

Validation of The 30 Second Asthma Test™ as a measure of asthma control

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BACKGROUND: The primary objective of asthma management is to help patients establish and maintain optimal disease control. Simple and efficient tools are needed to assess patient-reported symptoms so that they can be used with or without airway function to evaluate asthma control.

OBJECTIVE: The objective of the present study was to evaluate the validity of The 30 Second Asthma Test (GlaxoSmithKline Inc, Canada), based on the Canadian Asthma Guidelines, by estimating its relationship with criterion measures of control.

RESULTS: The discriminative and diagnostic validity of The 30 Second Asthma Test™ was examined in a sample of 81 patients with a confirmed diagnosis of asthma. Based on a cut-off score of two or greater on The 30 Second Asthma Test™, the overall agreement with specialist ratings was 65%, and 58% with per cent predicted forced expiratory volume in 1 s. The 30 Second Asthma Test™ scores distinguished between groups of patients who were classified based on the change in intensity of therapy.

CONCLUSION: The results support the use of The 30 Second Asthma Test™ as a brief screening tool for asthma control.

Key Words: Asthma; Outcome; Patient management; Patient reported questionnaire; Screening

Asthma is one of the most prevalent conditions affecting Canadians. According to the 1996 National Health Survey (1), asthma affects 6% of adults and 12% of children, and its prevalence is increasing. Asthma poses a heavy burden on national health care expenditures, and reduces the quality of life of affected individuals and their families (2).

The primary goal of asthma treatment is for patients to maintain optimal control to prevent exacerbations and unnecessary hospitalizations. Routine, formal assessments of control by physicians are infrequent, a shortcoming that may explain why poor asthma control is much more common than it should be (3,4). Consequently, physicians and patients tend to overestimate the adequacy of control (3,4). Many patients perceive their asthma as controlled, even if they experience significant limitations in leisure and work activities (3-5). As a result, patients often do not convey their limitations to physicians, which may increase the gap between actual and optimal asthma care (3).

Validation du Test de 30 secondes sur l'asthme^{MC} comme mesure de maîtrise de l'asthme

CONTEXTE : Le but principal du traitement de l'asthme est d'aider les patients à atteindre et à maintenir une maîtrise optimale de la maladie. Il faut donc disposer d'outils qui soient simples et efficaces pour évaluer les symptômes déclarés par les patients, et qui puissent s'utiliser seuls ou en association avec des épreuves fonctionnelles respiratoires pour évaluer la maîtrise de la maladie.

BUT : L'étude avait pour but d'évaluer la validité du Test de 30 secondes sur l'asthme (GlaxoSmithKline Inc, Canada), fondé sur les principes directeurs du consensus canadien sur l'asthme, par l'analyse du lien avec les scores critères de maîtrise.

RÉSULTATS : La validité diagnostique et discriminante du test a été vérifiée dans un échantillon de 81 patients chez qui un diagnostic d'asthme avait déjà été posé. D'après le score seuil de deux ou plus au Test de 30 secondes sur l'asthme^{MC}, la concordance globale de l'évaluation des spécialistes était de 65 % et de 58 % pour le volume expiratoire maximal par seconde prévu, exprimé en pourcentage. Le Test de 30 secondes sur l'asthme a fait la distinction entre les groupes de patients classés d'après les modifications de l'intensité du traitement.

CONCLUSION : Les résultats étayaient le recours au Test de 30 secondes sur l'asthme^{MC} comme outil d'évaluation rapide de la maîtrise de l'asthme.

Standardized measures of asthma control can help to guide appropriate changes in therapy. Spirometry is viewed as the most accurate means of evaluating adequate asthma control (6-9). Unlike the situation in specialty clinics, family physicians are limited in their capacity to administer spirometry tests to all patients. Therefore, there is a need for alternate tools that can be readily administered at home and in primary care practice. The Canadian Asthma Consensus Report (10) defined acceptable asthma control using both clinical symptoms and physiological parameters (Table 1). These variables included daytime symptoms, night-time symptoms, use of rescue bronchodilators, limitations in physical activity and missed school or work. The 30 Second Asthma Test (GlaxoSmithKline Inc, Canada) was developed based on the clinical symptoms outlined in the asthma guidelines (Table 1) (11). The properties of this measure have never been formally examined. The objective of the present study was to evaluate the validity of The 30 Second Asthma Test™ for assessing asthma control compared

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TABLE 1
Criteria for asthma control

Parameter	Poor control
Daytime symptoms	Three or more days per week
Night-time symptoms	One or more nights per week
Short-acting bronchodilator use	Three or more doses per week
Physical activity	Restricted over the previous three months
Absenteeism	Missed school or work, or social engagement over the previous three months
Exacerbations	Any exacerbation over the previous month

Data from reference 11

with spirometry-based assessment, specialist judgments and changes in intensity of therapy.

METHODS

The present study was approved by the Institutional Review Board of the Montreal General Hospital (Montreal, Quebec).

Study population

Patients with a confirmed diagnosis of asthma were recruited from the Montreal General Hospital asthma clinic (Table 2). Patients were excluded if they were unable to communicate in either English or French.

Measures and variables

The 30 Second Asthma Test™ consists of five questions on the presence or absence of nocturnal symptoms, daytime symptoms (coughing and wheezing), the use of rescue medications, symptom interference with daily activities and absenteeism from work or school. The maximum total score of five represents the unweighted sum of positive responses.

Criterion measures of control

Specialist ratings of patient level of control were evaluated using a five-point Likert scale ranging from very good to poor. Medications used by the patient were recorded at the time of the visit, including changes in the intensity of treatment, which was classified as unchanged, increased or decreased.

Forced expiratory volume in 1 s (FEV₁) was evaluated during the patient visit. The best FEV₁ measurement over the previous 12 months was also recorded. Asthma control was evaluated using FEV₁ estimates by calculating the ratio of patients' FEV₁ results at the time of the visit to the best recorded FEV₁ observed over the previous 12 months ($FEV_{1[control]} = FEV_{1[today]} / FEV_{1[best]}$). At the time of the visit, patients were classified as in control if the FEV₁ ratio was greater or equal to 90%, and out of control if the FEV₁ ratio was less than 90%, as has been suggested in the Canadian Asthma Guidelines (10).

To characterize the study population, age, sex and smoking history (patients who smoked over 10 packs/year) were obtained from patient medical records.

Procedure

The 30 Second Asthma Test™ was completed by the patient at the time of the visit to the asthma clinic, before seeing the specialist physician. Assessment of FEV₁ was performed in the pulmonary function laboratory. The specialist physician assessed the degree of

TABLE 2
Patient characteristics and medications (n=81)

Patient characteristics	Mean (range)
Age, years	48 (19–86)
Best FEV ₁ measurement (%) over the previous 12 months	82 (35–122)
	n (%)
Sex, female	43 (53)
Smoked over 10 packs/year	34 (42)
Medications	
Rescue bronchodilator	80 (99)
Inhaled corticosteroid	74 (91)
Long-acting beta agonist	41 (51)
Leukotriene receptor antagonist	14 (17)
Nasal corticosteroid	19 (23)
Other (eg, theophylline and Atrovent*)	7 (8)

*Boehringer Ingelheim (Canada) Ltd. FEV₁, Forced expiratory volume in 1 s

asthma control at the time of the visit and made changes, if any, to the intensity of drug therapy. The specialist physician knew the value of the FEV₁, the clinical history and results of the physical examination, but was not shown information from The 30 Second Asthma Test™.

Data analyses

The internal consistency of the items on The 30 Second Asthma Test™ was estimated using the Cronbach's alpha coefficient.

The screening accuracy of The 30 Second Asthma Test™ was calculated using the specialist ratings and per cent predicted FEV₁. Patients were classified as in control, according to the specialist ratings, if asthma control was classified as very good, good or acceptable, and out of control if classified as fair or poor. For The 30 Second Asthma Test™, in control was defined as a score of less than two, and out of control was defined as a score of greater than or equal to two. The sensitivity, specificity, and positive and negative predictive values were calculated for a cut-off score of two on The 30 Second Asthma Test™. To evaluate optimal cutpoints on The 30 Second Asthma Test™, the receiver operator characteristic (ROC) curve was constructed using specialist ratings, and the area under the curve was examined. Optimal sensitivity and specificity were estimated from the ROC curves, defined as the values corresponding to the point on the ROC curve lying in the left uppermost part of the curve.

Control status based on scores of The 30 Second Asthma Test™ was also evaluated across groups based on the change in intensity of therapy (unchanged, increased and decreased).

RESULTS

Seventy-five per cent of patients had at least one of the five symptoms (Table 3). Daytime symptoms were the most frequently reported (53%), followed by the use of rescue medications and limitations in physical activities (40%).

The internal consistency of the items on The 30 Second Asthma Test™ was moderate (Cronbach's alpha = 0.70) and the individual coefficient alpha for each item was 0.60 or greater.

The correlation between specialist and patient ratings of asthma control was moderate (r=0.5) and significant

TABLE 3
The 30 Second Asthma Test (GlaxoSmithKline Inc, Canada) and criterion measures of control (n=81)

Measure	n (%)
The 30 Second Asthma Test™	
Daytime symptoms*	43 (53)
Night-time symptoms*	30 (37)
Rescue medications*	32 (40)
Limitations in physical activity†	32 (40)
Absenteeism†	12 (15)
Specialist ratings	
Very good/good/acceptable	60 (74)
Poor/fair	21 (26)
Change in intensity of therapy	
Unchanged	44 (54)
Increased	22 (27)
Decreased	15 (19)
Emergency care	19 (23)
FEV _{1(control)} (poor)‡	20 (25)

*Evaluated over the previous week; †Evaluated over the previous three months; ‡Poor control is defined as forced expiratory volume in 1 s (FEV₁) less than 90% (FEV_{1(control)} = FEV_{1(today)}/FEV_{1(best)})

TABLE 4
Agreement between physician ratings and The 30 Second Asthma Test (GlaxoSmithKline Inc, Canada)

	Physician rating (n=2), n (%)		Total, n (%)
	In control	Out of control	
The 30 Second Asthma Test™			
In control	36 (44)	4 (5)	40 (49)
Out of control	24 (30)	17 (21)	41 (51)
Total	60 (74)	21 (26)	

The 30 Second Asthma Test™ had a sensitivity of 81%, specificity of 60%, positive predictive value of 41%, negative predictive value of 90% and an accuracy of 65%

($P < 0.001$). When the cut-off criteria of two or more symptoms were used, 51% of patients were classified as out of control based on The 30 Second Asthma Test™, and 26% were classified as out of control based on the specialist ratings (Table 4). The sensitivity and specificity of The 30 Second Asthma Test™ (cut-off score of two or greater) using the specialist ratings as the criterion measure were 81% and 60%, respectively. The area under the ROC curve was 0.79 (Figure 1). The optimal sensitivity and specificity, defined as the values corresponding to the point on the ROC curve lying closest to the left uppermost part of the curve, were 68% and 79%, respectively, which corresponded to a cut-off score of three on The 30 Second Asthma Test™.

The sensitivity and specificity of The 30 Second Asthma Test™ using FEV_{1(control)} as the criterion measure were 65% and 55%, respectively (Table 5). As expected, if the intensity of therapy was unchanged or decreased, a larger proportion of patients were classified as in control compared with out of control based on The 30 Second Asthma Test™ (Table 6).

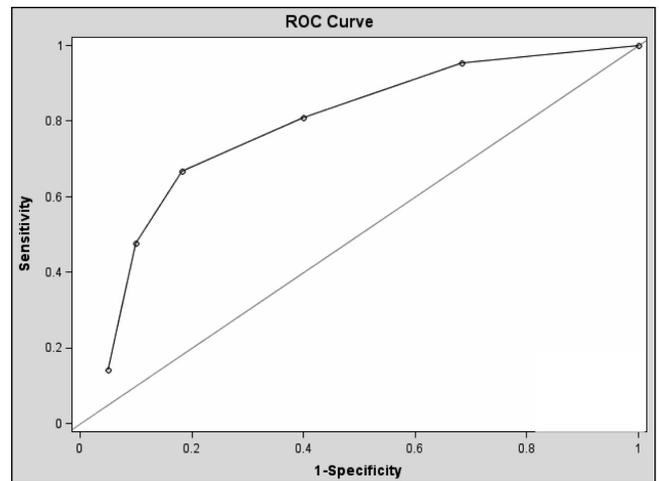


Figure 1 Receiver operating characteristic (ROC) curve for The 30 Second Asthma Test (GlaxoSmithKline Inc, Canada). Area under the ROC curve = 0.79

TABLE 5
Agreement between FEV_{1(control)} and The 30 Second Asthma Test (GlaxoSmithKline Inc, Canada)

	FEV _{1(control)}		Total
	In control	Out of control	
The 30 Second Asthma Test™, n (%)			
In control score < 2	33 (41)	7 (9)	40 (50)
Out of control score ≥ 2	27 (34)	13 (16)	40 (50)
Total, n	60	20	

The 30 Second Asthma Test™ had a sensitivity of 65%, specificity of 55%, positive predictive value of 33%, negative predictive value of 83% and accuracy of 58%. FEV₁ Forced expiratory volume in 1 s

TABLE 6
Agreement between the change in intensity of therapy and The 30 Second Asthma Test (GlaxoSmithKline Inc, Canada)

	Change in intensity of therapy*			Total n
	Increased n (%)	Unchanged n (%)	Decreased n (%)	
The 30 Second Asthma Test				
In control score, < 2	6 (27)	24 (55)	10 (67)	40
Out of control score, ≥ 2	16 (73)	20 (45)	5 (33)	41
Total	22 (100)	44 (100)	15 (100)	

* $\chi^2 P < 0.05$

DISCUSSION

The Canadian Asthma Guidelines (11) were developed to standardize and highlight the importance of evaluating asthma control routinely. These guidelines were the basis for the content and development of The 30 Second Asthma Test™. There was support for the validity of The 30 Second Asthma Test™, which performed as expected in relation to specialist ratings, FEV_{1(control)} and change in intensity of therapy. A cut-off score of two or higher was an indication of poor control as evidenced by the sensitivity analysis. The patient ratings corresponded better with specialist ratings than FEV_{1(control)}

TABLE 7
Summary of measures of asthma control

Measures	Construct	Control items						Other items/ domains	Scoring	Item selection/ psychometrics	Criteria for poor control comments
		NTS	DTS	Act	RM	Missed work/ school	Perception				
30 Second Asthma Test*	Control	×	×	×	×	×		3 items over 1 week 2 items over 3 months (act/missed work/school)	Each item scored yes/no Total score 0–5	Acceptable sensitivity and specificity	≥2 symptoms
Asthma Control Test, (13)	Control	×	×		×	×†	×	5 items over 1 week	Total score 5–25 (poor to complete control) or 0–5 if each item scored yes/no	Item selection based on stepwise regression Known groups validation	Cut-off: ROC curves analyzed to identify optimal cutpoints
Asthma Control Questionnaire, (14)	Control	×	×	×	×			4 items respiratory symptoms Physiological assessment (FEV ₁ , PEF) Inflammatory assessment	5–20, 5-point Likert scale Percentages Total score is an average weighted percentage	Validation through significant correlations between symptoms and overall patient ratings of control and asthma quality of life scores	No criteria reported Inflammatory assessment not commonly performed
Asthma Control Questionnaire (15)	Control	×	×	×	×			6 self-report items over 1 week FEV ₁ over 1 week	0–6, well controlled to extremely poorly controlled 7-point scale/ different descriptions for each item	Tested for reliability, validity and responsiveness	No criteria reported
Asthma Therapy Assessment Questionnaire (16)	Control Barriers to good disease management	×		×	×	×	×	Relationship with medical doctor Attitudes toward treatment Perception of control HCU	Control items: yes/no over previous weeks 4 weeks and 12 months, except perception (only over 4 weeks) Score out of 4	Validity (correlations with HCU and QOL) Relative influence on HCU and QOL using stepwise regression	No criteria reported

Perception: Overall perception of asthma control. *GlaxoSmithKline Inc, Canada; †Role functioning. Act Activity limitations; DTS Daytime symptoms; FEV₁ Forced expiratory volume in 1 s; HCU Health care utilization; NTS Night-time symptoms; PEF Peak expiratory flow; QOL Quality of life; ROC Receiver operator characteristic; RM Rescue medications

estimates, which is in keeping with other studies (3,12,13). Thirty-four per cent of patients had more than two symptoms on The 30 Second Asthma Test™ but were classified as in control according to FEV_{1(control)}. This supports the fact that symptom assessments are capturing a different aspect of control that is not reflected in airway function tests alone.

Previously developed measures of asthma control assess a combination of the items found in The 30 Second Asthma Test™ with variations between measures in the aspects of the symptoms evaluated (eg, some ask about getting less done as opposed to missing work or school), the time period evaluated and the frequency of symptoms (Table 7). The only other measure that has been compared with criterion measures of control as we did in the present study is the Asthma Control Test

(ACT) (13). As opposed to asking about missed school or work, or limitations in physical activity as in The 30 Second Asthma Test™, the ACT has an item that asks “During the past four weeks, how often did your asthma keep you from getting as much done at work, school or at home?” The two items on physical limitations and their consequences on The 30 Second Asthma Test™ helps to discriminate between patients who have some limitations in physical activity and those who are significantly more impaired and are unable to attend school or work as a result of their asthma. The ACT, however, has an item that asks patients to rate their overall asthma control, which may help physicians to identify patients who have a disparity between their perceived level of control and actual symptoms. Future work is needed to compare The 30 Second

Asthma Test™ to other self-report measures of control, such as the ACT, to identify items and scoring scales that would be most discriminative and sensitive to changes in control.

Based on the ROC curve, the optimal cut-off score for The 30 Second Asthma Test™ was three. This corresponded to a higher specificity at the cost of reducing the sensitivity of The 30 Second Asthma Test™, which would decrease the number of false-positive cases (patients identified as not well controlled). Given the consequences of missing a patient who is not well controlled, the recommendation of a cut-off score of two, with a sensitivity of 81%, provides an appropriate balance between the risk of falsely labelling a patient as well controlled as opposed to poorly controlled.

The specialist ratings of control were made by two physicians who were considered to be experts in asthma care. The specialists weighed all the information at their disposal, such as past medical history recorded in the chart, prior assessments of the same patient (specialist ratings were obtained at follow-up but not initial visits), questioning the patient, physical examination, as well as current and past spirometric results. In the absence of a 'gold standard' of asthma control, we thought that the best approach for assessing the screening accuracy of The 30 Second Asthma Test™ was to use the summary ratings of experienced specialists.

One possible limitation of the present study is that 34% of patients had smoked over 10 packs/year. This raised the question of whether patients were truly asthmatic. For patients to qualify for the study, the physician specialists had to provide the

criteria for why they thought a diagnosis of asthma was justified. All patients in this study met the criteria for a diagnosis of asthma based on one or more of the following: response to a bronchodilator, a positive methacholine challenge test, variability in FEV₁ and/or response to therapy. We also examined the sensitivity of The 30 Second Asthma Test™ among non-smokers and found that the sensitivity was 76%, somewhat lower than the full sample. The specificity increased to 77% among nonsmokers.

The validity and simplicity of The 30 Second Asthma Test™ support its use in the clinic to provide an objective assessment of patients' symptoms that can be monitored over time. Self-reported measures ensure that an appropriate patient history is taken, and adds to the comprehensiveness of airway function and physician assessments of control. The use of The 30 Second Asthma Test™, in conjunction with patient education, may also prompt patients to seek physician care when their asthma is not well controlled. The items also serve as a reminder of the asthma guidelines, which are not always adhered to by physicians (3). Future work is needed to examine the responsiveness of The 30 Second Asthma Test™ by comparing it with criterion measures of change and comparing its performance with other patient-reported measures of control.

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