Comparison of a network of primary care physicians and an open spirometry programme for COPD diagnosis

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KEYWORDS
Case-finding; Cost-effectiveness; COPD; Primary care; Screening; Spirometry

Summary
Background: Early diagnosis of Chronic Obstructive Pulmonary Disease (COPD) remains the cornerstone for effective management. In this study we compared an open spirometry programme and a case-finding programme providing spirometry to high-risk subjects selected by primary care physicians.
Methods: A network of primary care physicians was created after invitation and all participants received training on COPD and spirometry. The study team visited 12 primary care settings in each programme in a 1-year period. Spirometry was performed in all eligible participants. COPD diagnosis and classification was based on GOLD guidelines and evaluation by a chest physician.
Results: Patients with acceptable spirometry were evaluated (n = 201 in the case-finding and n = 905 in the open spirometry programme). The proportion of newly diagnosed COPD was 27.9% in the case-finding programme compared to 8.4% in the open spirometry programme (p < 0.0001). The number needed-to-screen (NNS) for a new diagnosis of COPD was 3.6 in the case-finding programme compared to 11.9 in the open spirometry programme. The majority of newly diagnosed patients were classified in GOLD stages I and II. The average cost for a new diagnosis of COPD was 173€ in the open spirometry programme and 102€ in the case-finding programme.

Abbreviations: COPD, Chronic Obstructive Pulmonary Disease; PYS, Pack-Years; FEV₁, Forced Expiratory Volume in the 1st second; FVC, Forced Vital Capacity; GOLD, Global Initiative for chronic Obstructive Lung Disease; NNS, Number Needed-to-Screen; OR, Odds Ratio; CI, Confidence Interval; BMI, Body Mass Index.

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Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a common cause of morbidity and mortality, representing a significant burden for the health systems worldwide. COPD is characterized by airflow limitation that is not fully reversible and spirometry is essential for the definite diagnosis of this disorder. There is accumulating evidence that early intervention, including medication and smoking cessation, may alter the natural course of the disease, as expressed by the decline in lung function. Additionally, the identification of airflow limitation in spirometry may increase the success rate of smoking cessation interventions. The above evidence suggests that the early diagnosis of COPD through spirometry may be beneficial in the clinical course of COPD patients.

Different approaches have been implemented in the identification of COPD patients, including screening and case-finding strategies. The common observation in all such studies is that COPD remains largely underdiagnosed, with the newly diagnosed COPD cases ranging from 55% to 91% in spirometry programmes. In a recent study in a similar population in Greece, we have shown that in a screening spirometry programme 69% of the COPD cases were newly diagnosed and the majority of the newly diagnosed cases had mild-to-moderate disease. Both in that study and in a previous case-finding study in primary care practices in Belgium, the newly diagnosed COPD patients were younger and less symptomatic than patients with previously established COPD, suggesting that more efficient programmes are mandatory for the early identification of COPD patients.

It has been previously shown that the implementation of spirometry by primary care physicians can identify new cases of COPD, both in screening and in case-finding studies. Yet, a significant proportion of general practitioners in the UK are not confident in establishing a diagnosis of COPD. The fact that only a small fraction of primary care physicians in most countries both purchase and regularly use office spirometers, has led experts to suggest that a better alternative would be to provide access to spirometry for high-risk subjects. However, such a strategy has not been directly compared to a conventional spirometry programme in a similar population, to the best of our knowledge.

The aim of the present study was to compare two different strategies for the diagnosis of COPD in primary care settings: An open spirometry programme after public invitation and a case-finding strategy providing spirometry to high-risk subjects selected by a network of properly trained primary care physicians. We tested the hypothesis that the strategy involving primary care physicians would be more effective than the open spirometry programme. A cost-effectiveness analysis of the two programmes was also performed.

Materials and methods

The study was conducted in 24 primary health care practices of the National Health System in Thessaly, Greece, during a 12 month period (November 2008 to October 2009). Spirometry was offered to eligible participants using two different strategies: (1) an open spirometry programme based on public invitation and (2) a case-finding programme where spirometry was offered to subjects selected by properly trained primary care physicians. In both strategies, all subjects were over 30 years of age, resided near a primary health care practice, and were willing to participate in a spirometry programme. Exclusion criteria were a history of respiratory tract infection during the 4 weeks prior to inclusion and inability to perform spirometry. The study was approved by the Ethics Committee of the University Hospital of Larissa and all subjects provided written informed consent.

Open spirometry programme

During the first week of each month, study coordinators visited 12 primary care practices for two consecutive days. Public invitation with local advertisement offering free of charge spirometry to all subjects with chronic respiratory symptoms (e.g. cough, sputum production, wheezing or dyspnea), preceded the spirometry programme in each practice. A team of the study coordinators (including two young physicians properly trained in spirometry, a study nurse and an experienced chest physician) completed a structured questionnaire for every participant, and then spirometry was performed in all eligible subjects.

Case-finding programme involving primary care physicians

A network of primary care physicians was organized by the Respiratory Medicine Department of the University of Thessaly. All primary care physicians of the network attended two 2-h sessions of training on the diagnosis and management of COPD. During these sessions, the study coordinators additionally explained in detail the aims of the study and the study questionnaires, and provided basic information on the eligibility for spirometry and the interpretation of the results. All primary care physicians were then asked to identify patients with a probable diagnosis of COPD in their daily practice and to complete a validated screening questionnaire for COPD. During the first week of each month, a team of the study coordinators (including a young physician properly trained in spirometry, a study nurse and an experienced chest physician), visited 12 primary care practices after prior arrangement with the corresponding primary care physician.
subjects invited by the primary care physicians were then evaluated by the study team, who completed a structured questionnaire for every participant, and then spirometry was performed in all eligible subjects. In all patients with a COPD diagnosis, treatment options were discussed both with the patients and with their attending physicians.

**Study questionnaires and details**

The study questionnaire included questions about smoking habits, occupational exposure, history of common respiratory infections, and chronic respiratory symptoms (i.e. cough, sputum production, wheezing and dyspnea). A validated screening questionnaire was additionally completed by the primary care physicians involved in the case-finding programme. Subjects with a history of >100 cigarettes during lifetime were considered as smokers, whereas ex-smokers were smokers who had quit smoking for at least 12 months. Smoking status was measured in pack-years (PYS).

**Spirometry**

Spirometry was performed with a dry spirometer (KoKo Legend, Ferraris, UK), according to the American Thoracic Society recommendations. The spirometric reference values used were those proposed by the ERS statement. Calibration checks were performed every morning, before the beginning of the spirometry programme. Spirometry testing was performed by physicians who had undergone a special training programme by two chest physicians. Forced expiratory manoeuvres were repeated until the three reproducible acceptable tests were obtained and the best Forced Expiratory Volume in the 1st second (FEV1), Forced Vital Capacity (FVC), and FEV1 to FVC ratio (FEV1/FVC) values were recorded. A bronchodilator reversibility test with 400 μg of salbutamol was performed in all patients with obstructive spirometry, as defined by an FEV1/FVC ratio <0.70. An increase in FEV1 >12% and >200 mL from baseline was considered significant.

**Diagnosis of COPD**

Three experienced chest physicians who were present throughout the study (K K, C.H. and G.B.) evaluated the quality of all spirometries and classified patients with COPD. The diagnosis of COPD was based on a history of exposure to noxious particles or gases, particularly smoking, compatible symptoms and a post-bronchodilator FEV1/FVC ratio <0.70. Classification of COPD was based on post-bronchodilator FEV1 (%) predicted, according to the Global initiative for chronic obstructive lung disease (GOLD) guidelines (Stage I — mild COPD FEV1 ≥80.0; Stage II — moderate COPD 50.0% ≤FEV1 <80.0%; Stage III — severe COPD 30.0% ≤FEV1 <50.0%; Stage IV — very severe COPD FEV1 <30.0% or FEV1 <50.0% with respiratory failure). The cost of the spirometries and the cost of the training sessions for the case-finding programme involving primary care physicians. The salary estimations were based on current compensations in the National Health System of Greece (December 2008).

**Statistical analysis**

Demographic data are presented as mean ± standard deviation (SD). Differences in numerical variables were evaluated with unpaired t-tests or Mann–Whitney U-tests for normally and skewed data, respectively, whereas comparisons of proportions were performed using Fischer’s exact tests. Results from contingency tables regarding COPD diagnosis were reported as odds ratios (OR) with 95% Confidence Intervals (CI). Numbers needed-to-screen (NNS) were calculated as the reciprocal values of prevalence. Univariate logistic regression analysis was used for the evaluation of characteristics of the subjects with a new diagnosis of COPD in the two programmes, with COPD diagnosis as the dependent variable, and sex, age, Body Mass Index (BMI), occupational exposure, often respiratory infections, smoking habit (current, ex or never smokers), cough, sputum production, wheezing and dyspnea as independent variables and results were reported as odds ratios (OR) with 95% confidence intervals (CI). p-values <0.05 were considered statistically significant. Data were analyzed using SPSS 16.0 for Windows (SPSS Co, Chicago, IL, USA) and GraphPad Prism 5 (GraphPad Software Inc, La Jolla, CA, USA).

**Results**

The flow chart of the participants in the two programmes is presented in Fig. 1. A significantly higher exclusion rate was observed in the open spirometry programme (difference 8.3%, 95% CI 3.1%–13.5%; p = 0.001). The demographics of the study participants are presented in Table 1. The subjects included in the case-finding programme were more often male and current smokers and presented more often wheezing, sputum production and dyspnea, compared with the population that attended the open spirometry programme.

**Diagnosis of COPD in the two programmes**

The proportion of COPD patients in the case-finding programme was 36.3% compared to 10.8% in the open spirometry programme (OR 4.69, 95% CI 3.29–6.70). When patients with a previous diagnosis of COPD in their records were excluded, the proportion of new cases of COPD in the case-finding programme was 27.9% compared to 8.4% in the open spirometry programme (OR 4.21, 95% CI 2.86–6.21). However, the proportion of new cases of COPD among COPD patients did not differ between the two programmes (76.7% vs. 77.6% for the case-finding and the open spirometry programme respectively; OR 0.95, 95% CI 0.46–1.96).

The NNS for a single diagnosis of COPD was 2.7 patients in the case-finding programme compared to 9.2 spirometries in the open spirometry programme. Additionally, the NNS for a new diagnosis of COPD was 3.6 in the case-finding
programme compared to 11.9 in the open spirometry programme. The distribution of COPD patients, in total and for new cases, in the two programmes according to GOLD stages, gender and age groups is presented in Table 2. The majority of the patients diagnosed with COPD were classified into GOLD Stages I and II (81.6% and 83.6% for the open spirometry and the case-finding programme, respectively; Fig. 2). Similarly, the majority of the new cases of COPD patients were classified to GOLD Stages I and II (86.8% and 89.3% for the open spirometry and the case-finding programme, respectively; Fig. 2). However, no significant differences were observed between the two programmes. Additionally, the proportion of new cases of COPD patients was higher in all age groups in the case-finding programme compared to the open spirometry programme ($p < 0.05$ for all comparisons), with a trend for increase with age in both programmes (Fig. 3).

Characteristics of newly diagnosed COPD patients in the two strategies

The results of univariate logistic regression analysis for the evaluation of characteristics related to a new diagnosis of COPD in the two programmes are presented in Table 3. In the open spirometry programme, a new diagnosis of COPD

![Flow chart of the participants and the patients diagnosed with COPD in the two programmes of the study.](attachment:image.png)

Table 1  Demographic characteristics of the study participants.

<table>
<thead>
<tr>
<th></th>
<th>Open spirometry programme</th>
<th>Case-finding programme</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>905</td>
<td>201</td>
<td>0.34</td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.5 ± 13.5</td>
<td>63.5 ± 13.1</td>
<td>0.0001</td>
</tr>
<tr>
<td>Female gender (%)</td>
<td>326 (36.0%)</td>
<td>33 (16.4%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28.5 ± 8.9</td>
<td>27.9 ± 5.1</td>
<td>0.36</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smokers</td>
<td>328 (36.2%)</td>
<td>138 (68.6%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>PYS</td>
<td>45.1 ± 31.9</td>
<td>59.5 ± 45.9</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Non Smoker</td>
<td>332 (36.7%)</td>
<td>17 (8.5%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Ex Smoker</td>
<td>245 (27.1%)</td>
<td>46 (22.8%)</td>
<td>0.25</td>
</tr>
<tr>
<td>PYS</td>
<td>49.1 ± 39.4</td>
<td>49.6 ± 31.6</td>
<td>0.87</td>
</tr>
<tr>
<td>Symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>331 (36.6%)</td>
<td>96 (47.7%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Sputum</td>
<td>325 (35.9%)</td>
<td>97 (48.3%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Wheezing</td>
<td>296 (32.7%)</td>
<td>75 (37.1%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>334 (36.9%)</td>
<td>96 (47.7%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Any symptom</td>
<td>563 (62.2%)</td>
<td>144 (71.6%)</td>
<td>0.015</td>
</tr>
</tbody>
</table>

Categorical data are presented as $n$ with percentage in parenthesis, whereas numerical data are presented as mean ± SD.
was related to male gender, higher age, lower BMI, smoking habit and the presence of cough, sputum production and dyspnea. In the case-finding programme involving primary care physicians, a new diagnosis of COPD was related to higher age, smoking, and sputum production.

Comparison of the cost-effectiveness of the two strategies

The cost of the two programmes included the salaries of the study team (an average of 80€ for the physicians and 60€ for the nurses per day), the cost of two spirometers (approximately 1400€ each) and the cost of the spirometers (an average of 5€ for the consumables and the maintenance of spirometers), as well as the cost of the training sessions for the case-finding programme involving primary care physicians (including the salaries for two half-days for the study team and the primary care physicians). The average cost for a diagnosis of COPD was 134€ in the open spirometry programme and 78€ in the case-finding programme, whereas the average cost for a new diagnosis of COPD was 173€ in the open spirometry programme and 102€ in the case-finding programme.

Discussion

In this study we have shown that a case-finding strategy providing spirometry and specialist evaluation to high-risk subjects selected by a network of properly trained primary care physicians is a more cost-effective option for the identification of new cases of COPD, compared to an open spirometry programme after public invitation. The majority of COPD cases was classified in stages I and II, however with no significant difference between the two strategies. Factors associated with new diagnosis of COPD were identified in both programmes that may facilitate future case-finding studies involving primary care physicians. This is the first study to our knowledge that compares directly an open spirometry programme with a case-finding programme involving a network of primary care physicians in a semirural population.

Spirometry programmes have been implemented in various settings in primary care and have effectively identified new cases of COPD.8,13,14 However, recent guidelines from the American College of Physicians recommend against spirometry on asymptomatic individuals,22 and current evidence suggests that several asymptomatic subjects need to be submitted to spirometry to improve clinically significant end-points.23 In controversy, the
majority of COPD patients become symptomatic in advanced disease, thus the need for early intervention is imperative. The provision of spirometers to primary care physicians in order to identify new cases of COPD in their practice has been previously used. However, an observational study in Italy showed that primary care physicians practically discontinued using their spirometers after 9 months, despite proper training and compensation for each spirometry. Another approach from the UK used a nurse-led community respiratory assessment unit offering quality-controlled spirometry and diagnostic support for primary care physicians. However, such an approach is not feasible in all settings, especially when the communication between primary care and specialist physicians is not close. 

In the present study we have investigated an alternative approach, providing high quality spirometry along with specialist interpretation of patients to a network of primary care physicians that received a brief training in COPD by expert chest physicians. This approach has proven valid, since it increased by 4 times the chance of identifying new cases of COPD in the population that was evaluated. Moreover, less spirometries were performed and the exclusion rate was half of that of the open spirometry programme, and this may be attributed to the active participation of primary care physicians.

In a similar population we have previously shown that spirometry screening revealed a large proportion of undiagnosed COPD patients; however, the only differences between newly and previously diagnosed COPD patients was that the former were younger and less symptomatic, suggesting that they were difficult to be identified. In the present study we attempted to overcome this problem by inviting primary care physicians to identify possible candidates for a diagnosis of COPD from the patients they saw in their everyday practice. Interestingly, even in this strategy, one out of four subjects with COPD selected by primary care physicians had a previous diagnosis of COPD, in a similar manner with the open spirometry programme. A possible explanation for the referral of subjects with a previous diagnosis of COPD in their records may reflect the nihilistic views and the absence of confidence for the diagnosis of this disorder in a significant proportion of primary care physicians.

In another study from our group in a similar population it has been shown that the management of COPD patients by primary care physicians frequently does not comply with international guidelines. Therefore, in the present study, the chest physicians that evaluated COPD patients provided additional information about proper management in collaboration with the patients’ family doctors. Another factor that further supports the need for an active involvement of primary care physicians is that newly diagnosed COPD patients are less symptomatic which may reflect the fact that COPD patients often underestimate their symptoms. The results of the present study suggest that family doctors may overcome this characteristic by a more global evaluation of patients, especially when they are actively involved in COPD diagnosis.

The cost-effectiveness of spirometry programmes remains a subject of great debate. The reports of the cost per diagnosis range from 5 to 10€ for the identification of a smoker with airflow obstruction in a case-finding programme in the Netherlands to over 2000 per diagnosis of obstructive airway diseases in an opportunistic spirometry programme by visiting trained nurses in Australia. Profound differences among health care system costs and study design may account for such discrepancies. A consistent finding of our study was, however, the fact that, using the same resources in a similar population, the case-finding programme involving the network of primary care physicians resulted in a 40% lower cost per diagnosis of COPD, compared to the open spirometry programme. The modest cost of approximately 100€ per new diagnosis of COPD, the majority being classified in mild-to-moderate disease, has to be considered against the extreme costs of advanced disease. Another advantage of this programme that has to be estimated in the overall cost is the fact that beyond the diagnosis of COPD an experienced chest physician provided advice on the treatment of those patients, and this may further lead to more proper management of COPD in primary care settings. The results of this approach remain to be revealed in the follow-up of those patients in future evaluations.

Taken into account all the parameters discussed, we believe that the effectiveness of our case-finding programme involving primary care physicians has multiple aspects. Firstly, the primary care physicians received a special training, including the implementation of the GOLD guidelines, and this may have improved their skills in the management of their COPD patients. Secondly, this
programme has identified more effectively new cases of COPD and at a lower cost, compared to the open spirometry programme, and the majority of those patients were diagnosed at early stages of the disease. Finally, the identification of patients at early stages of COPD may be of great importance, since patients with stage II COPD may benefit more from smoking cessation interventions and early treatment initiation.3

A possible limitation of the present study is the selection biases related to the different design of the two strategies. Such biases may be related to the unwillingness of certain individuals for participation in an open spirometry programme and to the personal beliefs of primary care physicians regarding the diagnosis of COPD. We have tried to minimize these selection biases by the preceding local advertisement that provided detailed information about the open spirometry programme and by offering special training to the primary care physicians involved in the case-finding programme. We cannot overlook the possibility of "false negative" cases, representing subjects that were not investigated but with a COPD diagnosis if they had been examined. However, we believe that this may represent more of a problem in the open spirometry programme, compared to the strategy involving trained primary care physicians, and this might further support our findings. Another possible limitation is the fact that our cost-effectiveness analysis data may not be generally applicable, since they represent local conditions that apply to our settings. However, our study results clearly show that the relative cost of a new diagnosis of COPD in the case-finding programme involving primary care physicians was lower compared to the open spirometry programme. This is even more important since the same physicians and study nurses were involved in both programmes, using the same equipment and evaluating similar populations visiting primary care practices in the same area.

In conclusion, a case-finding programme involving primary care physicians was more effective for the identification of new cases of COPD as compared to the open spirometry programme. We cannot ignore the possibility of "false negatives", but with a COPD diagnosis if they had been examined.

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Conflicts of interest

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