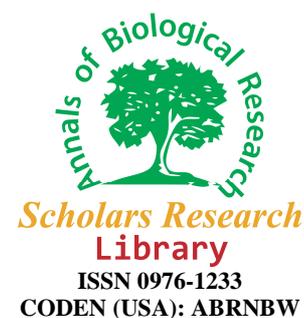




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Annals of Biological Research, 2010, 1 (4) : 248-253  
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### A study on the development of the lung function questionnaire (LFQ) to identify airflow obstruction in chronic obstructive pulmonary disease (COPD) patients

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#### ABSTRACT

*To describe the lung function questionnaire (LFQ) to identify airflow obstruction for patients with chronic obstructive pulmonary disease (COPD) along with spirometry tests. 200 COPD patients with age  $\geq 40$ -year-old were studied in department of chest diseases in Bhaskar medical college. The accuracy of the final subset of LFQ items for identifying individuals with airflow obstruction (forced expiratory volume in one second / forced vital capacity  $< 0.70$ ) versus those without it. The model with all five items (age; smoking history; the presence of wheeze, dyspnea, and phlegm) compared with models with combinations of fewer LFQ items had the highest classification accuracy (area under the curve [AUC] = 0.72) with sensitivity and specificity of 73.1% and 58.1%, respectively. The presence of three or more factors yielded the highest AUC, a result suggesting that three or more affirmative answers is the most appropriate criterion indicating presence of airflow obstruction. The above five-item LFQ retained sufficient accuracy, sensitivity, and specificity in identifying individuals with COPD for further validation testing.*

**Keywords:** spirometry, chronic obstructive pulmonary disease, lung function test, diagnosis, screening.

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## INTRODUCTION

Chronic obstructive pulmonary disease (COPD) affects approximately 12 million adults in the United States, where it causes approximately 1.5 million emergency department (ED) visits, 726,000 hospitalizations, and 119,000 deaths annually [1]. COPD is manifested by cough, sputum production, and breathlessness associated with airflow obstruction [2]. Deterioration in lung function impairs patients' general health and quality of life and eventually leads to respiratory failure and premature death. Contradicting this view, a convergence of evidence suggests that, although lung tissue damage in COPD appears to be permanent, the course of the disease can be altered through measures such as smoking cessation, pulmonary rehabilitation, and use of pharmacotherapy [3–6].

Primary care physicians, who are thought to provide care for the majority of patients with early or mild COPD, are crucial in efforts to prevent COPD and to diagnose it early [3]. Diagnosis of COPD is complicated by the fact that, during its initial, often prolonged stage, COPD symptoms can be confused with aging, de-conditioning, or symptoms of other chronic conditions and therefore not recognized as a respiratory issue by patients or their health care professionals. [3] Diagnosis of COPD is based on objective evidence of airflow limitation, usually defined as a prebronchodilator forced expiratory volume in one second/forced vital capacity ratio ( $FEV_1/FVC$ )  $< 0.70$  associated with risk factors such as smoking and/or symptoms of chronic sputum production, wheezing, and dyspnea. [2]. If detection of COPD is to be improved in primary care, screening tools for detection of early symptomatic COPD prior to the onset of disabling symptoms are needed.

Until then, a screening tool for detection of people appropriate for spirometry evaluation should be brief, self-completed, and easy to administer and score and must have high sensitivity and reasonable specificity for spirometry-confirmed airflow obstruction. The present study was being designed as a patient-completed screening tool that can be used efficiently in primary care settings to detect those appropriate for spirometry testing for airflow obstruction.

## MATERIALS AND METHODS

The study sample was taken from department of chest diseases, Bhaskar medical college. The study was conducted from 2009 to 2010. The study involved 200 patients came for medical examination that included a physical examination, completion of several questionnaires or interviews, and tests and procedures including spirometry. To be included in the current study, respondents had to be at least 40 years old.

Patients with airflow obstruction, defined as prebronchodilator  $FEV_1/FVC < 0.70$ , were compared with patients without airflow obstruction with respect to age; gender; smoking history; and presence of phlegm, dyspnea, wheeze, and cough. The groups were compared using the chi-square test for categorical variables and the *t*-test for continuous variables.

## RESULTS

The first phase of the study involved evaluating eight candidate items for potential inclusion. Stepwise selection procedures were conducted for eight base models based on varying cutoffs for the candidate items (Table 1). In each base model, the dependent variable was the presence of airflow obstruction; and the independent variables were age, body mass index, cough, phlegm,

dyspnea, wheeze, and smoke (Table 1 ). Cough, phlegm, dyspnea and wheeze were coded as binary variables (1 = yes; 0 = no). Smoke was coded as 1 if the respondent indicated smoking for at least 20 years; otherwise a value of zero was used. For each of the remaining two independent variables, two different cut points were used (Table 1). The base models were evaluated for classification accuracy in terms of sensitivity, specificity, and area under the receiver operating characteristic (ROC) curve (using probability cutoff of 0.500).

**Table 1: Base models explored as stepwise regressions and candidate items included in analysis**

S.No	Predictors of obstruction
1	Age (50+years), BMI (<18 kg/m <sup>2</sup> ), cough, phlegm, dyspnea, wheeze, smoke (≥20 years)
2	Age (60+years), BMI (<18 kg/m <sup>2</sup> ), cough, phlegm, dyspnea, wheeze, smoke (≥20 years)
3	Age (50+years), BMI (<25 kg/m <sup>2</sup> ), cough, phlegm, dyspnea, wheeze, smoke (≥20 years)
4	Age (60+years), BMI (<25 kg/m <sup>2</sup> ), cough, phlegm, dyspnea, wheeze, smoke (≥20 years)
5	Age (50+years), BMI (<18 kg/m <sup>2</sup> ), cough, phlegm, dyspnea, wheeze, smoke (≥20 years)
6	Age (60+years), BMI (<18 kg/m <sup>2</sup> ), cough, phlegm, dyspnea, wheeze, smoke (≥20 years)
7	Age (50+years), BMI (<25 kg/m <sup>2</sup> ), cough, phlegm, dyspnea, wheeze, smoke (≥20 years)
8	Age (60+years), BMI (<25 kg/m <sup>2</sup> ), cough, phlegm, dyspnea, wheeze, smoke (≥20 years)

Next, stepwise logistic regression procedures with the classification of accuracy of eight reduced models obtained from the stepwise procedure was comparison of the base models in terms of sensitivity, specificity, and area under the ROC curve (probability cutoff, 0.500). AUC values ≥ 0.7 were considered to reflect acceptable accuracy for detecting airflow obstruction.

### Sensitivity analysis

As a sensitivity analysis we re-defined the dependent variable to reflect GOLD stage II disease ie, FEV<sub>1</sub>/FVC fixed ratio < 0.7 and FEV<sub>1</sub>< 80% predicted (prebronchodilator) for those aged 65 and older. Subjects aged less than 65 years were classified as obstructed if FEV<sub>1</sub>/FVC < 0.7. Logistic regression models were used to identify items from the questionnaire most predictive of obstruction; screening accuracy was also tested using ROC curve analyses. Additionally, a general population comprising individuals aged 40 years and older were selected. The highest AUC was considered as accurate predictor of airflow obstruction.

**Table 2: Demographics and clinical characteristics**

Parameters	All Patients	Prebronchodilator FEV <sub>1</sub> / FVC		P-value
		≥0.70	<0.70	
N (%)	200 (100.0)	98 (49.0)	102 (51.0)	
Age (mean years)	61.4	56.5	66.0	<0.0001
Male (%)	46.8	38.3	55.0	<0.0008
Smoked for 20 years or more (%)	64.6	56.1	72.7	<0.0005
Pack-years (mean)	35.6	26.4	44.4	<0.0001
Phlegm	30.0	22.1	37.5	<0.0011
Dyspnea (%)	65.6	52.4	78.3	<0.0001
Wheeze (%)	49.9	42.4	57.1	<0.0037
Cough (%)	32.0	26.0	37.5	<0.0214
FEV <sub>1</sub> /FVC (mean)	67.1	78.0	55.9	<0.0001

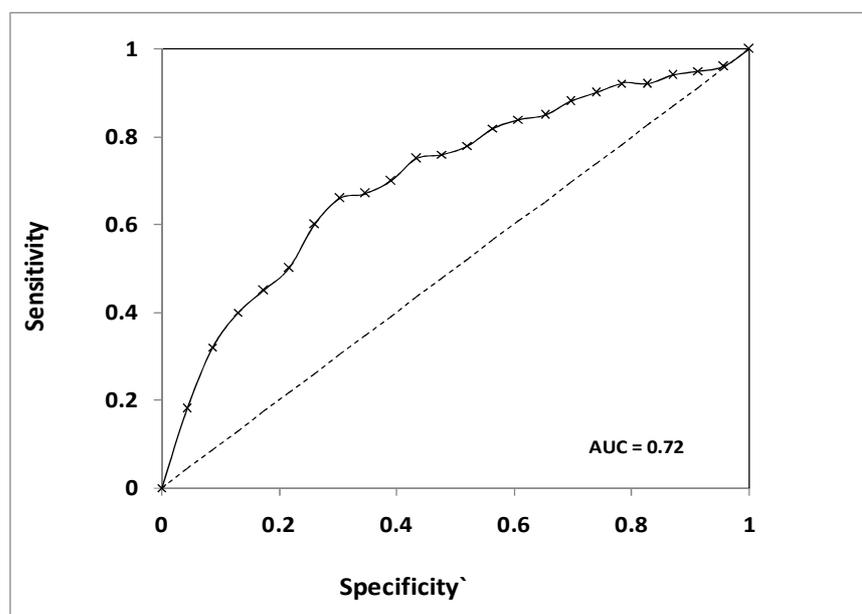
*P values were calculated using chi-square tests for categorical variables and t-tests for continuous variables.*

In stepwise selection procedures on the eight base models, AUC values ranged from 0.775 to 0.811 across models. Ranges for sensitivity and specificity were 57.6% to 64.8% and 68.4% to 83.9%, respectively. The following variables were statistically significant ( $<0.05$ ) across models: age, dyspnea, wheeze, and smoke. Although body mass index (BMI) (specifically, BMI  $< 25$ ) was also statistically significant in stepwise analyses, it was only weakly related to prebronchodilator FEV<sub>1</sub>/FVC in linear regression analyses. (Table 3) shows the odds ratios for presence of airflow obstruction from multivariate logistic regression of the reduced subset of five potential items.

The model with all five items (variables) had the highest AUC (0.72) with sensitivity and

**Table 3: Results of multivariate logistic regression of the specificity of 73.1% and 58.1%, respectively five lung Function questionnaire items**

Odds ratio estimates		
Items	Point estimate	95% CI
<b>Age</b>		
Less than 50 years	Reference	
50 years and older	3.32	1.86-5.91
<b>Wheeze</b>		
No		
Yes	1.62	0.91-2.57
<b>Dyspnea</b>		
No		
Yes	1.98	1.22-3.27
<b>Phlegm</b>		
No		
Yes	1.55	0.95-2.55
<b>Smoked for 20 years</b>		
No		
Yes	1.81	1.13-2.88



**Figure -1. Receiver operating characteristics for the five lung function questionnaire items**

**Abbreviation:** CI: confidence interval

Figure-1 Shows the ROC curve for the best model (ie, that with five items). The ROC curve describes the accuracy of a test regardless of the decision threshold. Each point in the ROC plot represents the combination of sensitivity and specificity values generated by a different decision threshold.

## DISCUSSION

Previously regarded as an inexorably progressive disease that is refractory to treatment, COPD is now understood to be treatable through measures such as smoking cessation, pulmonary rehabilitation, and use of pharmacotherapy [3-6]. Early identification of COPD is crucial to treatment efforts. Because spirometry is not practical as a screening tool in many healthcare settings [7] alternatives to spirometry are needed to screen patients for COPD. In this study, a set of items that accurately identifies patients with spirometry-based airflow obstruction, the primary manifestation of COPD, was identified. Items related to age; occurrence of wheezing, phlegm, and dyspnea; and smoking history were identified for inclusion in the study based on the statistical analysis, expert advice regarding the clinical relevance of the candidate items, and ease of administration of items. The balance of sensitivity (73.1%) and specificity (58.1%) was good as a relatively greater focus on sensitivity is desirable in noninvasive screening tools. That there is lack of higher specificity does suggest some practical implications for the LFQ in this current form. The high-risk population comprised middle-aged current smokers, [8] a finding that highlights the importance in the studies.

The sample for the study involved individuals at least 40 years old with a self-reported diagnosis [9]. The representativeness of the sample suggests that the findings of the current study are widely generalizable. Individuals aged 40 years or older were chosen for study because they are the target population for COPD screening; COPD is rare in those younger than 40 years. This study included patients reporting chronic bronchitis to ensure item selection in an “at-risk” sample. Selecting an initial pool of items from a general population may not have illustrated characteristics that one that was more “at risk” for COPD would. Lung capacity is known to diminish with age. [10]

The current research extends previous findings establishing the feasibility of using screening questionnaires to identify those at risk of airflow obstruction or COPD.[11,12–18] Several other screening tools for COPD have been explored.[11, 12–21] Question and response options showed to maximize their relevance to patients and to the disease of interest. The majority of patients with early, undiagnosed COPD (the targets of this questionnaire) are passed off as having smoker’s cough or chronic bronchitis, the initial pool of questions was developed using this population. This sample was felt to provide more disease-specific inputs for further testing. While COPD is underdiagnosed in primary care, it is also likely incorrectly diagnosed without the use of spirometry in many practices. Therefore, this group is appropriate to include in the question selection. The entire process of item selection was also repeated using a general population aged 40 years and older to examine any changes in item selection as a sensitivity analysis. This analysis did not change the pool of items selected.

The LFQ is being developed to help health care professionals screen for obstructive lung disease manifested by prebronchodilator  $FEV_1/FVC < 0.70$ , a likely marker for COPD. As a screening tool, the LFQ can help health care providers identify patients in need of further evaluation for possible COPD but is not intended as a diagnostic tool. Patients whose LFQ score suggests the

presence of airflow obstruction require clinical evaluation and spirometric assessment to assess for COPD.

### CONCLUSION:

In summary, the five-item LFQ can be used in the primary care setting as a patient-completed screening tool to identify patients with a high risk of airflow obstruction. The LFQ had adequate accuracy, sensitivity, and specificity in a sample in identifying individuals with COPD. The LFQ along with spirometry is a good candidate tool to facilitate earlier recognition of COPD.

### Acknowledgment:

The authors are very much thankful to the Chairman of JB group of Educational Institutions Sri. J.Bhaskar Rao for his constant help, support and encouragement to the academics generally and research particularly. The authors also thankful to the Principal of Bhaskar Medical College for his help and Department of Chest diseases for its involvement.

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