Validation of a new clinical scoring system for acute bronchitis

C. Mwachari, * V. Nduba, * R. Nguti, † D. R. Park, ‡ L. Sanguli, * C. R. Cohen§

* Centre for Respiratory Disease Research, Kenya Medical Research Institute, Nairobi, † Department of Statistics, University of Nairobi, Nairobi, Kenya; † Department of Medicine, University of Washington, Seattle, Washington, § Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco, California, USA

__ S U M M A R Y

INTRODUCTION: Although several clinical prediction rules exist for lower respiratory tract infection (LRTI), few are for acute bronchitis (acute bronchitis) and most have not been validated in high human immunodeficiency virus (HIV) prevalence settings.

METHODS: An Acute Bronchitis Severity Score (ABSS) was developed and validated during a randomized trial of antibiotic treatment for acute bronchitis. Ambulatory adults with productive cough of ≤2 weeks at out-patient respiratory disease clinics in Nairobi, Kenya, were recruited and assessed for clinical response to therapy. The ABSS quantitative ratings of LRTI-associated symptoms, physical signs and sputum Gram stain purulence were assessed using standard psychometric tests.

RESULTS: The ABSS was evaluated among 649 cases of acute bronchitis; 129 (20%) were HIV-seropositive. The

ABSS had small floor and ceiling effects (1.8/0.2) and demonstrated high internal consistency (α -coefficient of 0.66) and internal validity, with a mean inter item total correlation of \geq 0.25. Effect sizes from baseline to subsequent follow-up visits were large (>0.5). Wheezing and chest pain were associated with higher ABSS values, whereas irrelevant clinical variables were not.

CONCLUSION: The ABSS demonstrated good responsiveness, high internal consistency, good correlation with common respiratory signs and symptoms and high discriminatory validity among patients with acute bronchitis in a high HIV-seroprevalence setting.

KEY WORDS: outcome assessment; severity of illness index; sub-Saharan Africa; HIV; questionnaires; acute bronchitis severity score (ABSS)

SEVERAL clinical scoring systems have been used to measure the severity and predict the prognosis of patients with lower respiratory tract infection (LRTI).^{1–4} However, very few pertain to the management of acute bronchitis⁵ which, as the most common LRTI, is responsible for an enormous number of out-patient clinic visits worldwide. In Europe and the United States, about 90% of adults with self-reported acute bronchitis seek medical care.^{6,7} In Nairobi, we found a very high incidence of acute bronchitis in a human immunodeficiency virus (HIV) infected cohort.⁸

Although the vast majority of uncomplicated acute bronchitis cases are due to non-bacterial causes, over 66% of patients are treated with antibiotics.^{6,9} In part, this may be due to the considerable variation and poor reliability of the diagnostic criteria used to identify this condition. Misdiagnosis and inappropriate use of antibiotics to treat cases of acute bronchitis may be even more rampant in developing countries. Furthermore, previous studies on the effects of antibiotic treatment on acute bronchitis outcomes^{10–14} have been hampered by the lack of an accepted patient-centered outcome measure.

As acute bronchitis rarely results in hospitalization or death, other patient-centered outcomes would be useful to determine the impact of any new forms of treatment. The present study sought to validate a novel acute bronchitis severity score (ABSS) designed to measure the clinical response to treatment of acute bronchitis among HIV-infected and non-infected adult out-patients participating in a clinical trial of antibiotic treatment.

METHODS

The procedures followed were approved by the Kenya Medical Research Institute Ethical Review Committee, the University of Washington Human Subjects Review Committee and the University of California, San Francisco Committee on Human Research, and were in compliance with the Helsinki Declaration of 1975, as revised in 1983.¹⁵

Recruitment of participants

Eligible subjects were aged ≥ 18 years presenting with a productive cough of ≤ 2 weeks' duration at the

Rhodes Nairobi City Council Clinic (RNCC) between October 2001 and February 2004 and at the Outpatient Department of Mbagathi District Hospital (MDH) between October 2002 and August 2003. Eligibility was determined by one of two experienced study nurse-counselors previously trained to identify patients who met eligibility criteria. Patients were excluded if they had another potential explanation for cough (a self-reported history of chronic bronchitis, allergic rhinitis, sinusitis, asthma, gastric reflux), or serious medical comorbidity (heart disease or diabetes). Due to the requirements of the antibiotic treatment trial parent study, we also excluded patients with penicillin allergy, antibiotic use in the preceding 2 weeks or a concurrent infection (including tuberculosis [TB]) requiring antibiotic treatment. Otherwise eligible patients were not enrolled if they were unwilling or unable to participate or if they lived outside Nairobi, making follow-up impractical.

Eligible patients who gave written informed consent were tested for HIV seropositivity using a rapid HIV-1/2 test (Determine, Abbott Park, IL, USA) with positive results confirmed using a different rapid HIV-1/2 test (Unigold, Trinity Biotech, Bray, Wicklow, Ireland). A postero-anterior chest X-ray was performed on all subjects. Those with abnormal chest X-ray findings suggestive of pneumonia, TB or other diagnoses were excluded from further participation and were referred for appropriate management.

We did not perform spirometry, bronchoprovocation testing or otherwise confirm the subjects' selfreported medical histories.

An expectorated sputum specimen was obtained and examined for white blood cells (WBC), epithelial cells and bacteria on Gram and Ziehl-Neelsen stained smears. Sputum specimens were also cultured for *Mycobacterium tuberculosis* and other bacterial respiratory pathogens using standard microbiological procedures.¹⁶

ABSS development

Eleven items were identified from the literature and expert opinion as likely to track acute bronchitis disease severity, including: overall severity of illness, frequency of day and night cough, color and amount of sputum, limitation of daily activity, reported fever, rhonchi, increased temperature, overall clinical appearance and sputum Gram stain. These constituted an 11-item instrument that was pilot tested among 20 subjects with acute bronchitis who were not enrolled in the current study. Patients were requested to rate how bothersome they found each of the symptoms during the previous 24 h on a standardized 5-point Likert scale (Appendix A). Non-symptom elements (physical examination and sputum Gram stain findings) were rated by the study physician.

The study data were collected by trained personnel from all participants in the study. According to the parent study, subjects were randomly assigned to one of two intervention arms, receiving either amoxicillin 500 mg or placebo three times daily for 7 days. The study physician (VN) performed all clinical examinations and history at baseline and follow-up visits. Subjects whose condition worsened clinically during follow-up were treated with open-label erythromycin 500 mg, administered orally every 8 h for 7 days. Subjects recruited on Monday, Tuesday and Friday were expected to return for the initial follow-up after 3 days, those enrolled on Thursday were first re-evaluated on Monday (4 days), and those recruited on Wednesday were re-evaluated initially on Friday (2 days). Subjects were also asked to return for a re-evaluation after 7 and 14 days. At each visit, the study clinician repeated a physical examination and assessment. The acute bronchitis questionnaire was developed in English and administered concurrently during assessment visits. Clinical improvement was defined as alleviation of chest pain and wheezing along with normalization of the respiratory rate and other vital signs (if abnormal at enrollment), and no need for open-label antibiotics at any subsequent visit.

Data were analyzed using SPSS version 10.5 for Windows (SPSS, Chicago, IL, USA). The acute bronchitis questionnaire was analyzed using standard psychometric tests.¹⁷

Psychometric tests and criteria

Item analysis and reduction were used to identify variables for possible elimination from the score based on their weak psychometric performance. Items retained in the final ABSS were loaded by a factor of \geq 0.30 on the first component in factor analysis and had an itemtotal correlation of \geq 0.25.

The acceptability of each component of the ABSS was assessed by completeness (i.e., each item had to have <5% missing data). Floor and ceiling effects were determined by the percentage of subjects with the lowest score and highest score, respectively. Recommended values were not to exceed 20%.¹⁸

Test-retest reliability was assessed over time during the follow-up of subjects. Correlations between the test and retest scores were calculated, and with a changing score such as the one under evaluation, these correlations were expected to be high between adjacent time points (e.g., baseline and 3 days) and low for time points further apart (e.g., baseline and 14 days).

Analyses against external criteria assessed the ability of the ABSS to differentiate between known groups defined as clinically cured and clinical failures. The mean ABSS was expected to be significantly higher in subjects in the clinical failure group compared to subjects with clinical improvement.

Content validity, determining the extent by which the scale was representative of the conceptual domain it was intended to cover, was measured qualitatively through pretesting in subjects with the condition, expert opinion and literature review. Construct validity (within-scale) analysis was used to demonstrate evidence that a single entity (construct) was being measured and that items included in the ABSS could be combined to form a summary score using principal component analysis. Such a score is assessed on the basis of good internal consistency and moderately high item-total correlations, evidenced by a Cronbach alpha coefficient of at least 0.70 and a mean inter item total correlation of $\geq 0.3.19,20$

Face validity was demonstrated by showing the extent to which the ABSS changed during the clinical course of acute bronchitis after 3, 7 and 14 days. Convergent validity to assess whether the ABSS was correlated with other measures of the same or similar constructs was performed using the regression analysis between the ABSS and respiratory rate.

Discriminant validity was assessed by determining the correlation of different constructs such as body weight, height, age and sex of the patient with the ABSS by performing regression analysis for continuous variables and Student's *t*-test for dichotomous variables.

Responsiveness, the ability of the scale to detect clinically significant change from enrollment, was assessed by comparing the effect size in ABSS from baseline to the three follow-up assessment points. The effect size was defined as change in mean score from baseline to follow-up divided by the standard deviation of the baseline score.^{21,22}

Written informed consent was obtained from each participant in the study. The protocol was approved by the Ethical Review Committee at the Kenya Medical Research Institute, Nairobi, Kenya. Written informed consent was obtained from study subjects before participation in the study.

RESULTS

Participants

Of the 2677 subjects with an acute productive cough who were screened for study eligibility, 1230 were ineligible because of one or more exclusion criteria, and an additional 787 were excluded due to abnormal chest X-ray findings. Of the 660 participants enrolled in the randomized trial, 649 had complete data and were used to evaluate the acute bronchitis questionnaire: subjects had an average age of 29.9 years (standard deviation [SD] 9.1), 394 (61%) were female and 129 (20%) were HIV-seropositive (Table 1). The most common presenting symptoms were chest pain (74%), fatigue (63%) and fever (60%).

Item reduction and analysis

Among the seven patient-reported symptoms, three clinician-rated signs and Gram stain findings, only five symptoms, including overall severity of the illness, night cough, day cough, limitation of daily activities and fever, had a mean item-total correlation

Table 1 Characteristics of 649 subjects participating in study on acute bronchitis

Characteristic	Frequency n (%)	
Female sex	394 (61)	
Age, mean ± SD	29.9 ± 9.1	
Fever	386 (60)	
Fatique	408 (63)	
Night sweat	210 (32)	
Wheezing	283 (44)	
Chest pain	477 (74)	
Shortness of breath	214 (33)	
Smoker	78 (12)	
Current alcohol intake	131 (20)	
Respiratory rate, mean ±SD	22.4 ± 6.2	
HIV-seropositive	129 (20)	

SD = standard deviation; HIV = human immunodeficiency virus.

and principal component loadings exceeding 0.25 and 0.30, respectively, and thus were retained in the model to constitute the final ABSS (Appendix B). All of the clinician-reported signs were excluded from the model, including the quantity of sputum, which had a principal component loading of 0.42 and an itemtotal correlation of 0.27. In addition, the Gram stain score was not retained in the final score (Table 2).

Reliability

The Cronbach β coefficient for the ABSS was 0.66, indicating moderate internal consistency based on the standard criterion of \geq 0.70 to indicate high internal consistency. As expected, the ABSS for adjacent measurements had higher correlations in comparison to visits farther apart: baseline and 3-day visit (r = 0.21), 3-day and 7-day visits (r = 0.36), 7-day and 14-day visits (r = 0.28) in comparison to baseline and 7-day

 Table 2
 Item analysis and reduction of the acute bronchitis questionnaire

	Item total correlation	First principal component loading
Symptoms		
Patient-reported severity of illness*	0.378	0.602
Dry cough*	0.453	0.696
Night cough*	0.462	0.687
Sputum color	0.203	0.297
Sputum quantity [†]	0.266	0.424
Limited daily activity*	0.330	0.547
History of fever*	0.361	0.569
Signs		
Clinician-rated severity of illness	0.224	0.365
Temperature	0.062	0.009
Rhonchi	0.156	0.217
Laboratory findings		
Sputum Gram stain	0.055	0.007

^{*} These variables had an item-total correlation and principal component loadings exceeding 0.25 and 0.30, respectively, and thus were retained in the final ARSS

 $^{^{\}dagger}$ Sputum quantity's loading to the first principal component decreased to <0.25 when the other five symptoms with low loadings were eliminated from the score.

ABSS = acute bronchitis severity score.

Table 3 Convergent and discriminant validity of the ABSS

Measures	Mean ± SD or easures mean change ± SE			
Wheeze (yes vs. no)	$6.7 \pm 3.7 \text{ vs. } 5.9 \pm 3.5^{*}$	0.009		
Chest pain (yes vs. no)	$6.6 \pm 3.6 \text{ vs. } 5.5 \pm 3.4^{*}$	0.001		
Pulse rate, per min	$0.05 \pm 0.02^{\dagger}$	0.03		
Sex (males vs. females)	$6.2 \pm 3.5 \text{ vs. } 6.3 \pm 3.7^{*}$	0.83		
Age	$0.0001 \pm 0.015^{\dagger}$	0.99		
Body weight	$-0.004 \pm 0.004^{\dagger}$	0.31		
Height	$0.0004 \pm 0.001^{\dagger}$	0.94		

^{*} Mean ABSS score ± SD.

visit (r = 0.08), baseline and 14-day visit (r = 0.09) and 3-day and 14-day visits (r = 0.17). All correlations were significant at P < 0.05. The floor and ceiling effects of the ABSS at baseline were 1.8% and 0.2%, well below the recommended maximum of 20%.²³ High item-total correlations and Cronbach's α coefficients and factor analysis results indicated that a single construct was being measured and that the items could be combined to form a summary score.

Validity

The association between the ABSS and other common clinical LRTI signs and symptoms is shown in Table 3. Patients who reported wheezing and chest pain had significantly higher mean ABSS than those without these symptoms. In addition, the mean change in ABSS increased significantly, by 0.058~(P=0.03), for every additional unit count/min increase in the respiratory rate. The ABSS was not associated with irrelevant variables such as age, sex, body weight and height, thus supporting the discriminant validity of the score. Table 4 demonstrates the significant difference in the mean ABSS for patients who met the definition for clinical improvement in comparison to clinical failures after 3, 7 and 14 days; all comparisons were significant at P < 0.001.

Responsiveness

Table 5 depicts effect sizes and mean scores for clinical change of the ABSS between baseline and days 3, 7 and 14. The Figure demonstrates the magnitude of change by median scores which also decreased substantially at baseline and 14 days, demonstrating good responsiveness.

Table 4 Known group differences validity of ABSS

Visit, days	Clinical improvement n (mean ± SD)	Clinical failure n (mean ± SD)	<i>P</i> values
3	545 (2.5 ± 2.4)	61 (5.6 ± 4.8)	< 0.001
7	470 (1.5 ± 2.0)	91 (4.7 ± 3.4)	< 0.001
14	389 (1.5 ± 2.1)	112 (3.6 ± 3.9)	< 0.001

ABSS = acute bronchitis severity score; SD = standard deviation.

Table 5 Responsiveness (effect sizes) of the ABSS

Visit	n (mean score \pm SD)	Effect size
Baseline to 3 days Baseline to 7 days Baseline to 14 days	649 (6.3 ± 3.6) 607 (3.0 ± 3.1) 576 (2.1 ± 2.7) 530 (2.1 ± 2.9)	0.89 1.14 1.16

ABSS = acute bronchitis severity score; SD = standard deviation.

DISCUSSION

To our knowledge, the ABSS is the first validated clinical severity score for accurately following acute bronchitis disease resolution. In addition, the ABSS was validated in a population with high HIV seroprevalence. The ABSS, relying on patient-reported symptoms, was simple and practical to administer in the ambulatory clinical settings used in this study.

Although sputum color and amount were thought by expert opinion to characterize acute bronchitis, they have also been used in a previous randomized clinical trial to evaluate acute bronchitis.²⁴ In this investigation, the two items were excluded by the analysis as not being part of the construct being measured by the five items in the new ABSS. Despite the exclusion of these items, the ABSS demonstrated good responsiveness among subjects with mild illness, suggesting that it was very sensitive to small changes in the clinical condition of the patients. This characteristic ensures that the ABSS can be used successfully to monitor clinical improvement even in patients with mild disease. As depicted in Table 4, the ABSS was able to clearly distinguish between subjects who clinically improved in comparison to those that did not.

A major limitation in the validation of the score included the lack of a gold standard for comparison. It was therefore difficult to evaluate the sensitivity and specificity of the score in detecting clinical improvement or failure at various assessment points. Given that there is no accepted gold standard to measure the severity of acute bronchitis, we relied on an arbitrary but reasonable definition of clinical improvement (resolution of wheezing and chest pain plus normalization of vital signs). In addition, developing the tool

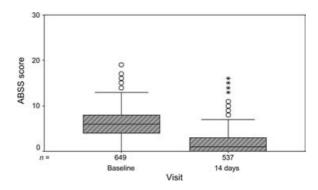


Figure Distribution of the ABSS score at baseline and 14 days. ABSS = acute bronchitis severity score.

 $^{^\}dagger$ Mean change in ABSS score per unit increase in characteristic \pm SE. ABSS = acute bronchitis severity score; SD = standard deviation; SE = standard error of the mean.

within focus group discussions and one-to-one discussion with patients rather than relying on expert opinion would have improved the tool further. Another limitation was the relatively mild nature of the illness in most subjects. There was a tendency for subjects with improved symptoms to stop attending the clinic for follow-up which may have biased the clinical outcome. Nevertheless, the ABSS appeared very responsive even in patients with mild illness.

Our primary aim was to develop and validate the ABSS as a tool to measure clinical improvement of acute bronchitis during the conduct of clinical trials. In the current investigation, the tool was validated in English. Future investigations should consider evaluating the new ABSS using local languages appropriate for other settings. We believe that the ABSS is a simple, practical clinical scoring system that will be useful in monitoring disease resolution in acute bronchitis and, in the case of clinical trials, detect differences in patient-centered treatment outcome.

Acknowledgements

The authors would like to thank M Munene, N Mwachari, P Omuom, R Wanjala and J Achando who collected these data and most importantly cared for the study participants, E Mwachari for volunteering to perform data management, the Director, Kenya Medical Research Institute, for allowing the performance of this investigation and most of all the study participants themselves. This study was supported by a grant from the Rockefeller Foundation and the World Health Organization.

References

- 1 Lamping D L, Schroter S, Marquis P, et al. The community-acquired pneumonia symptom questionnaire: a new, patient-based outcome measure to evaluate symptoms in patients with community-acquired pneumonia. Chest 2002; 122: 920–929.
- 2 Fine M J, Auble T E, Yealy D M, et al. A prediction rule to identify low risk patients with community-acquired pneumonia. N Engl J Med 1997; 336: 243–250.
- 3 Eisner M D, Trupin L, Katz P P, et al. Development and validation of a survey-based COPD severity score. Chest 2005; 127: 1890–1897.
- 4 Singal B M, Hedges J R, Radack K L. Decision rules and clinical prediction of pneumonia: evaluation of low-yield criteria. Ann Emerg Med 1991; 20: 1215–1219.
- 5 Watson L, Little P, Moore M, et al. Validation study of a diary for use in acute lower respiratory tract infection. Family Practice 2001; 18: 553–554.
- 6 Metlay J P, Stafford R S, Singer D E. National trends in the use of antibiotics by primary care physicians for adult patients with cough. Arch Intern Med 1998; 158: 1813–1818.

- 7 Mainous A G D, Zoorob R J, Hueston W J. Current management of acute bronchitis in ambulatory care: the use of anti-biotics and bronchodilators. Arch Fam Med 1996; 5: 79.
- 8 Mwachari C W, Cohen C R, Meier A S, et al. Respiratory tract infection in HIV-1-infected adults in Nairobi, Kenya: evaluation of risk factors and the world health organization treatment algorithm. J Acquir Immune Defic Syndr 2001; 27: 365– 371.
- 9 Gonzales R, Steiner J F, Sande M A. Antibiotic prescribing for adults with colds, upper respiratory tract infections, and bronchitis by ambulatory care physicians [see comments]. JAMA 1997; 278: 901.
- 10 Mainous A G D, Zoorob R J, Hueston W J. Current management of acute bronchitis in ambulatory care: the use of anti-biotics and bronchodilators. Arch Fam Med 1996; 5: 79.
- 11 Smucny J J, Becker L A, Glazier R H, McIsaac W. Are antibiotics effective treatment for acute bronchitis? A meta-analysis. J Fam Pract 1998; 47: 453.
- 12 Smucny J, Fahey T, Becker L, Glazier R, McIsaac W. 2000. Antibiotics for acute bronchitis. Cochrane Database Syst Rev 2004; 4: CD000245.
- 13 Verheij T J, Hermans J, Mulder J D. Effects of doxycycline in patients with acute cough and purulent sputum: a double blind placebo controlled trial. Br J Gen Pract 1994; 44: 400.
- 14 Mainous A G III, Saxena S, Hueston W J, Everett C J, Majeed A. Ambulatory antibiotic prescribing for acute bronchitis and cough and hospital admissions for respiratory infections: time trend analysis. J R Soc Med 2006; 99: 358–362.
- 15 US National Institutes of Health. 'Declaration of Helsinki', human participant protections education for research teams. Bethesda, MD, USA: NIH, 1983.
- 16 Cheesbrough M. District laboratory practice in tropical countries. Part 2. Cambridge, UK: Cambridge University Press, 2000.
- 17 Streiner D L, Norman G L. Health measurement scales: a practical guide to their development and use. 2nd ed. Oxford, UK: Oxford University Press, 1995.
- 18 Holmes W C, Shea J A. Performance of a new, HIV/AIDS-targeted quality of life (HAT-QoL) instrument in asymptomatic seropositive individuals. Qual Life Res 1997; 6: 561–571.
- 19 Eisen M, Ware J E Jr, Donald C A, et al. Measuring components of children's health status. Med Care 1979; 17: 902–921.
- 20 Cronbach L J. Coefficient alpha and the internal structure of tests. Psychometrika 1951; 16: 297–334.
- 21 Liang M H, Fassel A H, Larson M G. Comparison of five health status instruments for orthopaedic evaluation. Med Care 1990; 28: 632–642.
- 22 Kazis L E, Anderson J J, Meenan R F. Effect sizes for interpreting changes in health status. Med Care 1989; 27: S178–S189.
- 23 Lohr K N, Aaronson N K, Alonso J, et al. Evaluating quality-of-life and health status instruments: development of scientific review criteria. Clin Ther 1996; 18: 979–992.
- 24 Stott N C, West R R. Randomized controlled trial of antibiotics in patients with cough and sputum. BMJ 1976; 2: 556-559

APPENDIX A

Eleven-item acute bronchitis questionnaire

Introduction to the ABSS to be read to the patient

Patients with acute bronchitis will experience ailments which we are evaluating as part of the study in which you are currently participating. We would like to ask you a few questions regarding your experience during this illness. I will read the symptoms to you.

For each of them I will ask you the extent to which the problem has bothered you in the past 24 h: Very mild, Mild, Moderate, Serious and Very serious. These options will rate your overall feeling about the illness, daily activities and fever. If you have a cough, I will read through the various options as a guide.

Please let me know if you have not had any of the symptoms I mention in the past 24 h.

Thank you for your participation.

In the past 24 h, how much have you been bothered by:

Symptoms	0	1	2	3	4
Overall severity of illness	Very mild	Mild	Moderate	Serious	Very serious >20 times/day >20 times/night Dark green/yellow Very profuse Very severe Very severe
Day cough	1–2 times/day	3–5 times/day	6–10 times/day	11–20 times/day	
Night cough	1–2 times/night	3–5 times/night	6–10 times/night	11–20 times/night	
Sputum color	Clear/white	White	Mild green/yellow	Moderate green/yellow	
Sputum amount	Very slight	Slight	Moderate	Profuse	
Limit daily activity	None	Mild	Moderate	Severe	
Fever	None	Mild	Moderate	Severe shaking chills	
Examination	0	1	2	3	4
Overall appearance	Very mild	Mild	Moderate	Serious	Very serious
Temperature (°C)	≤37.4	37.5–37.9	38.0–38.4	38.5–38.9	≥39
Rhonchi	None	Mild	Moderate	Severe	Very severe
Laboratory	0	1	2	3	4
Gram stain	0 WBC/hpf* <u>or</u>	1–5 WBC/hpf &	6–10 WBC/hpf &	11–20 WBC/hpf &	>20 WBC/hpf &
	no sputum	0 epi/hpf†	≤1 epi/hpf†	<2 epi/hpf [†]	<3 epi/hpf†

^{*} White blood cells per high power field.

ABSS = acute bronchitis severity score; WBC = white blood cells; hpf = high power field; epi = epithelial cells.

APPENDIX B

New ABSS

Introduction to the ABSS to be read to the patient

Patients with acute bronchitis will experience ailments which we are evaluating as part of the study in which you are currently participating. We would like to ask you a few questions regarding your experience during this illness. I will read the symptoms to you.

For each of them I will ask you the extent to which the problem has bothered you in the past 24 hours: Very mild, Mild, Moderate, Serious and Very serious. These options will rate your overall feeling about the illness, daily activities and fever. If you have a cough I will read through the various options as a guide.

Please let me know if you have not had any of the symptoms I mention in the past 24 h.

Thank you for your participation.

In the past 24 h, how much have you been bothered by:

Symptoms	0	1	2	3	4
Overall severity of illness	Very mild	Mild	Moderate	Serious	Very serious
Day cough	1–2 times/day	3–5 times/day	6–10 times/day	11–20 times/day	>20 times/day
Night cough	1–2 times/night	3–5 times/night	6–10 times/night	11–20 times/night	>20 times/night
Limit daily activity	None	Mild	Moderate	Severe	Very severe
Fever	None	Mild	Moderate	Severe shaking chills	Very severe

ABSS = acute bronchitis severity score

[†] Epithelial cells per high power field.

RÉSUMÉ

INTRODUCTION: Malgré l'existence de plusieurs schémas de prédiction clinique des infections du tractus respiratoire inférieur (LRTI), il y en a peu pour la bronchite aiguë, et la plupart d'entre elles n'ont pas été validées dans des contextes à haute prévalence du virus de l'immunodéficience humaine (VIH).

MÉTHODES: Un score de gravité de la bronchite aiguë (ABSS) a été élaboré et validé au cours de l'essai randomisé d'un traitement antibiotique pour la bronchite aiguë. Des adultes ambulatoires se plaignant d'une toux productive depuis ≤2 semaines et fréquentant les polycliniques des maladies respiratoires à Nairobi, Kenya, ont été recrutés et évalués pour la réponse clinique au traitement. Les scores quantitatifs de l'ABSS des LRTI associés aux symptômes, aux signes physiques et à la présence de pus à la coloration de Gram des crachats ont été évalués au moyen de tests psychométriques standard.

RÉSULTATS: On a pu évaluer l'ABSS dans 649 cas de bronchite aiguë, dont 129 (20%) étaient séropositifs pour le VIH. L'ABSS a peu d'effets de plancher et de plafond (1,8/0,2) et a fait preuve d'une forte cohérence interne (coefficient α de 0,66) et d'une validité interne, avec une corrélation moyenne inter item total ≥0,25. L'importance des effets entre l'état de base et les visites ultérieures de suivi a été importante (>0,5). Il y a une association entre les sifflements et la douleur thoracique et des valeurs plus élevées de l'ABSS, alors qu'il n'y en a pas pour les variables cliniques non concernées.

CONCLUSION: L'ABSS a fait preuve d'une bonne sensibilité, d'une cohérence interne élevée, d'une bonne corrélation avec les signes respiratoires habituels et d'une valeur discriminatoire importante chez les patients atteints de bronchite aiguë dans un contexte de séroprévalence élevée du VIH.

_RESUMEN

MARCO DE REFERENCIA: Se conocen diversas reglas clínicas pronósticas de la infección de las vías respiratorias inferiores, pero pocas de la bronquitis aguda, y la mayoría carece de validación en ámbitos con alta prevalencia de infección por el virus de la inmunodeficiencia humana (VIH).

MÉTODOS: En un estudio aleatorizado de antibioticoterapia por bronquitis aguda, se elaboró y validó la escala de gravedad de la bronquitis aguda (ABSS). Se estudió la respuesta clínica al tratamiento de los pacientes adultos participantes, con tos de una duración máxima de 2 semanas, que acudieron al consultorio de enfermedades respiratorias en Nairobi, Kenia. La puntuación de la escala ABSS para los síntomas asociados con infección de las vías respiratorias inferiores, los signos físicos y la cantidad de bacterias en la coloración de gram se validó mediante pruebas psicométricas normalizadas.

RESULTADOS: L'ABSS se evaluó en 649 casos, de los cuales 129 (20%) fueron positivos para el VIH. L'ABSS presentó escasa limitación en las respuestas de los valores extremos inferior y superior de la distribución (1,8/0,2) y exhibió alta homogeneidad interna (coeficiente α de 0,66) y alta validez interna, con un promedio de correlación total entre los elementos ≥0,25. Se observó una amplia magnitud del efecto desde estado inicial hasta las consultas posteriores de seguimiento (>0,5). Las sibilancias y el dolor torácico se asociaron con puntuaciones más altas en la escala de gravedad, mas no así las variables clínicas irrelevantes.

CONCLUSIÓN: L'ABSS demostró una buena sensibilidad, alta homogeneidad interna, buena correlación con los signos y síntomas respiratorios frecuentes y una alta validez discriminatoria en pacientes con bronquitis aguda, en un medio con alta seroprevalencia para el VIH.