Validation of a Chronic Obstructive Pulmonary Disease screening questionnaire for population surveys

Hana Müllerová, Jadwiga Wedzicha, Joan B. Soriano, Jørgen Vestbo

Worldwide Epidemiology, GlaxoSmithKline Research and Development, Greenford, Middlesex UB6 OHE, UK
Academic Respiratory Medicine, St. Bartholomew’s and Royal London School of Medicine, London, UK
Health Promotion Research Unit, London School of Hygiene and Tropical Medicine, London, UK
Department of Respiratory Medicine, Hvidovre University Hospital, Copenhagen, Denmark

Received 20 February 2003; accepted 21 August 2003

Summary
The Confronting Chronic Obstructive Pulmonary Disease (COPD) Survey in North America and Europe conducted during 1999–2000 aimed to identify international differences in the clinical management of COPD and the patients’ perspectives on their disease. Our aim was to validate the screening questionnaire used in this study in a sample of patients presenting at a respiratory clinic.

Interviews were conducted at an outpatient clinic of the London Chest Hospital. Of the 136 patients contacted, 25 refused or were not able to participate. Questionnaire data were validated by comparison with medical records and spirometry on 104 patients.

Overall, the questionnaire correctly identified 86.5% of patients with a diagnosis of COPD with a chance-corrected agreement ($k = 0.66$, SE 0.098), which indicates good agreement between the questionnaire and the medical records. The questionnaire had a high sensitivity (92.0%) and specificity (72.4%) with respect to the diagnosis of COPD.

The screening questionnaire used in The Confronting COPD Survey appears to be a valid screening tool to differentiate COPD from other respiratory diseases.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is defined by the Global Initiative for Chronic Obstructive Lung Diseases as “a disease state characterised by airflow limitation that is not fully reversible. The airflow is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases”. High personal and society burden and mortality accompany COPD. Projections for 2020 indicate an increase in COPD mortality from the 6th position to the 3rd position, surpassed only by cardiovascular and cerebrovascular disorders.

An important contribution to the investigation of COPD is provided by epidemiological studies conducted in large population-based samples. In such samples working definitions of COPD must be implemented in order to discriminate with reasonable accuracy between individuals at risk of COPD and those who are not. These kind of screening tools can make descriptive epidemiology studies...
more efficient, by restricting the number of patients who require more detailed survey interviews.

Our validation study aimed to determine the potential diagnostic value of a screening questionnaire used in The Confronting COPD International Survey. The questionnaire presented here could potentially be used to screen COPD out from the general population by means of face-to-face, mail or telephone surveys. Because COPD prevalence rates in all ages vary from 0.5% to 2% by country, we tested this screening questionnaire in a respiratory clinic population with a high attendance of COPD patients. As the sensitivity and specificity of a diagnostic test are constant for the instrument, by applying this questionnaire in an enriched COPD sample with higher than usual prevalence of the condition, we could determine its sensitivity and specificity vs. the gold standard, in this case a respiratory physician diagnosis of COPD.

Methods

Study population

Data were obtained from the 104 outpatients who signed an informed consent and were older than 45 years, visiting for respiratory problems a specialised respiratory outpatient clinic at the London Chest Hospital during winter months’ 2001/2002. Patients were unselected attendants of a 1-day/week clinic. The study protocol was approved by the East London & City Health Authority and all study patients signed an informed consent in concordance with the Helsinki declaration. Each outpatient responded to a questionnaire administered by a single person. Demographic and diseasesspecific data were retrieved from medical records.

Questionnaire

The Personal Level Screener for COPD (see Appendix) is a five-item questionnaire used in the Confronting COPD Survey which aimed to identify international differences in the current clinical management of COPD, and the patients’ perspective on their disease.

The development of the Confronting COPD Survey questionnaires was based on pre-existing questionnaires, mainly on the International Union Against Tuberculosis and Lung Disease and the European Community Respiratory Health Survey questionnaires.

Validation procedure

The aim of the study was to determine the questionnaire validity as an instrument. Sensitivity, specificity, positive and negative predictive values and $\kappa$ coefficient of agreement were obtained.

The questionnaire case definition of COPD was: (1) age 45 years or older, (2) at least 10 pack-years of smoking, and (3) physician diagnosis of COPD, emphysema or chronic bronchitis or symptoms matching the definition of chronic bronchitis with or without breathlessness (at least 3 months of bronchitis or chronic coughing with phlegm/sputum from the chest in the past 12 months for the last 2 years and/or repeatedly short of breath over the past 12 months).

The medical records’ case definition of COPD was: (1) age 45 years or older, (2) diagnosis of COPD (emphysema, chronic bronchitis, COPD, chronic obstructive airways disease, chronic obstructive lung disease, or $\alpha$1 antitrypsin deficiency), (3) ratio of forced expiratory volume in 1 s/forced vital capacity ($\text{FEV}_1/\text{FVC}$) < 70%, and (4) at least 10 pack-years of smoking (except in cases diagnosed with $\alpha$1 antitrypsin deficiency).

Smoking history was assessed using calculated pack-years ([number of cigarettes per day/20] × the length of smoking in years). The sex–age specific values of LFT were calculated according to the European Community for Coal&Steel guidelines.

Statistical methods

Sample size was calculated prior to the study. Based on the threshold level of sensitivity 70% and specificity 90%, the sample size of 100 patients was considered satisfactory to calculate $\kappa$ statistics of 0.6 (± 0.099), which indicates good agreement of an instrument.

The EPIINFO 6.1 software was used for the epidemiology-related calculations (sensitivity, specificity, and $\kappa$). The relationships between responders vs. non-responders and COPD vs. non-COPD patients were tested using the two-tailed student $t$-test ($\alpha$ = 5%). The relationship between LFT and age was measured using the Spearman correlation coefficient.

Results

Of 136 patients contacted, 25 refused or were not able to participate. In addition, seven patients were excluded from the final analyses because of
missing LFT data. Questionnaire data were compared with medical records and spirometry based on 104 patients.

The reasons for refusal can be split into two main categories: time restrictions because of transport, other investigations (n = 14); and communication barrier (physical/emotional distress, language barrier, unwillingness to sign a consent form) (n = 11). The gender ratio, diagnosis and spirometry values were comparable between patients who refused to participate and the final sample (see Table 1). The average age was significantly higher in those who refused to participate compared to study participants (mean = 70.3 vs. 65.5 years; P < 0.05).

The average age of the final analysed sample (n = 104) was 65.5 years (SD 10.3), and the male to female ratio was 49:51%. In the Table 2, the distribution of demographic variables, main spirometry and smoking history characteristics are presented. There were 75 COPD cases and 29 non-COPD patients in the final sample. Non-COPD diagnosis included asthma (n = 8), bronchiectasis (n = 8), asbestosis, fibrotic alveolitis, obstructive sleep apnoe, pulmonary fibrosis, pulmonary hypertension and sarcoidosis (all <3 patients each). Age and gender distributions were comparable. In all patients with a diagnosis of COPD at the Chest Clinic, the diagnosis was confirmed by spirometry values. The forced expiratory ratio was substantially lower (P < 0.001) in COPD cases (49.6% ± 14.8%) than non-COPD cases (71.8% ± 11.9%). In the group of COPD patients, the ratio of absolute to predicted values of FEV1 (49.6% ± 14.8%) and FEV1/FVC (65.6% ± 37.7%) point out the significant reduction in the lung functions. There were no statistically significant relationships between age and LFT variables among COPD or the other patients.

Almost 50% of non-COPD participants declared themselves as non-smokers in contrast to only 5% of COPD cases. The difference in smoking history between the COPD and non-COPD cases is reflected in the value of pack-years, which represented 36 pack-years in COPD cases vs. five pack-years in non-COPD cases.

The measure of association between the questionnaire- and medical records-based diagnosis is presented in Table 3. Overall, the questionnaire correctly identified 88.5% patients with a diagnosis of COPD, chance-corrected agreement κ was 0.66 (SE 0.098). Sensitivity, the chance for a COPD patient to be correctly recognised by the questionnaire, equaled to 92.0%. Specificity, the chance for a non-COPD patient to be correctly recognised as non-COPD case by the questionnaire, was 79.4%. The positive and negative predictive values, proportion of people with a positive test who have the target disorder and proportion of people with a negative test who do not have the target disorder, was 92.0% and 79.3%, respectively.

Six COPD patients were not recognised by the questionnaire, and hence, screened out (false negative). In all cases, they were correctly sorted by the disease-specific questions B and/or C (see Appendix for the questionnaire), but they failed to report a smoking history of more than 10 pack-years. The significant differences, from the population of COPD cases correctly detected, include gender ratio

### Table 1 Comparison of respondents and non-respondents—demographic and disease-related variables (one patient might be diagnosed with more than one disease).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Non-respondents</th>
<th>Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>25</td>
<td>104</td>
</tr>
<tr>
<td>Age (mean, se) †</td>
<td>70.3 ± 9.7</td>
<td>65.5 ± 10.3</td>
</tr>
<tr>
<td>Gender (F/M)</td>
<td>12/13</td>
<td>53/51</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPD (%)</td>
<td>64.7</td>
<td>71.1</td>
</tr>
<tr>
<td>Asthma (%)</td>
<td>5.9</td>
<td>8.6</td>
</tr>
<tr>
<td>Other (%)</td>
<td>29.4</td>
<td>36.5</td>
</tr>
<tr>
<td>FEV1 (mean, se) (ml)</td>
<td>1025.0 ± 462.8</td>
<td>1228.4 ± 780.5</td>
</tr>
<tr>
<td>FEV1, % of predicted value (mean, se)</td>
<td>52.5 ± 23.9</td>
<td>51.5 ± 21.2</td>
</tr>
<tr>
<td>FEV1/FVC (mean, se)</td>
<td>58.7% ± 17.9%</td>
<td>55.8% ± 17.2%</td>
</tr>
<tr>
<td>FEV1/FVC, % of predicted value (mean, se)</td>
<td>75.2 ± 18.3</td>
<td>73.1 ± 22.0</td>
</tr>
</tbody>
</table>

FEV1 = forced expiratory volume in 1 s.
FEV1/FVC = forced expiratory ratio (forced expiratory volume in 1 s/forced vital capacity).
*Age, diagnosis and lung functions analyses based on available data from the population (n = 23 for age, 20 for diagnosis, 19 for FEI).
†P < 0.05.
(more females among screened out) and FER value higher in screened outpatients). Those recognised by the screening questionnaire but not by medical records (false positive; \( n = 6 \)) did not differ significantly from non-COPD patients. Of the eight asthma patients in the sample, only one was misdiagnosed by the questionnaire as a COPD patient.

### Discussion

This study shows high specificity and sensitivity of the validated questionnaire and the \( \kappa \) coefficient value of 0.66 indicates good agreement between the Confronting COPD Survey screening questionnaire and medical records data.

This study does not describe the sensitivity and specificity of the Personal Level Screening questionnaire in an unselected population. Instead, we aimed to see if the Screener was able to distinguish patients with COPD from patients with other respiratory disorders. This is probably the most important issue regarding the use of the instrument, as few subjects without recognised respiratory disease are likely to be diagnosed with COPD—especially given the well-known level of under-diagnosis of the disease.4

Even though COPD represents a common respiratory disorder, few standardised instruments have been developed for screening of this disease. Most instruments deal with respiratory symptoms and health status assessment, or quality of life (St. George’s Respiratory Questionnaire and the Chronic Respiratory Disease Questionnaire).11,12 A search for diagnostic screening scales revealed several questionnaires related to specific respiratory disorders.13–15 None of these questionnaires specifically targeted COPD with the aim to screen with high-sensitivity potential COPD cases which can be assessed later in detail.

The screening criteria as proposed here, are easy to use, specifically constructed for COPD with low demand on time and associated cost. The Personal level Screener takes under 5 min per individual to be completed and might be useful to estimate COPD prevalence in population-based settings. Very high sensitivity (92.0%) and specificity (79.3%) and
resulting $\kappa$ of 0.66 indicate high probability that a COPD is identified by the validated questionnaire.

The relatively high refusal rate (25%) to participate can be explained by busy environment of the specialised clinics, where the majority of patients were referred from relatively distant areas. Time restrictions represented the main reason for the refusal. The second main reason for refusal, physical and/or emotional distress, can be explained by the clinical picture of COPD as a severe, quality-of-life reducing disorder.

Patients incorrectly classified by the questionnaire (false positives, false negatives) represented 11.5% of those interviewed. In the case of false negatives (patients with COPD not recognised by a questionnaire), the failure to report adequate smoking history was the exclusive cause of misdiagnosis. The false positives (recognised as COPD patients by the screener but not by medical records) represented a mixed group of patients with restrictive respiratory disorders with long-term history of smoking and the symptom of breathlessness.

In conclusion, the screening properties of the Confronting COPD Survey Personal-level questionnaire confirmed its applicability as a screening tool for surveys in database patient samples and clinical practice.

Acknowledgements

The authors would like to thank the team of the London Chest Hospital Outpatient Respiratory Clinic for assistance with the survey fieldwork.

Appendix A. Personal level screener for COPD

A. Are you over 45 years old?

YES (continue)

NOT (stop)

Could you take a couple of minutes to read carefully this patient information leaflet and then sign this approval form?

Could we begin now?

YES............1 (continue)

NO .............2 (stop)

B. Have you ever been diagnosed by a physician as having………

DIAGNOSED

NO YES

1. Emphysema 1 2

2. Chronic bronchitis 1 2

3. Chronic Obstructive Pulmonary Disease (COPD), Chronic obstructive airways disease (COAD), or Chronic obstructive lung disease (COLD) 1 2

4. Alpha one antitrypsin deficiency 1 2

5. Asthma 1 2

C1. How many MONTHS in the past 12 months have you had bronchitis or chronic coughing with phlegm/sputum from the chest?

_______ NUMBER OF MONTHS PER YEAR IF LESS THAN THREE SKIP TO C3

C2. For how many years have you had bronchitis or chronic coughing with phlegm/sputum from the chest for at least three months?

_______ YEARS WITH REPEATED BRONCHITIS IF LESS THAN TWO SKIP TO C3

If three months or more in C1 and 2 years or more in C2, eligible as chronic bronchitis, skip to D.

C3. Have you been repeatedly short of breath over the past 12 months?

YES............1 ELIGIBLE FOR BREATHLESSNESS

NO............2 SCREEN OUT
D. Have you ever smoked cigarettes on a daily basis?

YES............1

NO ............2 SCREEN OUT UNLESS DIAGNOSED as ALPHA ONE ANTITRYPSIN DEFICIENCY IN B4

E. For how many years, in total, have you smoked cigarettes on a daily basis?

_________ YEARS smoking

F. How many cigarettes do you/did you smoke per day, on average? _______________

[calculate # of pack years = (F/20) * E]

IF FEWER THAN 10 THEN SCREEN OUT UNLESS DIAGNOSED as ALPHA ONE ANTITRYPSIN DEFICIENCY IN B4

References


