1Evaluation of Asthma Control using Patient Based Measures and Peak Expiratory Flow Rate

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ABSTRACT

Objective: Asthma control has not been formally evaluated in the Caribbean. This study evaluated disease control on The Asthma Control Test (ACT), The Royal College of Physicians "Three questions" for Assessing Asthma Control (RCP), peak expiratory flow rate (PEFR) and patients' self-assessment of control.

Subjects and Methods: Asthma control was examined in a cross-section of 205 asthmatics above 16 years of age using the ACT, RCP and on the PEFR % predicted. Scores below 20 and equal to or above 1 on the ACT and RCP respectively, and PEFR below 80% predicted indicated uncontrolled asthma. Patients stated whether they perceived their asthma was controlled or uncontrolled.

Results: Overall there were more females (63.9%, $p < 0.001$) than males (36.1%). Males aged between 17–30 years predominated (60.8%, $p < 0.001$) with gender reversal beyond 30 years of age (33.2%, $p < 0.002$) years. Self-assessed control was higher (69.3%, $p < 0.001$) than control evaluated by the ACT and RCP tests, which were comparable ($p > 0.05$). Fewer patients (13.2%) achieved control on PEFR > 80% predicted than on the ACT (22.4%) and RCP (18%). The Kappa statistic indicated good reproducibility of the RCP and ACT and concordance between the PEFR and RCP (0.63) and the PEFR and ACT (0.56). Higher education was associated with control on the ACT ($p < 0.0005$) and RCP ($p < 0.002$) but not on PEFR or self-assessment ($p > 0.05$).

Conclusion: Approximately 80% of study asthmatics were uncontrolled, and patients tended to overestimate their disease control. The ACT and RCP instruments were comparable with the PEFR. Efforts to study their validity and formal evaluation of asthma control in Trinidad are recommended.

Evaluación del Control del Asma usando Medidas Basadas en el Paciente y Tasas de flujo Expiratorio Máximo

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RESUMEN

Objetivo: El control del asma no ha sido evaluado formalmente en el Caribe. El estudio evaluó el control de la enfermedad utilizando el Test de Control del Asma (TCA), las "tres preguntas" del Colegio Real de Médicos para evaluar el control del asma (CRM), y la tasa de flujo expiratorio máximo (FEM) así como la autoevaluación del control por parte de los pacientes.

Sujetos y métodos: El control del asma fue examinado en una sección transversal de 205 asmáticos de más de 16 años de edad, mediante el TCA, el CRM, y la predicción del FEM%. Las puntuaciones por debajo de 20 e iguales o por encima de 1 en el TCA y el CRM respectivamente, por debajo del 80% de predicción de la FEM, indicaban asma no controlada. Los pacientes informaban si percibían su asma como controlada o no controlada.

Resultados: En general hubo más ($p < 0.001$) mujeres (63.9%) que hombres (36.1%). Los hombres predominaron ($p < 0.001$) entre los 17 – 30 años (60.8%) con reversión del género ($p < 0.002$) pasados los 30 (33.2%) años. El control autoevaluado (69.3%) fue mayor ($p < 0.001$) que el control evaluado por las pruebas TCA y CRM, que fueron comparables ($p > 0.05$). Menos pacientes (13.2%) lograron un control con FEM > 80% de predicción que con TCA (22.4%) y CRM (18%). La estadística Kappa

indicó una buena reproductibilidad de CRM y TCA, así como concordancia entre FEM y CRM (0.63) y FEM y TCA (0.56). Un nivel de educación más alto estuvo asociado con el control en TCA (p < 0.0005) y CRM (p < 0.002) pero no en FEM o autoevaluación (p > 0.05).

Conclusión: *Aproximadamente el 80% de los asmáticos fueron no controlados, y los pacientes sobrestiman su control de la enfermedad. Los instrumentos TCA y CRM fueron comparables con la FEM. Se recomienda hacer esfuerzos por estudiar la validez de estos, así como la evaluación formal del control del asma en Trinidad.*

INTRODUCTION

Asthma, one of the most common chronic diseases with a global estimate of 300 million people, is projected to affect an additional 100 million by 2025 (1). Current asthma consensus guidelines provide criteria for optimum control and have re-classified asthma from severity-based to the level of control (2). Physicians and patients share optimism about adequate disease control though guideline-based evaluation suggests otherwise, and patients reportedly believe their asthma is better controlled than their physicians do (3). Patients seem complacent about their disease severity perhaps because physicians underestimate the burden it places on them.

The global AIRE (Asthma Insights and Reality) surveys in Europe, North America and Asia (4) reported suboptimal asthma control and disease management short of the Global Initiative for Asthma (GINA) goals (2). The study demonstrated poor correlation of objective measures and subjective patient perceptions of control and severity. Guideline-defined asthma control can be achieved (5) and hospitalization rates have decreased in countries where asthma management plans have been implemented (6).

In the Caribbean, asthma control is not routinely assessed in specialist or community healthcare using formal scoring systems. In an early report from Trinidad's Chest Clinic, 6.8% of patients were controlled using the GINA guidelines (7). In a study at three primary healthcare facilities in Trinidad, 58.9% of patients perceived they had a 'well-controlled' status but just 11% achieved control using the Royal College of Physicians "Three questions" for Assessing Asthma Control questionnaire [RCP] (8). These studies utilized different assessment indicators in different settings of specialist and community healthcare. A simple and accurate method to determine control with or without lung function testing allows patients to monitor and understand their disease. Busy practices constrained by time and resources, require simple and accurate measures of disease control based on symptoms and pulmonary function (9). Asthma control has not been formally evaluated in Caribbean populations as far as the authors are aware.

The Asthma Control Test ™ (ACT) is a validated five-item patient-based questionnaire of selected items that parallel control dimensions outlined in management guidelines. Questions are based on day-to-day activities over the last month, symptoms, use of rescue medication and impact of disease on everyday functioning. Answers are scored from 5 (poor control) to 25 (complete control) and a score < 20 indicates uncontrolled asthma (9, 10). The ACT is a scored tool which allows numerical targets to be set and evaluated. The Royal College of Physicians "Three questions" test for Assessing Asthma Control pulls together the experience of doctors and nurses with ten years of experience in questioning patients using three simple questions: *"In the last month: 1. Have you had difficulty sleeping because of your asthma symptoms (including cough)? 2. Have you had your usual asthma symptoms during the day (eg cough, wheeze, chest tightness or breathlessness)? 3. Has your asthma interfered with your usual activities (eg housework, work school, etc)?"* "Yes" is scored as one, "no" as zero, and a zero score points to disease control" (11).

Peak Flow readings provided a quantitative measure of lung function. Patients were trained to use the peak flow meter and the best of three trials was considered. Subjects with a PEFR < 80% predicted had uncontrolled asthma.

SUBJECTS AND METHODS

The study examined control in adult asthmatic Trinidadian patients on derived scores on The Asthma Control Test and the RCP questionnaire. The following question was also asked "Does disease control measured by the ACT and the RCP questionnaire (recommended in the BTS/SIGN British Guidelines) compare with patients' self assessment of their asthma?" The hypothesis was that the ACT was as efficient as the RCP and the PEFR in estimating asthma control.

The Ethics Committee of the Faculty of Medical Sciences, The University of the West Indies and the Director of the Chest Clinic approved the study. Adult outpatients with a doctor's diagnosis of asthma who were being treated at the Ministry of Health Chest Clinic were recruited in the random order in which they presented to the clinic. The clinic is supervised by physicians with a special interest in chest medicine.

Trained researchers examined control in adult asthmatics using the ACT and the RCP questionnaire. Patients observed demonstrations to learn the correct use of the peak flow meter, and the best of three readings was noted. Each patient provided his personal estimate of perceived asthma control. Peak Expiratory Flow Rate (PEFR) % predicted for gender, age and height provided an objective measure of impaired pulmonary function. From a pre-test on 25 patients, sample size was calculated on the *nQuery Advisor 6.0 Programme* at approximately 205 to estimate the proportion

of asthmatics in Trinidad controlled to within 0.07 at 95% confidence level. Patients with respiratory conditions other than asthma, known congenital respiratory tract abnormalities, current respiratory tract infections and smokers were excluded. Four domains of the interview were demography, emergency room (ER) admittance in the past 12 months, prescribed treatment and treatment compliance. To determine treatment compliance, patients answered "yes" or "no" to the question, *"Do you take your treatment as your doctor told you?"* The final field recorded disease control as scored on the ACT and the RCP questionnaire, the PEFR % predicted and patients' perceived self-assessment of controlled or uncontrolled disease status.

Data were analyzed using Minitab Version 14.0 for descriptive statistics and the McNemar test to compare self-assessed control with control evaluated on the tests. The Kappa measure of concordance was applied for assessing agreement between the PEFR and the RCP and PEFR and the ACT. The chi-square test was used to test for associations between patients' demographics and the tests for asthma control.
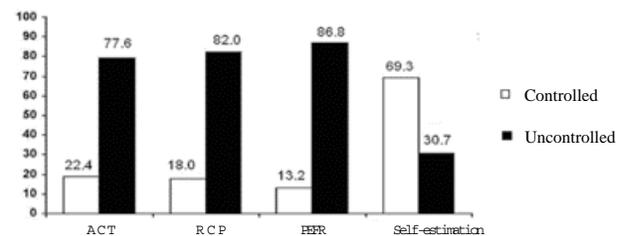
RESULTS
Demography
Two hundred and five patients presenting at the clinic were invited to participate (100% response rate). There were more females (63.9%, $p < 0.001$) than males [36.1%] (Table 1), and most (88.8%) patients were over 31 years old. Representation of gender distribution showed a higher proportion ($p < 0.002$) of younger males between 17 – 30 years (60.9%) had asthma, whereas above 31 years of age, female asthmatics (67.0%) were in the majority. Persons of East Indian descent (67.3%) were most ($p < 0.001$) represented among the ethnic groups. Approximately half the population (51.2%) had primary or no education. Most asthmatics ($p < 0.051$) lived in non-rural areas (56.6%) such as urban neighbourhoods, bordering main roads or industrial districts. About half the number of patients (50.7%) had visited the emergency room for nebulization at least once in the last twelve months.

Asthma control
Asthma was controlled in less than a third of patients on any of the evaluating instruments. Compared with 13.2% (95% CI 9, 18) of patients controlled on the PEFR, 18.0% (95% CI 13, 23) achieved control on the RCP questionnaire and 22.4 % (95% CI 17, 28) were controlled on the ACT (Fig. 1). The Kappa statistic to compare agreement between the measures of asthma control showed concordance between the PEFR and the two patient- based measures of control. The kappa statistic of 0.56 (CI 95% 0.41, 0.70) demonstrated moderate agreement between the PEFR and the ACT, and substantial agreement (0.63, CI 95% 0.49, 0.72) between the PEFR and the RCP. Disease control was comparable between proportions of patients controlled on the ACT and the RCP instru-

Table 1:   Demographic characteristics of adult asthmatics

Characteristics	n (%)	p-value
Gender		
Male	74 (36.1)	**< 0.001**
Female	131 (63.9)	
Age groups and gender distribution		
17–30 years (n = 23)		**< 0.001**
Male	14 (60.9)	
Female	9 (39.1)	
31–59 years (n = 94)		**< 0.002**
Male	25 (26.6)	
Female	69 (73.4)	
> 60 years (n = 88)		
Male	35 (39.8)	
Female	53 (60.2)	
Ethnicity		
Indo-Trinidadian	138 (67.3)	**< 0.001**
Afro-Trinidadian	59 (28.8)	
Mixed	8 (3.9)	
Educational Level		
Primary or none	105 (51.2)	**< 0.001**
Secondary	71 (34.6)	
Tertiary	29 (14.2)	
Location of Residence		
Rural area	88 (43.4)	**< 0.051**
Non-rural area	115 (56.6)	
ER utilized at least once in last 12 months		
Yes	104 (50.7)	**> 0.80**
No	101 (49.3)	

Kappa statistic for PEFR and RCP =0.63 and for PEFR and ACT = 0.56

Fig. 1:   Patients (%) controlled on the ACT, the RCP, PEFR and on self-assessment, showing reproducible control on the PEFR, RCP and the ACT.

ments ($p > 0.05$). However proportionally more ($p < 0.001$) patients (69.3%) perceived their asthma was controlled compared with those who were controlled on the ACT and the RCP.

More patients with secondary and tertiary education were controlled when evaluated by the ACT ($p < 0.01$) and the RCP ($p < 0.02$). Less than 10% of patients without any formal education were controlled on any of the assessment indicators whereas 34.6% of patients with primary or no education believed their disease was controlled.

Asthma control was associated with age irrespective of the assessment instrument ($p = 0.05$). Compared with pa-

tients who were below 30 years of age or the elderly, above 60 years, more patients between 31– 60 years were controlled on the ACT (50.0%), the RCP (51.4%) and on % predicted PEFR (55.6%). Comparable numbers of patients between 31– 60 years (45.1%) and above 60 years (41.4%) perceived they had controlled asthma (Fig. 2). Proportionally fewer
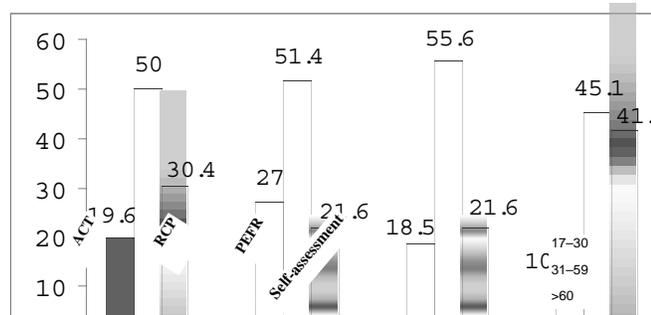

Fig. 2:   Bar graph showing the effect of age on each of the four measures of asthma control

younger patients between 17–30 years were controlled on any of the test indicators and appeared to be more realistic about their disease control.

Treatments

All drugs were prescribed from the hospital formulary. Inhaled salbutamol (67%) and beclomethasone (92%) were most frequently prescribed. Few patients received theophylline (25, 12.2%) and the budesonide-formeterol combination (27, 13.2%) which had recently become available on the formulary. At least 46% of patients used inhaled salbutamol *pro re nata* (PRN) and beclomethasone. However, the inhaled beclomethasone was available as 50 ?g per actuation and the average dose was 100 ?g twice daily which may account for the poor control observed.

Compliance with treatment

A large proportion of patients (86.8%) declared they took medications as prescribed. The reported treatment compliance of patients was significantly ($p < 0.006$) associated with disease control regardless of the method of assessment (Table 2). Of those patients who declared they were compliant with treatment, 80.4% were controlled on the ACT, 83.8% on the RCP, 85.2% were controlled using the measure of PEFR % predicted and 85.2% believed they had control of their asthma.

Table 2:   The distribution of compliance in controlled patients (n) under each asthma control assessment method

	Asthma control assessment method			
	ACT	RCP	PEFR	Self-assessment
Compliance	37	31	23	121
Non-compliance	9	5	4	21
p-value*	< 0.001	< 0.001	< 0.006	< 0.001

*Each *p*-value is based on normal distribution for testing if the proportion of compliant subjects in each category is 0.50.

DISCUSSION

In this study, the patients overrated their perception of asthma control. Approximately 80% of adult patients in specialty care have suboptimal asthma control and are unaware of poor disease control. Questionnaire-type assessments of control provide simple evaluations with or without lung function. The significant association between disease control on the ACT and the RCP assessments underscores the need for literacy so that patients could understand the nature of the disease and its severity. The educational needs of low literate patients are recognized in asthma management (12) and poor knowledge of asthma and inhaler use are barriers to asthma care (13). In designing asthma plans with self-evaluation patients, literacy skills must be considered. Pictorial representations and graphics may assist patients to understand their disease better and realistically evaluate its control.

The significant association between the higher proportion of controlled 31 to 60-year old patients regardless of the evaluating instrument or self-assessment suggests that adult patients appear to take responsibility for management of their disease. Godard *et al* (14) reported a significant association between asthma control in general practice patients between 15–50 years compared with those above 50 years. The asthma burden takes its toll on elderly patients (15) above 65 years (16) as steadily declining lung function sets in after 40 years.

A major contributor to the poor level of asthma control is that a significant number of people with asthma tend to underestimate the severity of their condition and overestimate how well their asthma is being controlled. The Asthma Insights and Reality surveys in seven European countries observed that patients' perception of asthma control did not match their symptom severity. Approximately 50% of patients reporting severe persistent symptoms considered their asthma was completely or well controlled (17). More recently, 91% of 468 asthmatics across the United Kingdom said their asthma was controlled, yet two-thirds experienced symptoms 2 – 3 times per week (18). In recent international surveys, a third to half of patients with severe persistent symptoms thought their asthma was completely or well controlled (17, 19). Physicians and patients share optimism about good disease control but patients reportedly believe their asthma is better controlled than their physicians do (3). Patients' understanding of their disease state differs from the actuality of control and is worsened by complacency as physicians may underestimate its burden. Instruments which score control as composite measures of symptoms, patient's functional status, lung function, and use of rescue medication provide a better predictor of likely improvement in quality of life or of likely failure to improve as compared with the measurement of single clinical endpoints (20). Such scoring can educate patients, narrowing the gap between perceived and actual disease control. Absence of a formal system to assess control leads to reliance on the patient's feedback and physician's global evaluation to guide treatment, leading to

less than optimal control. The study highlights a need for formal objective evaluation of asthma control in Trinidad.

Self-assessed measures of asthma control can help to identify and manage patients who are at greatest risk for future health impairment. When patients set goals to control their asthma, they are responsive to change and improved disease outcomes (21). In the majority of patients with uncontrolled asthma across a wide range of severities, comprehensive guideline-defined control can be achieved and maintained in patients who fail to achieve guideline-defined control (22). The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens Study prospectively evaluated 987 patients over 12 months and found that asthma control was an independent predictor of disease-specific quality of life and general health and a better predictor of health status than asthma severity at baseline (23).

In this study, the ACT and the RCP instruments were comparable with the PEFR in assessing asthma control. The ACT and the RCP are patient-based measures and as validated tools they have the potential to influence long-term asthma outcomes (24). It does not seem satisfactory any longer to simply ask patients "how is your asthma doing?". An "ideal" measure of asthma control may be regarded as being practical, meaningful, applicable to patients, clinicians and researchers, reflective of long term asthma control, discriminatory and responsive to change (25), all of which feature in the ACT and the RCP "three question" test. We suggest that simple scoring systems with composite measures will provide long-term management goals set out in international treatment guidelines affording patients likely improvement in quality of life. Many patients either did not know how to use the peak flow meter or did not use it, so that the best blow may not have been captured and information on the personal best was therefore not available. The greater observed prevalence of asthmatic females may not reflect a national gender majority but rather a tendency for females to seek medical attention.

In summary, asthma control was poor and patients overestimated their disease control. The ACT and the RCP "Three questions" for Assessing Asthma Control are comparable with the PEFR and can be used to evaluate asthma control in busy clinics.

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REFERENCES
1. Masoli M, Fabian D, Holt S, Beasley R. The global burden of asthma: executive summary of the GINA Dissemination Committee Report Allergy 2004; **59:** 469–78.
2. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. GINA 2002; http://www.ginasthma.com/
3. Boulet LP, Phillips R, O'Byrne P, Becker A. Evaluation of asthma control by physicians and patients: comparison with current guidelines. Can Respir J 2002; **9:** 417–23.
4. Rabe KF, Adachi M, Lai CK, Soriano JB, Vermeire PA, Weiss KB et al. Worldwide severity and control of asthma in children and adults: the global asthma insights and reality surveys. J Allergy Clin Immunol; **114:** 40–7.
5. Bateman ED. Using clinical measures of disease control to reduce the burden of asthma. Pharmacoeconomics 2001; **19 (Suppl 2):** 7–12.
6. Haahtela T, Laitinen LA. Asthma programme in Finland 1994–2004. Report of a Working Group. Clin Exp Allergy 1996; **26 (Suppl 1:** i–ii): 1–24.
7. Sealy P, Bird B, Thomas C, St Aimee N, Pinto Pereira LM. Control of asthma in patients attending the Chest Clinic in Trinidad. West Indian Med J 2002; **51S:** 33
8. Villaroel-Stuart AR, Gibson TT, Griffith TN, Rangoo-Madhosingh C, Samaroo D, Matthew J et al. A preliminary report of patients' perception of disease severity, treatment and control of asthma in three health institutions in Trinidad. Carib Med J 2006; **66:** 20.
9. Nathan RA, Sorkness CA, Kosinski M, Schatz M, Li JT, Marcus P et al. Development of the Asthma Control Test: A survey for assessing asthma control. J Allergy Clin Immunol 2004; **113:** 59–65.
10. Lenoir M, Williamson A, Stanford RH, Stempel DA. Assessment of asthma control in a general population of asthmatics. Curr Med Res Opin 2006; **22:** 17– 22.
11. Royal College of Physicians' three questions. RCPLondon. pp. 638–34 .http://www.rcplondon.ac.uk/news/news.asp?PR_id=70
12. Lang DM, Sherman MS, Polansky M. Guidelines and realities of asthma management. The Philadelphia story. Arch Inter Med 1997; **157:** 1193–200.
13. Williams MV, Baker DW, Honig EG, Lee TM, Nowlan A. Inadequate literacy is a barrier to asthma knowledge and self-care. Chest 1998; **114:** 1008 –15.
14. Godard P, Huas D, Sohier B, Pribil C, Boucot I. Asthma control in general practice: a cross-sectional survey of 16 580 patients. Presse Med 2005; **34:** 1351–7.
15. McCoy L, Redelings M, Sorvillo F, Simon PA. A multiple cause-of-death analysis of asthma mortality in the United States, 1990–2001. J Asthma 2005; **42:** 757– 63.
16. Moorman JE, Mannino DM. Increasing U.S. asthma mortality rates: who is really dying? J Asthma 2001; **38:** 65– 71.
17. Rabe KF, Vermeire PA, Soriano JB, Maier WC. Clinical management of asthma in 1999: the Asthma Insights and Reality in Europe (AIRE) study. Eur Respir J 2000; **16:** 802–7.
18. Haughney J, Barnes G, Partridge M, Cleland J. The Living & Breathing Study: a study of patients' views of asthma and its treatment. Prim Care Respir J 2004; **13:** 28–35.
19. Lai CK, De Guia TS, Kim YY, Kuo SH, Mukhopadhyay A, Soriano JB et al. Asthma control in Asia-Pacific region: The Asthma Insights and reality in Asia-Pacific Study. J Allergy Clin Immunol 2003; **111:** 263–8.
20. Schatz M, Sorkness CA, Li JT, Marcus P, Murray JJ, Nathan RA et al. Asthma Control Test: reliability, validity and responsiveness in patients not previously followed by asthma specialists. J Allergy Clin Immunol 2006; **117:** 549–56.
21. Bateman EF, Frith LF, Braunstein GL. Achieving guideline-based asthma control: does the patient benefit? Eur Respir J 2002; **20:** 588–95.
22. Bateman ED, Boushey HA, Bousquet J, Busse WW, Clark TJ, Pauwels RA et al. GOAL Investigators Group. Can guideline-defined asthma control be achieved? The Gaining Optimal Asthma Control study. Am J Respir Crit Care Med 2004; **170:** 836–44.
23. Chen H, Gould MK, Blanc PD, Miller DP, Kamath TV, Lee JH et al. For the TENOR Study Group. Asthma control, severity, and quality of life: quantifying the effect of uncontrolled disease. J Allergy Clin Immunol 2007; **120:** 396–02.
24. Kruithof N, Cleland J, Moffat M, Crescenzi K, Price D. Patient set treatment goals: a tool to measure patients' perceptions of changes in asthma outcomes. Primary Care Respir J 2004; **13:** 118–19.
25. Boulet LP, Boulet V, Milot J. How should we quantify asthma control? A proposal. Chest 2002; **122:** 2217–23.