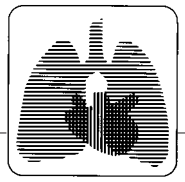

Development and Validation of a Survey-Based COPD Severity Score*

Mark D. Eisner, MD, MPH, FCCP; Laura Trupin, MPH; Patricia P. Katz, PhD; Edward H. Yelin, PhD; Gillian Earnest, MS; John Balmes, MD, FCCP; and Paul D. Blanc, MD, MSPH, FCCP

Objective: **To develop a comprehensive disease-specific COPD severity instrument for survey-based epidemiologic research.**

Study design and setting: **Using a population-based sample of 383 US adults with self-reported physician-diagnosed COPD, we developed a disease-specific COPD severity instrument. The severity score was based on structured telephone interview responses and included five overall aspects of COPD severity: respiratory symptoms, systemic corticosteroid use, other COPD medication use, previous hospitalization or intubation, and home oxygen use. We evaluated concurrent validity by examining the association between the COPD severity score and three health status domains: pulmonary function, physical health-related quality of life (HRQL), and physical disability. Pulmonary function was available for a subgroup of the sample (FEV_1, n = 49; peak expiratory flow rate [PEFR], n = 93).**

Results: **The COPD severity score had high internal consistency reliability (Cronbach $\alpha = 0.80$). Among the 49 subjects with FEV_1 data, higher COPD severity scores were associated with poorer percentage of predicted FEV_1 ($r = -0.40$, $p = 0.005$). In the 93 subjects with available PEFR measurements, greater COPD severity was also related to worse percentage of predicted PEFR ($r = -0.35$, $p < 0.001$). Higher COPD severity scores were strongly associated with poorer physical HRQL ($r = -0.58$, $p < 0.0001$) and greater restricted activity attributed to a respiratory condition ($r = 0.59$, $p < 0.0001$). Higher COPD severity scores were also associated with a greater risk of difficulty with activities of daily living (odds ratio [OR], 2.3; 95% confidence interval [CI], 1.8 to 3.0) and inability to work (OR, 4.2; 95% CI, 3.0 to 5.8).**

Conclusion: **The COPD severity score is a reliable and valid measure of disease severity, making it a useful research tool. The severity score, which does not require pulmonary function measurement, can be used as a study outcome or to adjust for disease severity.** ***(CHEST 2005; 127:1890–1897)***

Key words: chronic bronchitis; pulmonary disease, chronic obstructive; outcome assessment (health care); pulmonary emphysema; severity of illness index

Abbreviations: CI = confidence interval; HRQL = health-related quality of life; NHIS = National Health Interview Survey; OR = odds ratio; PEFR = peak expiratory flow rate; SF = Short-Form

COPD is a major cause of impaired health status, disability, and mortality. The disease is responsible for > 2 million emergency department visits and hospitalizations annually in the United States.[1] Despite public awareness about the health risks of smoking, mortality from COPD continues to increase.[1] Consequently, there is an urgent need for epidemiologic studies that better delineate the risk factors for adverse health outcomes among adults with COPD. The conduct of such studies has been hampered by the lack of a validated disease-specific COPD severity measure beyond the basic physiologic assessment of pulmonary function. A comprehensive survey-based measure of COPD severity

*From the Department of Medicine (Drs. Eisner, Balmes, and Blanc, Ms. Trupin and Ms. Earnest), University of California, San Francisco; of and Institute for Health Policy Studies (Drs. Katz and Yelin), University of California, San Francisco, San Francisco, CA.

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Correspondence to: Mark D. Eisner, MD, MPH, FCCP, University of California, San Francisco, 350 Parnassus Ave, Ste 609, San Francisco, CA 94117; e-mail: eisner@itsa.ucsf.edu

would be valuable for use in epidemiologic studies as a health outcome or to adjust for disease-specific severity.

Pulmonary function measurement, especially FEV_1, has traditionally been used to stage the severity of COPD in clinical practice; the recent Global Initiative for Chronic Obstructive Lung Disease has codified this practice in its guidelines.[2–6] Although pulmonary function is an essential clinical tool for characterizing COPD and is a potent predictor of mortality,[7] it is not a comprehensive disease-severity measure. FEV_1, for instance, correlates weakly with other measures of health-related quality of life (HRQL) and respiratory symptoms.[8–10] Moreover, FEV_1 did not capture important treatment-related clinical improvements, manifested by fewer COPD exacerbations, in clinical trials of inhaled corticosteroids.[11–15] In addition, spirometry can be difficult and expensive to perform in large-scale epidemiologic studies.

HRQL instruments, both generic and disease-specific, have also been used to gauge the severity of COPD.[8,16,17] HRQL, however, is conceptually different from disease severity. HRQL is a patient-centered measurement of perceived satisfaction with life, as it is affected by health.[18] COPD severity is a distinct construct that reflects the biological impact of disease pathophysiology on diverse aspects of physical functioning. Consequently, COPD severity is proximal to and influential of HRQL. Although HRQL instruments provide an important patient-level assessment, they cannot substitute for a specific measure of COPD severity.

We developed a comprehensive disease-specific COPD severity score for use in epidemiologic and health-outcomes research. The score, which was designed for survey administration, is an integrated measure of disease severity, based on disease status, receipt of clinical treatments, and recent hospitalization for COPD. Using a population-based sample of US adults with COPD, we assessed the reliability and validity of the COPD severity score.

Materials and Methods

Overview

In a population-based sample of 383 US adults with COPD, we developed a disease-specific COPD severity instrument. The severity score was based on responses to a structured telephone interview. Internal consistency reliability was established using standard psychometric techniques. We evaluated concurrent validity by examining the association between the COPD severity score and three aspects of health status: pulmonary function, physical HRQL and health status, and physical disability. Pulmonary function measurements were obtained for a subset of respondents subsequent to the interviews.

Recruitment of Adults With COPD

Survey methods have been previously described in detail.[19] The study was approved by the University of California, San Francisco Committee on Human Research. Briefly, 383 adults with COPD were selected from a random sample of 2,061 US adults aged 55 to 75 years identified by random-digit dialing telephone interviews. Approximately one half of the overall sample (n = 1,001) was randomly identified among residents in the 48 contiguous states of the United States. The remainder of the sample (n = 1,060) was recruited from persons who resided in geographic "hot spots" that had the highest COPD mortality rates based on the National Institute of Occupational Safety and Health Atlas of Respiratory Disease Mortality in the United States: 1982–1993.[20] The hot-spot sample was enriched for subjects with COPD. The overall study participation rate was 53% among households with an eligible respondent present.

During each telephone contact, one randomly selected adult per household was interviewed. Subjects were asked if they had ever received a physician's diagnosis of any of several chronic respiratory conditions. Those who reported physician diagnoses of chronic bronchitis or emphysema were considered to have COPD, along with those who specifically reported a diagnosis of COPD. We included respondents with COPD who had concomitant asthma because they clinically resemble persons with COPD alone.[21]

Development of the COPD Severity Score

Participants underwent structured telephone interviews that elicited respiratory symptoms and medications, health status, smoking history, employment history, and sociodemographic characteristics. Survey-item responses were used to construct a disease-specific COPD severity score. The instrument and scoring instructions are available from the authors, on request.

We previously developed a disease-specific severity-of-asthma score for use in epidemiologic and outcomes research.[22,23] Using a similar process, we created a COPD severity score based on responses to survey items that comprise five overall aspects of COPD severity: respiratory symptoms, systemic corticosteroid use, other COPD medication use, previous hospitalization or intubation for respiratory disease, and home oxygen use (Table 1). Each item was assigned an *a priori* weight based on clinical aspects of the disease and its expected contribution to overall COPD severity. In order to assess the performance of the *a priori* weighting scheme, we derived an alternate weighting scheme by factor analysis with orthogonal rotation. Possible total scores range from 0 to 35, with higher scores reflecting more severe COPD.

The COPD severity score takes into account both current symptom status and the therapy necessary to achieve this status. For example, a person with few respiratory symptoms who is receiving multiple medications for COPD would have greater COPD severity, and a higher COPD severity score, than another person with comparable symptom status and no medication use. In addition, recent prior hospitalization or intubation for COPD are assigned high weights, as they are indicators of poor future health outcomes.[24] Oxygen use, because it is recommended for persons with advanced disease,[3] was also heavily weighted.

Missing values for COPD severity score components were rare, ranging from 0 to 2% per item. We used previously established methods to impute missing values.[23] For dyspnea during the past 14 days or nights, we assigned missing values the maximum of either the day or night response (n = 9 subjects and n = 5 subjects, respectively; no subjects were missing both values). Respondents who indicated antibiotic use during the past 12 months but who did not indicate the number of courses were