparisons between the control tests and the AQLQ/PAQLQ are not intended to assess validity but to provide another avenue of assurance that both the ACT™/CACT™ and the Asthma APGAR system appear to be assessing similar concepts.³⁰ Both have similar associations with the AQLQ/PAQLQ. The association with the Asthma APGAR system is negative because higher Asthma APGAR system scores are associated with less control while higher AQLQ/PAQLQ scores are associated with higher quality of life.

The primary limitation of this substudy is its cross-sectional design. With only these scores it is not possible to know whether the high rate of those individuals not in control is due to acute changes in control status or a longer term difference. However, this should not affect the comparison of the 2 instruments. The recall time of the 2 questionnaires, however, may affect the comparison. The ACT™/CACT™ uses asthma symptoms over the past 4 weeks, whereas the Asthma APGAR system uses a 2-week recall period. It is possible that some of the individuals had loss of control only in the past 2 weeks and might therefore have different scores considering

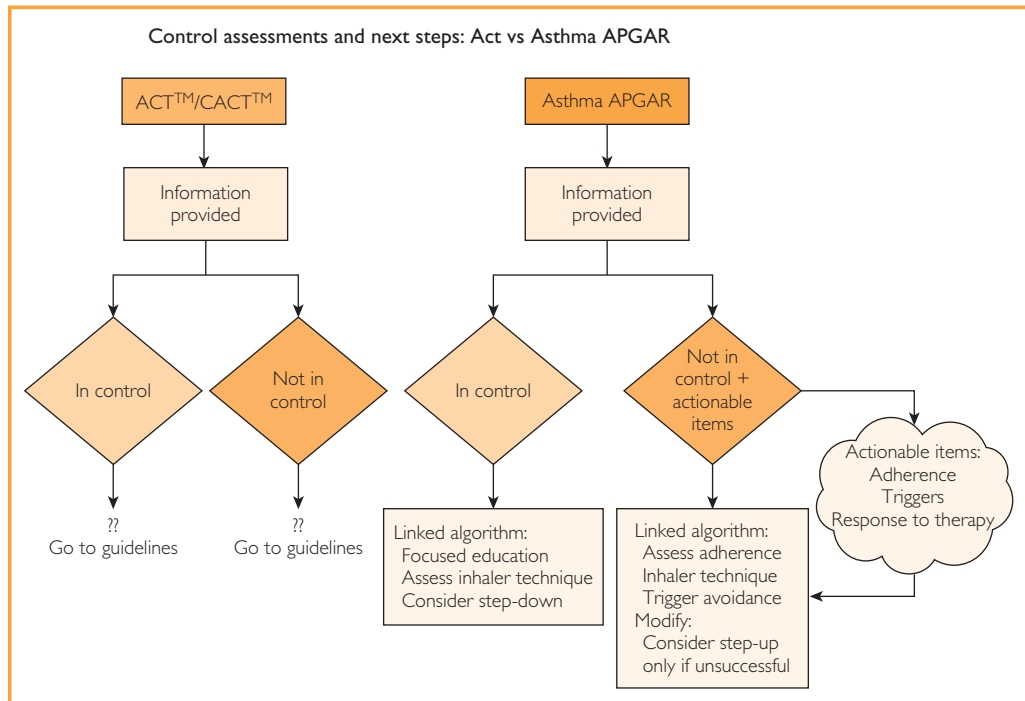


FIGURE 4. Control assessments and next steps: The ACT™ vs the Asthma APGAR system.

the Asthma APGAR system's and ACT™/CACT™'s differing recall periods of 2 and 4 weeks, respectively. The Asthma APGAR system and the ACT™/CACT™ track closely with the AQLQ/PAQLQ, an instrument that uses a 2-week recall. These limitations do not detract from the overall finding that the Asthma APGAR system and the ACT™/CACT™ similarly assessed asthma control in the sample we studied.

The strengths of this study are the external validity to patients and family medicine/pediatric providers in community settings, the multicenter sample, and the moderate to large sample size. The ACT™/CACT™ was developed as a control assessment by asthma specialists, whereas the Asthma APGAR system was developed in collaboration with primary care health professionals to meet their self-reported needs.^{2,31} An additional strength is the ability to compare immediately identified action items for primary care providers between the ACT™/CACT™ and the Asthma APGAR system.

CONCLUSION

In summary, the Asthma APGAR system and the ACT™/CACT™ similarly assess asthma control

in a multicenter primary care–based sample, both of which are strongly associated with the measurement of asthma-specific quality of life (AQLQ/PAQLQ). The Asthma APGAR system appears to be a promising tool based on the analysis of this study, which found that more than 70% of the individuals had an “actionable item,” providing direction to primary care clinicians who consider management options in individuals with poorly controlled asthma.

ACKNOWLEDGMENTS

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Abbreviations and Acronyms: ACT™ = Asthma Control Test; ACQ = Asthma Control Questionnaire; AQLQ = Asthma Quality of Life Questionnaire; CACT™ = Childhood Asthma Control Test; GINA = Global Initiative for Asthma; IRB = institutional review board; PAQLQ = Pediatric Asthma Quality of Life Questionnaire

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