

Validation of the Chronic Airways Assessment Test in the NOVELTY Study

Erin Tomaszewski,¹ Mark J. Atkinson,² Christer Janson,³ Niklas Karlsson,⁴ Barry Make,⁵ David Price,⁶ Helen K. Reddel,⁷ Claus F. Vogelmeier,⁸ Hana Müllerová,⁹ Paul Jones¹⁰

¹*BioPharmaceuticals Medical, AstraZeneca, Gaithersburg, MD, USA;* ²*Evidera, Bethesda, MD, USA;*

³*Department of Medical Sciences: Respiratory, Allergy and Sleep Research, Uppsala University,*

Uppsala, Sweden; ⁴*BioPharmaceuticals Medical, AstraZeneca, Gothenburg, Sweden;* ⁵*National Jewish*

Health and University of Colorado Denver, Denver, CO, USA; ⁶*Observational and Pragmatic Research*

Institute, Singapore, and Centre of Academic Primary Care, Division of Applied Health Sciences,

University of Aberdeen, Aberdeen, UK; ⁷*Woolcock Institute of Medical Research, University of Sydney,*

Sydney, Australia; ⁸*Department of Medicine, Pulmonary and Critical Care Medicine, University of*

Marburg, member of the German Center for Lung Research (DZL), Marburg, Germany;

⁹*BioPharmaceuticals Medical, AstraZeneca, Cambridge, UK;* ¹⁰*Global Respiratory Franchise,*

GlaxoSmithKline, Middlesex, UK.

Presenting author: Erin L. Tomaszewski

Length: 400 words (maximum: 400 words [abstract body plus any references]; excludes title, authors' information, tables and figures)

Number of figures/tables: 1 (maximum 1)

Rationale: Very few patient-reported tools assess health status across different obstructive lung diseases. The Chronic Airways Assessment Test (CAAT) is a modification of the chronic obstructive pulmonary disease (COPD) Assessment Test (CAT) that is intended to assess health status in patients with asthma and/or COPD. With permission, minor modifications were made to the CAT to replace the term 'COPD' with 'chronic airways' and 'pulmonary disease' in the questionnaire title and instructions, respectively. In all other respects the CAAT is the same as the CAT, including the wording of all items, response options, and the scoring. The CAAT score (range: 0–40) is the sum score of the 8 items (scored 0–5); higher scores indicate worse health status.

Methods: The CAAT was evaluated in patients with asthma and/or COPD using cross-sectional baseline data from NOVELTY (NCT02760329), a global, prospective, observational study. The total sample (N=1,530) for this validation analysis comprised three randomly-selected samples (N=510 each) from each physician-assigned diagnostic group (asthma, asthma+COPD, COPD). The total sample included a subset of patients who also completed the CAT (asthma+COPD: n=37; COPD: n=46). Psychometric analyses included descriptive statistics, tests of validity and reliability, and differential item functioning via Item Response Theory (IRT).

Results: CAAT items were internally consistent in each diagnostic group (Cronbach's alphas ranged from 0.84 to 0.87; Table), a prerequisite for use as a single-factor tool in patients with asthma and/or COPD. Tests for convergent and divergent validity coefficients between the CAAT and clinical assessments found strong convergent correlations (>0.7) with health status assessed by the St. George's Respiratory Questionnaire, and divergent (i.e. weak) correlations with some spirometry measures (Table). CAAT scores also differed significantly between clinically identifiable groups (physician-assigned diagnosis and physician-assessed severity groups, mMRC dyspnea scale grades, exacerbation history, and, in patients with an asthma diagnosis, Asthma Control Test scores). Furthermore, IRT analysis suggests that items had a good overall fit; item response boundary

locations were monotonic and in the expected order. Models of measurement and structural invariance were strong.

Conclusions: Overall, this analysis demonstrates that the CAAT is a valid patient-reported tool with established cross-sectional psychometric properties. It correlated well with health status measures in NOVELTY patients with diagnoses of asthma and/or COPD. The CAAT is a suitable diagnosis-agnostic patient-reported tool for use in obstructive lung disease, and because of its brevity, may be particularly relevant for real-world clinical studies and routine clinical practice where time is limited.

Table. Patient demographics and clinical characteristics, internal consistency, and correlations by physician-assigned diagnosis

Variable	Asthma (N=510)	Asthma+ COPD (N=510)	COPD (N=510)	Total sample (N=1,530)
Demographic and clinical characteristics				
Age, mean years (SD)	54.6 (15.7)	65.2 (9.9)	67.3 (9.6)	62.4 (13.3)
Female, n (%)	328 (64.3)	240 (47.1)	203 (39.8)	771 (50.4)
CAAT score, mean (SD)	13.7 (8.2)	17.2 (8.6)	16.9 (8.2)	15.9 (8.5)
Internal consistency				
Cronbach's alphas for each diagnosis group	0.87	0.86	0.84	0.86
Convergent correlations^a with CAAT score				
CAT score	NA	0.86*** (n=37)	0.93*** (n=46)	0.90*** (n=83)
SGRQ total score	0.79*** (n=500)	0.81*** (n=502)	0.76*** (n=501)	0.79*** (n=1,503)
EQ VAS	-0.53*** (n=434)	-0.56*** (n=451)	-0.57*** (n=450)	-0.57*** (n=1,335)
RSQ score	0.67*** (n=508)	0.72*** (n=507)	0.71*** (n=509)	0.71*** (n=1,524)
mMRC dyspnea scale grade	0.49*** (n=488)	0.53*** (n=499)	0.53*** (n=501)	0.54*** (n=1,488)
Divergent correlations^a with CAAT score				
Post-bronchodilator FEV ₁ (% predicted)	-0.26*** (n=400)	-0.23*** (n=433)	-0.30*** (n=420)	-0.31*** (n=1,253)
Post-bronchodilator FVC (% predicted)	-0.24*** (n=400)	-0.27*** (n=432)	-0.29*** (n=419)	-0.29*** (n=1,251)
Post-bronchodilator FEF 25–75% (% predicted)	-0.13* (n=385)	-0.07 (n=411)	-0.12* (n=409)	-0.16*** (n=1,205)
Exacerbations in the past 12 months	0.13 (n=173)	0.20** (n=261)	0.21* (n=174)	0.19*** (n=608)

The CAAT is a trademark of the GlaxoSmithKline group of companies. © 2009 GlaxoSmithKline. All rights reserved. It has been modified from the CAT, with permission, by replacement of the term 'COPD' with 'chronic airways' and 'pulmonary disease' in the questionnaire title and instruction, respectively.

^aCorrelation coefficients (Pearson's *r*) >0.70 are regarded as strong; 0.4–0.7 as moderate; and <0.4 as weak.

CAAT, Chronic Airways Assessment Test; CAT, COPD Assessment Test; COPD, chronic obstructive pulmonary disease; EQ VAS, EuroQol Visual Analog Scale; FEF, forced expiratory flow; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; mMRC, modified Medical Research Council; N, total number of patients in the sample; n, number of patients with non-missing data; NA, not applicable; RSQ, Respiratory Symptoms Questionnaire; SD, standard deviation; SGRQ, St. George's Respiratory Questionnaire.

p*<0.05; *p*<0.001; ****p*<0.0001.