Prevalence of Airway Obstruction Assessed by Lung Function Questionnaire

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OBJECTIVE: To estimate the prevalence of unidentified chronic obstructive pulmonary disease (COPD) and determine the screening accuracy of the Lung Function Questionnaire (LFQ).

PATIENTS AND METHODS: Cigarette smokers who had a smoking history of 10 or more pack-years and were aged 30 years or older were recruited from 36 centers from February 18, 2009, to May 29, 2009. A total of 1575 patients completed a Web-based survey including the 5-item LFQ. Spirometry was performed on patients with an LFQ total score of 18 or less and on a subset scoring more than 18. The primary outcome was the proportion of patients at risk of airflow obstruction as measured by the LFQ (score, ≤ 18) in whom an airflow obstruction was confirmed by spirometry.

RESULTS: Of the patients who completed the LFQ, 849 (54%) had standardized spirometry data available. On the basis of LFQ and spirometry results, the estimated prevalence of possible COPD was 17.9% (95% confidence interval, 15.3%-20.6%). At a cut point of 18 or less, sensitivity, specificity, positive predictive value, and negative predictive value of the LFQ were 88%, 25%, 21%, and 90%, respectively. Approximately 1 in 5 patients (21%) aged 30 years or older and 1 in 4 (26%) aged 50 years or older scored 18 or less on the LFQ and had a ratio of forced expiratory volume in the first second of expiration to forced vital capacity less than 0.70.

CONCLUSION: On the basis of postbronchodilator spirometry results using weighted estimates, approximately 1 in 5 patients (21%) aged 30 years or older with a smoking history of 10 or more pack-years seen in a primary care setting is likely to have COPD. The LFQ could be a helpful COPD case-finding tool for clinicians to identify patients who need further evaluation.

Trial Registration: clinicaltrials.gov Identifier: NCT01013948

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COPD = chronic obstructive pulmonary disease; **FEV₁** = forced expiratory volume in the first second of expiration; **FVC** = forced vital capacity; **LFQ** = Lung Function Questionnaire

Chronic obstructive pulmonary disease (COPD) is currently the third leading cause of death in the United States,¹ and the number of deaths is increasing, especially among women.² Currently, more than 12 million people in the United States are diagnosed as having COPD, but the true prevalence is estimated to be more than double this number.^{3,4} The Third National Health and Nutrition Examination Survey (NHANES) examined more than 14,000 adults from across the United States with a battery of tests that included spirometry and respiratory symptom questionnaires and found that COPD was undiagnosed in almost two-thirds of individuals with airflow obstruction.^{5,6} In the NHANES, most of those with undiagnosed obstruction reported having chronic respi-

ratory symptoms and COPD-related physical impairment that negatively affected their day-to-day lives.⁷ Although clinical trials such as the Lung Health Study demonstrated that early diagnosis and aggressive interventions in COPD can improve long-term outcomes,⁸⁻¹¹ COPD is not diagnosed in most patients until they have long-standing symptoms, experience complications such as pneumonia, or develop other smoking-related conditions such as cardiovascular disease or cancer.

Screening programs for COPD have not gained widespread acceptance.¹²⁻¹⁴ Demonstration of airflow obstruction with spirometry is considered the standard for confirming

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the diagnosis of COPD but is a more physically challenging screening test than other screening tests, such as blood pressure or serum glucose screening. A recent US Preventive Services Task Force investigation did not support the routine use of spirometry for COPD screening.^{13,15} Among the reasons cited for this decision were the large time commitment for both the patient and the health care system for successful testing, lack of data suggesting a positive cost-benefit ratio, and a small but significant false-positive rate among healthy individuals. Spirometry is also not recommended as a screening tool among asymptomatic patients.¹⁶ Therefore, efficient screening tools for identifying persons at risk of undiagnosed COPD are still needed.¹⁷

To address this issue, we developed the Lung Function Questionnaire (LFQ), a 5-item self-administered questionnaire intended for use in COPD screening programs and in primary care settings.¹⁸ In a previous publication, we described the development and initial testing of the LFQ.¹⁸ The objectives of this study were to estimate, within a primary care setting, the prevalence of unidentified COPD and to determine the screening accuracy of this simple, self-administered screening tool for COPD.

PATIENTS AND METHODS

This multicenter, noninterventional, cross-sectional study was conducted from February 18, 2009, to May 29, 2009, in the primary care setting and included patients with a history of cigarette smoking who were not taking medication for COPD or asthma. The primary objective of this study was to estimate the prevalence of chronic airway obstruction in patients in a primary care setting with a history of cigarette smoking (previous and current smokers) using the LFQ as a screening tool and spirometry for subsequent confirmation. Secondary objectives included examining psychometric properties of the LFQ overall as well as its performance in patients with abnormal spirometry results.

SITE RECRUITMENT AND PATIENT ENROLLMENT

The study was conducted at 36 primary care centers in the United States. Sites were recruited from 4 geographic regions (the Northeast, South, Midwest, and West) using a proprietary database of about 1400 physicians who had previously expressed interest in conducting research and were members of the Primary Care Network. The study was approved by a central institutional review board, and each patient provided written informed consent before study procedures.

The study population included current or previous cigarette smokers aged 30 years or older at screening who had a minimum smoking history of 10 pack-years. Patients were ineligible to participate if they reported any regular (ie, on

a daily basis) use of respiratory medications in the 4 weeks before the study visit. A known diagnosis of substantial lung conditions was exclusionary. A previous diagnosis of an obstructive lung disease was not exclusionary if the patient met the criteria for medication use.

STUDY ASSESSMENTS

Lung Function Questionnaire. Patients completed the LFQ, which consists of 5 questions scored on a 5-point scale, with lower scores indicating increased risk of airflow obstruction. On the basis of previous validation of the LFQ, a total score of 18 or less suggests an increased risk of airway obstruction. In addition to the LFQ, the patient questionnaire included questions about current medical history, smoking habits, resource utilization history, and demographics.

Spirometry. All patients with a total LFQ score of 18 or less, and the first 2 patients completing the questionnaire who scored more than 18 at each site, were selected for prebronchodilator and postbronchodilator spirometry, performed by trained site staff. After an initial prebronchodilator maneuver, each patient selected for spirometry self-administered 4 puffs (360 µg) of albuterol via metered-dose inhaler for the spirometric determination of postbronchodilator ratio of forced expiratory volume in the first second of expiration (FEV₁) to forced vital capacity (FVC); a ratio less than 0.70 was considered to demonstrate airway obstruction characteristic of the disease.¹⁹ Spirometry was conducted using standardized equipment (Biomedical Systems, St Louis, MO) that meets or exceeds the minimum performance recommendations of the American Thoracic Society.²⁰ Only data collected from acceptable spirometric maneuvers were included in the analysis. If spirometric maneuvers were unacceptable, patients were allowed to repeat this procedure within 7 days of completion of the study visit; those who did not return were withdrawn from the study.

STATISTICAL METHODS

Data from all patients who completed all questions on the LFQ were included in the analysis. The estimated prevalence of COPD was based on LFQ and spirometry results. Patients who scored 18 or less were classified as having an airflow obstruction if the postbronchodilator FEV₁/FVC ratio was less than 0.70.

To minimize potential selection bias, weighted estimates of prevalence were calculated by taking the weighted mean of the prevalence estimates within each of the 4 geographic regions. The region weight was defined as the proportion of people residing in each specified region who would qualify to participate in the study compared with the total number of people in the United States who would qualify

to participate in the study. Other ad hoc analyses were undertaken to further understand LFQ results among patients not classified as having an airflow obstruction. These included outcomes for both prebronchodilator and postbronchodilator spirometry values and distributions on the basis of the age and smoking history of patients who were at risk according to the LFQ and were confirmed as such by prebronchodilator or postbronchodilator spirometry.

Estimates of screening accuracy (ie, sensitivity, specificity, positive predictive value, negative predictive value, and percentage correctly classified) were computed using the methods described by Begg and Greenes.²¹ Positive predictive value was defined as [Number of Patients With LFQ score ≤ 18 and $FEV_1/FVC < 0.70$] / [Number of Patients With LFQ score ≤ 18]. Similarly, negative predictive value was defined as [Number of Patients With LFQ Score > 18 and $FEV_1/FVC \geq 0.70$] / [Number of Patients With LFQ score > 18].

The LFQ was designed as a case-finding tool rather than an instrument measuring a single health-status concept; consequently, a high level of internal consistency was not anticipated. By design, the items serve as indicators of disparate factors that, taken together, predict the likelihood of obstruction. For the proportion of patients who scored

18 or less on the LFQ without completing spirometry satisfactorily according to the American Thoracic Society/European Respiratory Society criteria, weighted estimates of regional prevalence were derived.

RESULTS

STUDY SAMPLE

Of 4956 patients with a smoking history who were invited, 2284 current or former smokers (46%) completed the case-finding questionnaire. Of these 2284 patients, 1724 (75%) were eligible according to study criteria. Completed LFQs were obtained from 1575 patients (69%) during the study visit. On the LFQ, 1216 patients (77%) scored 18 or less, and 359 patients (23%) scored more than 18.

Of the 1288 patients eligible for spirometry, 849 (66%) completed a postbronchodilator spirometry session meeting American Thoracic Society/European Respiratory Society criteria. The consort diagram for the study is shown in Figure 1.

DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Demographic characteristics and general health information are shown in Table 1. These results are grouped by

FIGURE 1. Consort diagram of disposition of patients in study. ATS = American Thoracic Society; ERS = European Respiratory Society; LFQ = Lung Function Questionnaire.

LFQ cut-point score (LFQ ≤ 18 , 1216 patients; LFQ > 18 , 359 patients) and for the subsample who completed spirometry (LFQ ≤ 18 and spirometry, 800 patients; LFQ > 18 and spirometry, 49 patients).

In general, the demographics were similar across groups, with a few exceptions. The group with an LFQ score of more than 18 had a slightly different ethnic distribution (fewer non-Hispanic white patients) and a larger percentage of patients from the West than the group with an LFQ score of 18 or less. In addition, patients with an LFQ score of more than 18 who completed spirometry were less likely to have a body mass index greater than 30 (calculated as the weight in kilograms divided by height in meters squared). Finally, on average, patients with an LFQ score of more than 18 reported fewer comorbid conditions and fewer pack-years than patients with lower LFQ scores, independent of whether they had completed spirometry.

PREVALENCE OF AIRWAY OBSTRUCTION

On the basis of LFQ and spirometry results, the weighted estimate of prevalence of not fully reversible airflow obstruction (defined as LFQ score ≤ 18 and confirmed by a postbronchodilator FEV₁/FVC ratio < 0.70) in current or former smokers seen in primary care is 17.9% (95% confidence interval, 15.3%-20.6%). Approximately 1 in 5 patients (21%) aged 30 years or older and 1 in 4 patients (26%) aged 50 years or older scored 18 or less on the LFQ and had an FEV₁/FVC ratio less than 0.70 (Table 2).

When age was considered in combination with smoking (measured by pack-years), the trend of patients with obstruction identified by the LFQ and confirmed by spirometry moved in an expected direction (Table 2). For instance, of patients aged 50 years or older who had a smoking history of 30 pack-years or more, 1 in 3 scoring 18 or less on the LFQ was confirmed to have an obstruction.

We also examined patients who had abnormal spirometry results (FEV₁ $< 80\%$ of predicted, both prebronchodilator and postbronchodilator) and restricted spirometry results (FEV₁/FVC ratio ≥ 0.70 but FEV₁ $< 80\%$, all postbronchodilator).

Of the 191 patients who had an FEV₁/FVC ratio of 0.70 or more and whose FEV₁ was less than 80% of predicted, 182 (95%) scored 18 or less on the LFQ, thus underscoring the usefulness of the LFQ as a case-finding tool. This group had an average smoking history of 36.5 pack-years, mean body mass index of 31, and mean age of 54 years. The demographic characteristics of this patient population reflect those of the larger study population.

EVALUATION OF THE LFQ

Patients who completed spirometry (n=849) included 800 (94%) selected because they scored 18 or less on the LFQ. The cut point of 18 was suggested by earlier studies to be the most predictive of patients who should be evaluated with spirometry for possible obstruction.^{18,22} In these 849 patients, 175 postbronchodilator spirometry tests (21%) resulted in an FEV₁/FVC ratio of less than 0.70, indicating

TABLE 1. Patient Demographic Characteristics by LFQ Cut Point and for Sample Completing Spirometry^a

	LFQ ≤ 18 (n=1216)	LFQ > 18 (n=359)	LFQ ≤ 18 and completed spirometry (n=800)	LFQ > 18 and completed spirometry (n=49)
Age (y)	55.0 $\pm$ 11.8	50.0 $\pm$ 11.8	54.6 $\pm$ 11.5	45.1 $\pm$ 10.7
Male	620 (51.0)	187 (52.1)	402 (50.3)	28 (57.1)
Race/ethnicity				
Non-Hispanic white	908 (74.7)	202 (56.3)	618 (77.3)	33 (67.3)
Non-Hispanic African American	113 (9.3)	36 (10.0)	61 (7.6)	2 (4.1)
Non-Hispanic other	60 (4.9)	44 (12.3)	39 (4.9)	5 (10.2)
Hispanic	71 (5.8)	57 (15.9)	42 (5.3)	4 (8.2)
Unspecified	64 (5.3)	20 (5.6)	40 (5.0)	5 (10.2)
Region				
Northeast	146 (12.0)	20 (5.6)	72 (9.0)	2 (4.1)
Midwest	204 (16.8)	59 (16.4)	127 (15.9)	8 (16.3)
South	641 (52.7)	86 (24.0)	456 (57.0)	29 (59.2)
West	225 (18.5)	194 (54.0)	145 (18.1)	10 (20.4)
BMI ^b	29.8 $\pm$ 6.6	28.9 $\pm$ 6.3	29.9 $\pm$ 6.7	26.9 $\pm$ 4.3
BMI > 30	498 (41.0)	129 (35.9)	332 (41.5)	14 (28.6)
No. of comorbid conditions	4.0 $\pm$ 3.4	2.8 $\pm$ 2.6	4.0 $\pm$ 3.3	2.4 $\pm$ 2.6
No history of comorbid conditions	161 (13.2)	74 (20.6)	93 (11.6)	18 (36.7)
Smoking status				
Current smoker	748 (61.5)	159 (44.3)	475 (59.4)	26 (53.1)
No. of pack-years	34.3 $\pm$ 21.9	21.8 $\pm$ 11.5	34.2 $\pm$ 21.7	20.6 $\pm$ 8.9

^a Categorical values are provided as number (percentage) of patients and continuous values as mean $\pm$ SD unless specified otherwise. BMI = body mass index; LFQ = Lung Function Questionnaire.

^b Calculated as the weight in kilograms divided by height in meters squared.

TABLE 2. Proportion of Patients Scoring ≤ 18 on the LFQ in Whom Obstruction Was Confirmed by Prebronchodilator or Postbronchodilator Spirometry^{a,b}

	Smoking history (pack-years)			
	>10	>20	>30	>40
Prebronchodilator				
Age (y)				
≥30	237/800 (30)	203/610 (33)	163/410 (40)	113/243 (47)
≥40	223/713 (31)	199/572 (35)	162/399 (41)	113/238 (47)
≥50	196/532 (37)	176/439 (40)	147/322 (46)	107/210 (51)
Postbronchodilator				
Age (y)				
≥30	170/800 (21)	146/610 (24)	118/410 (29)	81/243 (33)
≥40	162/713 (23)	144/572 (25)	118/399 (30)	81/238 (34)
≥50	136/532 (26)	121/439 (28)	102/322 (32)	75/210 (36)

^a Obstruction is defined as the ratio of forced expiratory volume in the first second of expiration to forced vital capacity less than 0.70.

^b Data are provided as number (percentage) of patients. The denominator indicates the number of patients in each category who scored ≤ 18 on the Lung Function Questionnaire (LFQ) and were "at risk" of obstruction. The numerator denotes the number of these patients in whom obstruction was confirmed using prebronchodilator or postbronchodilator spirometry.

obstruction, and 674 (79%) resulted in an FEV₁/FVC ratio of 0.70 or more, indicating no obstruction.

Of the 800 patients with an LFQ score of 18 or less, 170 (21%) had confirmed obstruction on the basis of their FEV₁/FVC ratio of less than 0.70. Figure 2 provides a graphic display of the total LFQ score frequency for all patients in the study sample, as well as the frequency for patients who successfully completed spirometry (n=849). Most patients who completed spirometry had an LFQ score between 13 and 19.

On the basis of the current cut point (≤ 18), the LFQ has a sensitivity of 88% and a specificity of 25%. At a score of 18 in patients aged 30 years or older, 21% of those who were screened as possibly having an airflow obstruction on the basis of the LFQ were confirmed by spirometry to have one (positive predictive value), and 90% of those who were screened as not having an airflow obstruction by the LFQ were confirmed by spirometry not to have one (negative predictive value). Overall, 37% of the patients were correctly classified as having airflow obstruction on the basis of postbronchodilator spirometry results at this LFQ cut point. Of patients who were not taking any respiratory medications, who scored 18 or less on the LFQ, and who

FIGURE 2. Frequency of total score on Lung Function Questionnaire (LFQ) for patient population with successful spirometry and the subset confirmed to have airway obstruction.

had an FEV₁/FVC ratio of less than 0.70, 762 (95%) did not report a previous diagnosis of COPD.

DISCUSSION

This study sought to determine the prevalence of airway obstruction in smokers in a primary care setting using the LFQ as a case-finding tool and confirming the diagnosis with spirometry. Previous epidemiological studies of COPD prevalence either have been non-clinic-based⁴ or have used ambulatory care claims data. This cross-sectional survey of ambulatory clinics is representative of what primary care physicians are likely to see in their offices.

In the primary care offices studied, obstructive airway disease was not uncommon in any age group screened, even in those younger than 50 years, who are rarely assessed for COPD in primary care. The LFQ retained high sensitivity and negative predictive value, important characteristics for case-finding purposes.

A simple, cost-effective strategy to identify a large group of patients with undiagnosed symptomatic obstructive lung disease is needed to address this important public health concern. Most primary care physicians do not have office spirometry equipment and thus do not have ready access to an objective test necessary for both diagnosis and management of COPD. The LFQ may be adopted as a method to identify patients at risk of obstructive lung disease. An LFQ score of 18 or less might encourage primary care physicians to refer patients for spirometry. Given its high negative predictive value, the LFQ also has the potential to decrease the use of spirometry in asymptomatic patients and guide other diagnostic evaluations in symptomatic patients with spirometric evidence of obstructive lung disease.^{22,23}

Although our primary aim in the development of the LFQ was to identify patients who were candidates for further assessment using spirometry (and potentially to identify undiagnosed cases of COPD), a substantial number of abnormal spirometry measures (eg, FEV₁ <80% of predicted) were also identified using the LFQ. We based our a priori criteria for the success of the LFQ on its ability to detect airway obstruction, but its clinical utility may actually be much greater because of its potential also to detect clinically important restrictive diseases.

The National Lung Health Education Program previously recommended screening spirometry for all current or former smokers aged 40 years or older to identify undiagnosed COPD.²⁴ However, on the basis of the results of the Agency for Healthcare Research and Quality evidence report and the recommendations of the US Preventive Services Task Force, most organizations no longer recommend this approach of universal screening.²³ We found that 762

(95%) of 800 patients recruited from a primary care setting who were not taking any respiratory medications, who scored 18 or less on the LFQ, and who had an FEV₁/FVC ratio of less than 0.70 did not report a previous diagnosis of COPD. Thus, the LFQ, as a preliminary case-finding tool, may be an acceptable alternative to mass screening.

The estimated COPD prevalence of 17.9% in primary care practice is much higher than the 3.0% to 5.0% prevalence in the general population.⁶ This finding may not be entirely unexpected because people visiting primary care physicians are a population generally more inclined to seek care for signs, symptoms, and previously recognized diseases. The practice-based prevalence will of course vary by age and smoking prevalence in this population.

This study has limitations. Selection bias is a potential limitation that could lead to an overestimation or underestimation of prevalence if outcomes of interest are significantly different in study patients vs the general population. To limit selection bias at the initial recruitment stage, sites were trained to use standardized recruitment protocols to screen and recruit eligible patients. Further, spirometry was performed only on a subset of patients. It should also be noted that the assessment of screening accuracy in the current study was limited because only a small subset scoring more than 18 on the LFQ completed spirometry. This study population may not be representative of the entire primary care population.

CONCLUSION

Case finding using the LFQ identified an estimated 18% prevalence of obstructive lung disease in patients aged 30 years or older visiting primary care practices in this study. The LFQ can be self-administered or administered by physicians' office staff in the waiting room, potentially saving time that can be used for follow-up questions and symptom identification. It could prove useful and acceptable in the identification of patients who are candidates for spirometric evaluation.

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