

**ASTHMA CONTROL TEST (ACT)**

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**ABSTRACT**

Measurement of asthma control began with a severity focus and asthma was categorized into mild intermittent, mild, moderate, and severe persistent asthma. It was then recognised that the documented severity of asthma does not necessarily correspond to the control of symptoms at a given time. A patient with documented mild persistent asthma when assessed over time went through times of different categories of severity. Thus, trying to titrate the treatment of asthma by documented severity was not satisfactory. The search for a better index of control resulted in multidimensional instruments that measure patient's reported control of symptoms. One of these is the Asthma Control Test (ACT). It promises to be an easy-to-use instrument that can be used in the consultation setting to assess the control of asthma. The instrument consists of a 5-item questionnaire filled by the patient. It measures symptoms (daytime and nocturnal), use of rescue medications, and the effect of asthma on daily functioning. The ACT when compared against specialist rating of asthma control was found to be comparable, and also was able to indicate when changes in asthma control are needed. Thus, an ACT score of 19 or less indicates control problems which might require assessment of the patient's asthma treatment regimen or other measures are required to improve asthma control. The ACT can be used with or without FEV1 testing. The ACT score should be able to help physicians in their efforts to improve assessment of asthma control in the busy clinical practice setting.

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**INTRODUCTION**

Patients with poor asthma control suffer from recurrent exacerbations that result in the need for emergency visits, admissions, and impairment of quality of life. An expert panel in 1991 worked on classifying asthma based on severity of the asthma on the premise that if we can define severity of asthma we can define if the patient's asthma is controlled or not and we can also define the intensity of treatment that will be required to improve things.

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**Classifying asthma**

Classifying asthma into different patient groups with different needs for management has therefore been a key component of guideline development (Graham LM, 2006)<sup>1</sup>. The National Asthma Education and Prevention Program (NAEPP) 1997 guidelines<sup>2</sup> adopted a "stepped-care" approach to pharmacotherapy: increasing treatment intensity with asthma severity. Figure 1 and Figure 2 show respectively the asthma severity classification and the recommended pharmacotherapy based on the severity classification. The asthma severity classification also forms the basis of the Global Initiative for Asthma guidelines (GINA, 2004)<sup>3</sup>.

**Difficulties in using the asthma severity classification**

Several difficulties are encountered in using the asthma severity classification to direct a hierarchy of treatment based on what is described in Figure 2.

**INADEQUACY OF ASTHMA SEVERITY AS A CONTROL TEST**

The asthma severity system as a measurement of control has the following difficulties:

- κ Severity classification may not correlate with functional impairment
- κ Severity may vary over time
- κ "Mild" asthma is not that mild
- κ Classifying asthma by severity can only be used for patients not on controllers.

**Severity classification may not correlate with functional impairment**

In a study by Fuhlbrigge et al (Fuhlbrigge et al, 2002)<sup>4</sup>, designed to assess asthma burden in the United States, the severity classification was found to increase as additional factors were taken into account. Thus, based on daytime symptoms, 19.1% patients (out of 42,022 households surveyed) had moderate-to-severe disease. The percentage of moderate-to-severe disease rose to 28.2% if nocturnal symptoms were used. If one combines the daytime and nocturnal symptoms, the prevalence of moderate-to-severe grew to 35.9%. Finally, if global criteria from the NAEPP were used, the percentage of patients with moderate-to-severe asthma will rise to 77.3%.

**Severity may vary over time**

A study by Calhoun et al of 85 patients (Calhoun et al, 2003)<sup>5</sup> showed intra-patient variability in asthma classification over time. At baseline, all patients met the criteria for moderate or

**Figure 1. Classification of Asthma Severity**

Category of severity	Day time symptoms	Night time symptoms	FEV1 or PEF	PEF variability
Severe persistent	Continual	Frequent	Less than or equal to 60%	More than 30%
Moderate persistent	Daily	More than or equal to 5 times/month	More than 60%. Less than 80%	More than 30%
Mild persistent	More than 2 times/week	3-4 times/month	More than or equal to 80%	20-30%
Mild intermittent	Less than or equal to 2 times/week	Less than or equal to 2 times/month	More than or equal to 80%	Less than or equal to 20%

Source: National Asthma Education and Prevention Program. NIH. 1997;97-4051:iii-86.

severe persistent asthma. However, the mean percentage of the 12 treatment weeks when these patients could be reclassified as having intermittent, mild, moderate, and severe asthma was 9%, 14%, 71%, and 6%, respectively.

This variability is due to changes on any one of the measures of severity: PEF, beta-agonist use, or symptoms. The lack of correlation between the factors used to the NAEPP 1997 guidelines is of concern, as they can all be used to make the final severity assessment. In addition, the observed variability over time means that a severity classification may depend on which particular day that patient is assessed and their recent symptom history.

**“Mild” asthma is not that mild**

To assess the variability of the asthma in patients with mild persistent asthma over time, Zeiger et al (Zeiger et al, 2004)<sup>6</sup> studied 400 patients with documented mild persistent asthma looking at rescue-free days, asthma symptoms, salbutamol use, medical resource use, and exercise in the period between the month before study enrollment and the last 2 weeks of the run-in period.

It was found that as a group the patients exhibited symptoms (mean +/- SD) 3.6 +/- 1.3 days/week, beta-agonist use 3.5 +/- 1.3 days/week, and normal FEV1 (94.0 +/- 9.9% predicted) during the last 2 weeks of the run-in period.

**Figure 2. NAEPP 1997 Guidelines Severity Classification and Recommended Therapy**

Severity classification	Recommended Pharmacotherapy
Mild intermittent	No daily medication; as needed short acting beta agonist
Mild persistent	As-needed short acting beta agonist; low dose ICS or other anti-inflammatory
Moderate persistent	As-needed short acting beta agonist; medium dose ICS or low dose ICS plus long-acting bronchodilator; increase ICS dose and add long-acting bronchodilator if needed
Severe persistent	As-needed short-acting beta agonist; high dose ICS plus long acting bronchodilator plus oral corticosteroids

Source: NAEPP, 1997 Guidelines

In the year before enrollment into the study, medical intervention for asthma flares was common: 38.5% made office visits, 15.8% had oral corticosteroids, and 8.3% required emergency room or hospitalized care.

In the month before enrollment, 11.8% experienced daily symptoms, and 28.3% had limitations of normal activity. Patients with daily symptoms in the month before study enrollment, compared with those having less-than-daily symptoms, experienced fewer rescue-free days (P = 0.024) and had more days per week with symptoms (P = 0.008) and requiring salbutamol (P = 0.048) during the run-in; FEV1 was similar for both groups (93.1% vs. 94.2% predicted, respectively).

Thus, it can be seen that patients with mild persistent asthma reported a substantial disease burden in the year before enrollment into the study. The asthma burden experienced by these patients both before and during the run-in period was of sufficient severity to support the notion that mild persistent asthma is not that mild. The authors recommended that mild persistent asthma should be managed with daily controller therapy.

**Classifying asthma by severity can only be used for patients not on controllers**

Severity classification is not applicable once the patient is put on treatment. In practice, it is part of routine management to step-down therapy in stable, well-controlled patients to try to maintain control with minimum therapy. This will change the patient’s severity classification and consequently the treatment regimen which may then become inadequate.

**THE CONCEPT OF ASTHMA CONTROL**

Instead of classifying asthma by severity to decide on therapy with its attendant difficulties described earlier, a solution would be to focus on symptom control instead. Classifying asthma based on symptom control takes a patient-focussed, tailored approach to therapy, which is flexible enough to change over time rather than a set solution for every patient assigned to a particular category of severity at one point in time.

Any measure of symptom control has to be multidimensional to overcome the effects of patients underestimating their

symptoms. This has been shown in surveys in the United States and Europe, with many patients initially reporting that their symptoms are well controlled until further questioning reveals that their symptoms are in fact present. (Graham LM, 2006)<sup>1</sup>

## MULTIDIMENSIONAL INSTRUMENTS TO TEST ASTHMA CONTROL

The search for a better way to define asthma control more precisely began in the latter part of the 1990s and three multidimensional instruments have since been developed and validated on symptom control, namely, (1) The Asthma Control Questionnaire (ACQ) (Juniper et al, 1999)<sup>7</sup> (2) the Asthma Therapy Assessment Questionnaire (Vollmer et al, 1999)<sup>8</sup>; and (3) The Asthma Control Test (ACT) (Nathan et al, 2004)<sup>9</sup> which has been validated for use in asthma patients seen in the community (Schatz et al, 2006)<sup>10</sup>. The ACT is validated against the ACQ. Suffice to say, each succeeding asthma control instrument becomes simpler and simpler to use.

### The Asthma Control Questionnaire (ACQ)

The ACQ was developed from a list of symptoms generated by the authors and sent to be ranked by 100 asthma clinicians who were members of guidelines committees in 18 countries (Juniper et al, 1999)<sup>7</sup>. They scored each symptom for its importance in evaluating asthma control. From the 91 responses, the five highest scoring symptoms were selected for the ACQ.

The top 5 symptoms plus beta-agonist use and airway caliber were included in the final seven-point measure. The tool was assessed in a 9-week study of 50 adults with asthma which showed a high level of interclass reliability (intraclass correlation coefficient (ICC)=0.90) and high responsiveness to changes in asthma control ( $p<0.0001$ ). Cross-sectional and longitudinal validity were supported by correlations between the ACQ and other measures of asthma health status. Asthma Control Questionnaire has strong evaluative and discriminative properties and can be used with confidence to measure asthma control.

### Asthma Therapy Assessment Questionnaire

The Asthma Therapy Assessment Questionnaire was developed for use in population-based disease management by Vollmer et al (Vollmer et al, 1999)<sup>8</sup>. It is based on a simple index of control problems ranging from no control problems to four.

When applied to 5,181 adults, there were significant associations between the questionnaire and self-reported health-care utilization and quality of life using generic and disease-specific instruments. It was found that rates of acute care episodes were 3.5 times more likely for patients with three or four control problems, 1.7 times for those with two control

problems, and 1.4 times for those with one control problem vs. those with no control problems; all of these differences were significant. (Vollmer et al, 2002)<sup>11</sup>.

### The Asthma Control Test™ (ACT)

The Asthma Control Test (ACT) is a patient-based tool for identifying subjects with poorly controlled asthma. The test was developed by triangulating a 22-item survey of 471 patients with asthma specialist rating of asthma control after spirometry. (Nathan et al, 2004)<sup>9</sup>.

The 22 items used for the survey was developed by a working group consisting of 4 primary care physicians and 7 asthma specialists. Stepwise regression methods were used to select a subset of items that showed the greatest discriminant validity in relation to the specialist's rating of asthma control.

Five items were selected this way – shortness of breath, patient rating of control, use of rescue medication, asthma keeps you from getting much done at work/school, and asthma symptoms wake you up. A questionnaire – the ACT – was developed using these 5 items. Each of the item was scored from 1-5 and the total score for the 5 items computed (Figure 3).

The performance of ACT was tested using logistic regression methods and receiver operating characteristic (ROC) curves. The internal consistency reliability of the 5-item ACT scale was 0.84 in the total sample (n=436).

Among the 133 patients categorized as not controlled according to the specialist's rating (not controlled at all, poorly controlled, or somewhat controlled), the internal consistency reliability of the 5-item ACT survey was 0.83.

The internal consistency reliability of the 5-item ACT survey among the 303 patients categorized as controlled (well controlled or completely controlled) was 0.79.

As a screening tool, the overall agreement between ACT and the specialist rating ranged from 71% to 78% depending on the cut off points used (Figure 4, column % correctly classified). The area under the ROC curve was 0.77.

### USE OF THE ACT SCORE

The ACT score can be used by itself or with spirometry for assessment of the patient in the consultation setting.

### Interpretation of the ACT score

The following are interpretations of the ACT score have been described by (Schatz et al, 2006)<sup>10</sup>

- κ The higher the ACT score on the range of 5 to 25, the better the control.
- κ A score of 19 or less signal a need for further evaluation to determine whether adjustments to asthma treatment regimen or other measures are required to improve asthma control.
- κ A score of 15 or less is of particular concern because it predicts asthma that is poorly controlled or not controlled at all.

Figure 3. Asthma Control Test TM

Question	Scoring system	Patient score
1. In the past 4 weeks, how much of the time did your asthma keep you from getting as much work done at work, school or at home?	All the time – 1 Most of the time – 2 Some of the time – 3 A little of the time – 4 None of the time – 5	
2. During the past 4 weeks, how often have you had shortness of breath?	More than once a day – 1 Once a day – 2 3 to 6 times a week – 3 Once or twice a week – 4 Not at all – 5	
3. During the past 4 weeks, how often did your symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?	4 or more nights a week – 1 2 to 3 nights a week – 2 Once a week – 3 Once or twice – 4 Not at all – 5	
4. During the past 4 weeks, how often have you used your rescue nebuliser or nebulizer medication (such as salbutamol)?	3 or more times per day – 1 1 or 2 times per day – 2 2 or 3 times per week – 3 Once a week or less – 4 Not at all – 5	
5. How would you rate your asthma control during the past 4 weeks?	Not controlled at all – 1 Poorly controlled – 2 Somewhat controlled – 3 Well controlled – 4 Completely controlled – 5	
Total	Your patient's score:	

Interpretation

- o The higher the ACT score on the range of 5 to 25, the better the control.
- o A score of 19 or less signal a need for further evaluation to determine whether adjustments to asthma treatment regimen or other measures are required to improve asthma control.
- o A score of 15 or less is of particular concern because it predicts asthma that is poorly controlled or not controlled at all.

*Asthma Control Test™ Q. 2002 by QualityMetric Incorporated. All rights reservedSource: Schatz, 2006 (slightly adapted) 7*

**Applications of the ACT score**

As a screening test for poorly controlled asthma, the cut-off point of 19 provides the optimum balance of sensitivity (71%) and specificity (71%) for detection of such a patient.

If the desire is to pick out patients with poor control with a greater specificity (fewer false positive results), what cut-point score should be used? Since the higher the score, the better the control, a cut-point score of less than 19 might be appropriate in this instance. A score of 15 or less will be poorly controlled asthma or asthma that is not controlled at all.

If the intent is to improve asthma symptoms, or both symptoms and well being, at a minimum well-controlled level and with the goal of achieving complete asthma control, then what cut-point should be used? Since the goal is achieve complete asthma control, then a cut-point score of 20 or more will be appropriate with the goal of reaching the ideal score of 25.

**ACT as a screening test of poor asthma control**

The attractiveness of the ACT score as a screening test lies in its ability to provide the busy physician with an accurate,

reliable, and easy-to-use control tool that is essential in the management of asthma patients.

The ACT provides a simplified assessment of control without the need for FEV1 values. The latter might not always be available. The need for only five questions make is easier than the asthma control questionnaire (ACQ). The ACT is also more comprehensive in scope than the Asthma Therapy Assessment Questionnaire for evaluating the range of asthma control.

**ACT as a monitoring tool and research tool**

Schatz et al's study (Schatz, 2006)<sup>10</sup> on the use of the ACT on asthma patients showed the score to be responsive to changes in asthma control over time as evidenced by changes in specialist ratings, lung function, and ACQ scores. Repeated administration of the ACT to an individual patient over time, might allow the family physician to gauge the success of therapeutic interventions and in identifying deterioration in asthma control.

The use of ACT over time would also be useful as a research tool for studying the asthma control of patients

Figure 4. Performance of simple sum scoring at various cut points in screening for uncontrolled asthma (N=436)\*

Cut point score	Odds ratio	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)	% correctly classified	Area under ROC
< 10	7.41	9.0	98.7	75.0	71.2	71.3	0.539
< 11	7.04	14.3	97.7	73.1	72.2	72.3	0.560
< 12	9.11	21.8	97.0	76.3	73.9	74.1	0.594
< 13	7.96	29.3	95.1	72.2	75.4	75.0	0.622
< 14	7.58	36.1	93.1	69.6	76.8	75.7	0.646
< 15	9.27	44.4	92.1	71.1	79.0	77.5	0.682
< 16	9.41	52.6	89.4	68.6	81.1	78.2	0.710
< 17	7.68	57.9	84.8	62.6	82.1	76.6	0.714
< 18	6.72	62.4	80.2	58.0	82.9	74.8	0.713
< 19	7.20	69.2	76.2	56.1	84.9	74.1	0.727
< 20	6.31	75.9	66.7	50.0	86.3	69.5	0.713
< 21	5.01	82.7	51.2	42.6	87.1	60.7	0.669
< 22	4.35	87.9	37.3	38.1	87.6	52.8	0.626
< 23	5.32	94.0	25.4	35.6	90.6	46.3	0.597
< 24	3.31	94.7	15.1	33.0	87.0	39.6	0.551
Continuous	0.78	44.4	92.01	77.1	79.0	77.5	0.774

\* Specialist rating of not controlled at all, poorly controlled, or somewhat controlled

Source: Nathan et al, 2004<sup>9</sup>

longitudinally. We may then have a better understanding of the determinants of asthma deterioration, control, and also its natural history.

#### STUDIES USING THE ACT SCORE

So far the use of ACT has shown that in each of the populations of patients studied, a large proportion of patients are not well controlled.

Using the two studies from which the ACT score was developed, the control for the 407 patients attending asthma specialist clinics studied by Nathan et al (Nathan et al, 2004)<sup>9</sup> showed that only 52% patients were rated by specialists as well controlled and the study on 313 patients by Schatz et al (Schatz et al, 2006)<sup>10</sup> on asthma patients not seen by asthma patients showed only 39.2% were well controlled.

Two studies so far on patients getting their medications at pharmacies in Belgium (Mehuys et al, 2006)<sup>12</sup> and France (LaForest et al, 2005)<sup>13</sup> respectively using the ACT score showed only 28% and 23% respectively were well controlled. Also, more patients thought their asthma was well controlled compared to their ACT scores. One huge potential of the ACT score then is to alert patients who think they are well controlled when they are actually not. They will then hopefully take action to correct that.

#### CONCLUSIONS

Classifying asthma by severity was a start in directing the necessary intensity of treatment for patients with asthma. The shortcoming of this system of categorizing patients from the standpoint of asthma control has led to multidimensional instruments focused on patient's control of symptoms. Of the three instruments developed, the Asthma Control Test appears to be the simplest to use. It can be used in the consultation room for rapid ongoing assessment of the patient's asthma control and indicating if changes in treatment or other measures are necessary. Well controlled asthma for the majority should be possible.

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## LEARNING POINTS

- o Measurement of asthma control began with a severity focus and asthma was categorized into mild intermittent, mild, moderate, and severe persistent asthma but severity is not necessarily the same as control of symptoms.
  - o The Asthma Control Test (ACT) is a patient completed questionnaire of 5 items and is a clinical measure of control based on the symptoms (daytime and nocturnal), use of rescue medications, and the effect of asthma on daily functioning.
  - o The ACT has good reliability, criterion validity, discriminant validity, screening accuracy, and responsiveness to the changes in asthma control
  - o The ACT can be used with or without FEV1 testing.
  - o The ACT score was found to be valid when compared with the specialists' rating of asthma control.
  - o The ACT was also found to be valid when compared against patients who were not receiving specialist care.
  - o An ACT score of 19 or less indicates control problems which might require further assessments to asthma treatment regimens or other measures are required to improve asthma control.
  - o The ACT score should facilitate efforts to improve assessment of asthma control in the busy clinical practice setting.
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