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ORIGINAL RESEARCH

A combination of the IPAG questionnaire and PiKo-6® flow meter is a valuable screening tool for COPD in the primary care setting

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Abstract

Aims: To investigate the validity of the International Primary Care Airways Guidelines (IPAG) questionnaire and PiKo-6® (Ferraris Respiratory Europe Ltd.) flow meter as screening tools for diagnosing chronic obstructive pulmonary disease (COPD) in the primary care setting.

Methods: The first 50 patients in 25 general practice offices completed the IPAG questionnaire and underwent spirometry with the hand-held PiKo-6® flow meter. The results were compared with official spirometry parameters after bronchodilation. All participants had no previous medical diagnosis of respiratory diseases.

Results: Data from 1,078 out of 1,250 subjects (462 males, mean age 65.3±11.4 years) were analysed. The percentage of smokers was 48.4% (38±29 pack-years). COPD was diagnosed in 111 (10.3%) patients. In the subgroup of smokers the sensitivity and specificity for COPD diagnosis were 91% and 49%, respectively, for the IPAG questionnaire; 80% and 95% respectively for the PiKo-6® spirometer; and 72% and 97% for their combination. The negative predictive value of the questionnaire was 97%, whereas the positive predictive value of the questionnaire/ PiKo-6® combination was 82%. Using a cut-off score of 19 points for the IPAG questionnaire, we calculated the best combination of sensitivity (75%) and specificity (72%).

Conclusions: The IPAG questionnaire and the hand-held PiKo-6® spirometer can be used in combination to increase the possibility of an early and accurate diagnosis of COPD in the primary care setting.

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See linked editorial by Kotz and van Schayck on pg 113

The full version of this paper, with online Appendix is available at www.thepcrj.org

Introduction

Chronic obstructive pulmonary disease (COPD) is a major public health problem as it is one of the main causes of morbidity and mortality worldwide. According to current epidemiological data it is the fourth leading cause of death in the United States and Europe, and it is estimated that its prevalence and mortality will increase in the coming decades due to continued exposure to cigarette smoking and the changing age structure of the world's population.[1] The direct economic costs and indirect social burden of COPD are extremely high and increase as the disease progresses.[2,3]

The diagnosis of COPD is based on clinical features (age, smoking history, breathlessness, productive cough) and confirmed by spirometry.[1,4] Patients with COPD usually seek medical help when at least 50% of their lung function has been lost and their activity level is seriously reduced due to the insidiously progressive nature of the disease.[4] On the other hand, those with confirmed COPD underestimate the

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impact of the disease on everyday activities.[5]

In the USA the estimated number of people with reported physician-diagnosed COPD was approximately 10 million in 2000, while the estimated number of people with evidence of obstructive lung disease according to NHANES III (1988–1994) was 24 million.[6] An observational study in seven European countries showed that there were large variations in the use of different therapies (sometimes outside of guideline recommendations), even though study subgroups had comparable age ranges and degree of severity of COPD.[7] In a primary care study more than 50% of COPD patients (stages III–IV) were receiving incorrect treatment.[8]

There has been increasing interest during the last decade in the early diagnosis of COPD in the primary care setting as general practitioners (GPs) rather than pulmonary specialists make the initial diagnose and treat patients with respiratory symptoms.[9,10] The widespread application of spirometry by GPs[11,12] as well as by visiting trained nurses[13] may enhance the early diagnosis of COPD. On the other hand, in a multicentre randomised trial of the feasibility of performing spirometry in the GP surgery and the improvement in COPD/asthma diagnosis compared with conventional evaluation, only 104 out of 570 GPs agreed to participate in the spirometry group while the enrollment rate was remarkably low.[14]

The use of simple screening tools for patients at high risk of developing COPD may be more useful for GPs. The International Primary Care Airways Guidelines (IPAG) questionnaire consists of eight simple questions and has been validated in smokers (aged ≥40 years) as a screening tool for COPD diagnosis.[15] On the other hand, a recent study of subjects with no prior diagnosis of respiratory diseases found that 74 of 401 had positive results with a PiKo-6® flow meter (ratio of forced expiratory volume in 1 s (FEV_1) to forced expiratory volume in 6 s (FEV_6) <80%), and further investigations proved that 32 of them suffered from obstructive lung disease (18 with COPD and 14 with bronchial hyperresponsiveness or asthma).[16]

The aim of the present study was to investigate the validity of diagnosing COPD in the primary care setting using the IPAG questionnaire and PiKo-6® measurements after bronchodilation. We investigated the sensitivity and specificity of both methods as well as their combination in comparison with official spirometry performed and interpreted by pulmonologists (the 'gold' standard).

Methods

Twenty-five GPs in the counties of Pella and Kilkis in Northern Greece participated in the study. The first 50 patients aged >40 years who visited each GP during the period 1 March 2009 to 31 May 2009 were included in the study. Exclusion criteria were: (a) medically confirmed diagnosis of an obstructive lung disease (e.g. COPD, asthma, bronchiectasis) according to the insurance booklet of health; (b) medical history of any other pulmonary disease (e.g. tuberculosis, interstitial lung disease, lung cancer), thoracic surgery in the previous 6 months or acute respiratory infection; (c) uncontrolled cardiac disease (e.g. unstable angina, congestive heart failure, arterial hypertension, arrhythmia) because it could present as obstructive disease on spirometry or with symptoms such as dyspnoea or wheezing, suggestive of respiratory disease; and (d) those who could not perform an acceptable spirometry test.[17] The Medical Ethics Committee of the G. Papanicolaou Hospital, Thessaloniki, Greece approved the study protocol.

All participants, directed by the GP who had been trained, completed the IPAG questionnaire (see Appendix 1, available at www.thepcrj.org). Those with at least 17 points were considered as possible COPD patients.[18] Current and former smokers were defined as smokers and cigarette consumption in pack-years was calculated (pack-years= average number of cigarettes per day **x** years of smoking/20).

All participants also performed a forced expiratory manoeuvre with the PiKo-6® (Ferraris Respiratory Europe Ltd.) flow meter. All GPs in the study attended a 2-hr course on the correct use of PiKo-6® given by a pulmonary specialist. This simple hand-held spirometer measures FEV_1 and the FEV_1/FEV_6 ratio. All measurements were performed 15-30 min after inhalation of 400μg salbutamol via a metered dose inhaler. Patients with FEV_1/FEV_6 <0.7 after bronchodilation were defined as possible COPD patients.

After all the participants had been examined by the GPs, three pulmonary specialists visited all the general practices and performed spirometry (Vitalograph Ltd, Buckingham, UK) according to American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines[17] on the subjects. Predicted values of the ERS were used.[19] The spirometer had an accuracy of at least ±3% of reading or ±0.050L with flows between 0 and 14L/s. All manoeuvres fulfilled the acceptability (extrapolated volume <5% of FVC or 0.15L whichever was greater, duration of ≥6 s or a plateau in the volume–time curve) and reproducibility criteria (the two largest values of FVC and FEV_1 were within 0.150L of each other). Calibration was performed on the same day as the visit to the GP's surgery.

All measurements were performed before and 15-30 min after inhalation of 400mcg salbutamol via a metered dose inhaler. Patients with FEV_1/FVC <0.7 after bronchodilation were defined as COPD patients ('gold' standard). Patients with COPD were categorised according to Global initiative for Obstructive Lung Disease (GOLD) stages (FEV_1 % predicted after bronchodilation >80% for stage I, 50-80% for stage II, 30-50% for stage III and <30% for stage IV).

A sample size of approximately 1,250 individuals was

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enrolled in the study based on the following factors: an expected 10% prevalence of COPD; desired precision for the calculated result of ±2%; desired confidence level (·) of 0.05; patient participation, willingness and ability to comply with ATS/ERS criteria for spirometry rate (70%). We compared quantitative parameters between COPD and non-COPD subjects using the unpaired t-test and Mann-Whitney U test, whichever was more appropriate. Sensitivity, specificity, positive and negative predictive values were calculated for the IPAG questionnaire, PiKo-6® flow meter, and their combination – as performed by GPs – compared with spirometry performed and interpreted by pulmonary specialists.

Results

Of the 1,250 subjects examined (50 subjects x 25 GPs), 172 refused to participate in the second phase of the study (spirometry) or did not meet the ATS/ERS criteria for spirometry, so data on 1,078 subjects (57.1% males) were collected and analysed. The mean±SD age of the study population was 65.3±11.4 years and 48.8% were smokers (mean age 62.7±12.5 years, 77.9% males).

We diagnosed 111 (10.3%) patients with COPD according to official spirometry. None of them were diagnosed as having an obstructive pulmonary disease in the past. In the subgroup of smokers the prevalence of COPD was 17.2% (90/522). Based on the answers to the questionnaire given by the subgroup of COPD patients, 26 (23.4%) had no cough, 45 (40.5%) reported sputum production in the absence of a cold, and 71 (64%) had frequent or occasional wheezing.

Patients with COPD were older than those without COPD (71.1±8.7 years vs 64.6±11.5 years, p<0.001), with comparable body mass index (28.8±5 vs 29.3±4.6, p=0.228) and higher cigarette consumption. A comparison of the anthropometric data, smoking prevalence and spirometric parameters between the COPD and non-COPD groups is shown in Table 1; 82 of 90 smokers with COPD were males (91.1%) compared with only 12 of 21 (57.1%) non-smokers with COPD.

Forty (36%) patients were categorised as having mild COPD (GOLD stage I), 53 (48%) had moderate COPD (GOLD stage II), 16 (14%) had severe COPD (GOLD stage III) and two (2%) had very severe COPD (GOLD stage IV). Measurements of lung function by PiKo-6® for the subgroup of COPD patients were FEV_6: 2.82±0.88L; FEV_1: 1.82±0.64L; FEV_1/FVC_6: 0.64±0.07, which were comparable with official spirometry parameters.

A positive IPAG questionnaire for possible COPD (≥17 points) was obtained in 594 (55.1%) subjects. Of the 111 subjects who were found to have COPD, 101 had a positive questionnaire. Based on PiKo-6® measurements after bronchodilation, 139 (12.9%) subjects fulfilled the criteria for possible COPD and 89 were finally diagnosed as having COPD. Based on the combination of these two screening methods (both positive), 112 (10.4%) subjects presented with possible COPD of whom 80 proved to be true positive.

In Table 2 we present sensitivity, specificity, positive and negative predictive values for the IPAG questionnaire, PiKo-6® and their combination (both positive, either positive) in the whole study population and in the subgroup of smokers, in comparison with the 'gold' standard (official spirometry). For example, a smoker in the study had <1% possibility of having COPD if he had <17 points in the IPAG questionnaire or had a

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Table 1. Anthropometric data, smoking status and spirometric parameters of patients with (N=111) and without COPD (N=967).

	COPD group	Non-COPD group	p value
Age (years)	71.1±8.7	64.6±11.5	0.002
Males/Females	94 (84.7%)/17 (15.3%)	522 (54%)/445 (46%)	
Weight (kg)	82.2±15.2	78.9±13.9	0.06
Height (cm)	170±7.8	164±9	0.01
Body mass index	28.8±5	29.3±4.8	0.43
Smokers	90 (81.1%)	534 (55.2%)	<0.001
Pack-years	54.7±35.3	15.5±25.1	<0.001
FVC (L)	2.87±0.86	3.05±1	0.08
FEV_1 (L/s)	1.89±0.64	2.55±1.6	<0.005
FEV_1 % predicted	72±21.5	106.7±5.8	<0.001
FEV_1/FVC	0.65±0.06	0.96±3.36	<0.001

Values are presented as mean±SD. All spirometric data refer to values after bronchodilation.

FEV_1=forced expiratory volume in 1 s; FVC_6=forced vital capacity in 6 s.

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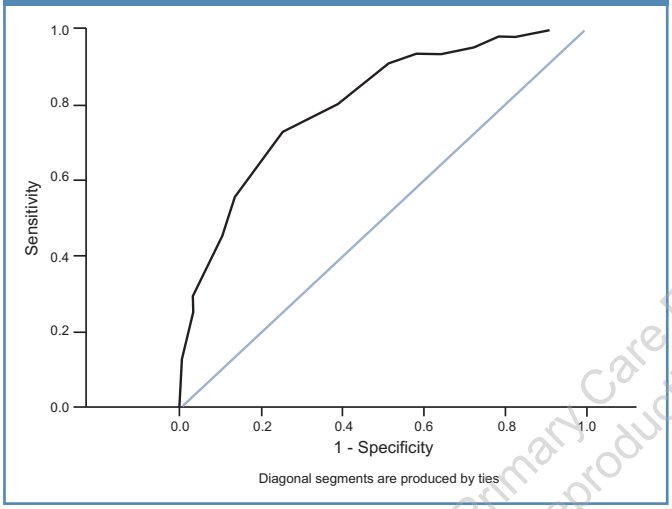
Table 2. Sensitivity, specificity, positive and negative predictive value of the IPAG questionnaire (≥17 points), PiKo-6® (post-bronchodilation FEV_1/FVC_6 <0.7) and their combination compared with official spirometry for COPD diagnosis.

	IPAG questionnaire		PiKo-6®		Combination (both positive)	
	Total (N=1,078)	Smokers (N=522)	Total	Smokers	Total	Smokers
Sensitivity	91%	93%	80%	80%	72%	74%
Specificity	49%	39%	95%	94%	97%	97%
Negative predictive value	98%	97%	98%	96%	97%	95%
Positive predictive value	17%	24%	64%	75%	71%	82%

Figure 1. ROC curve of IPAG questionnaire score for COPD diagnosis. A score of 19 represents the most distant point from the diagonal line.



normal PiKo-6® measurement. On the other hand, if both screening tests were positive in this patient, the possibility of COPD was 82% (Table 2).

Analysing the answers given to the first three questions (those related to the highest points, see Appendix 1), we found that, of the subjects with a positive questionnaire (≥17 points), 61.3% had 10 points for the first answer, 24.4% had seven points for the second answer, and 24.7% had five points for the third. We calculated the predictive power of the IPAG score using different cut-off points and found that, for scores of 18, 19 and 20, the sensitivity for a diagnosis of COPD was 78%, 75% and 72%, respectively, and the specificity was 65%, 72% and 77%, respectively. According to the ROC curve, the best combination of specificity and sensitivity corresponded to an IPAG questionnaire score of 19 (Figure 1).

Discussion

This study shows that the use of simple screening methods in the primary care setting for the early detection of COPD is quite reliable. Taking into account that the negative predictive value of the IPAG questionnaire for smokers was 97%, a patient with <17 points probably does not need to undergo spirometry. On the other hand, the probability of COPD was 82% if a smoker had positive results for both the IPAG questionnaire and PiKo-6®, so there was strong indication for official spirometry and consultation with a pulmonary specialist. These findings could not be generalised to patients with dyspnoea or a prior diagnosis of cardiac disease as we excluded this group of patients from the study. We also found that 10.3% of the study population (111/1,078) had COPD without a prior medical diagnosis.

The cost-effectiveness of the widespread use of spirometry in primary care for the early diagnosis of COPD remains a matter of debate.[8] To our knowledge, there are no large randomised studies on the effect of pharmacological treatment of asymptomatic COPD patients detected by screening programmes,[1] while the use of spirometry as a motivating tool in smoking cessation programmes only slightly improved success rates.[20] It is therefore proposed that spirometry in the primary care setting has a central role in the diagnosis of symptomatic patients (e.g. those with dyspnoea or cough), in the differential diagnosis from other diseases with similar clinical findings (e.g. asthma or congestive heart failure), and in the follow-up of patients with COPD.[21-23] In the Netherlands a GP will see an average of eight new cases of asthma and seven new cases of COPD annually, while managing 50 patients with diagnosed asthma and 60 with COPD.[9]

Underdiagnosis and misclassification of COPD as well as a low rate of implementation of treatment guidelines in primary care is a serious problem and could be attributed to the infrequent use of spirometry in everyday clinical practice. In a recent epidemiological survey of more than 1.5 million members of insurance organisations it was found that, among 5,039 patients with a new COPD diagnosis, only 32% had recently undergone spirometry.[24] Bednarek *et al*.[12] studied 1,960 patients aged ≥40 years and diagnosed COPD in 183 (9.3%), of whom only 18.6% had previously been diagnosed. The classification of COPD was as follows: 30.6% stage I, 51.4% stage II, 15.3% stage III and 2.7% stage IV, which is similar to the percentages in our study. In a multicentre Spanish study[25] among 4,035 subjects

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of the general population (age range 40–69 years), the prevalence of COPD was estimated to be 9.1%. We should emphasise that there was no previous diagnosis of COPD in 78.2% of cases while almost half of the patients with severe disease did not receive any kind of treatment.

Buffels *et al*.[11] studied 3,158 subjects aged 35–70 years in primary care who did not use bronchodilators and found that 7.4% of them had COPD while 18% were symptomatic; 39% of the COPD patients had mild disease and 51% had moderate disease (36% and 48%, respectively, in the present study).

Decreased availability, difficulty in applying the ATS/ERS criteria for technically acceptable manoeuvres, and incorrect interpretation of spirometry results are the main problems for GPs. Failures in general practice are predominantly end-of-test related (underestimation of FVC and overestimation of FEV_1/FVC ratio).[26] In a telephone-based study in the UK,[27] GPs were more confident about diagnosing COPD in 2005 than in 2001 (80% vs 52%). However, their self-reported confidence was not in accordance with the diagnoses, investigations and management strategies they proposed on case scenarios. A recent study in Australia[13] showed that visiting trained nurses performed spirometry in 59% of the eligible target population (76% technically correct), while in the optimised usual care model from GPs only 8% of the subjects underwent spirometry (44% technically correct). However, only 8% of the participants with airflow obstruction had an official diagnosis of COPD three months after spirometry in both models.

The use of specially designed questionnaires is the simplest screening method for increasing early COPD detection. The IPAG questionnaire was based on 52 questions; 818 smokers aged ≥40 years with no prior respiratory disease completed it and the investigators concluded that the sensitivity was 80.4% and the specificity 72% for the eight questions with the highest predictive ability.[15] In the present study the sensitivity and specificity of the questionnaire in the subgroup of smokers was estimated to be 93% and 39%, respectively. Our study population was older (62.7±12.5 vs 58.2±11.2 years) with higher cigarette consumption (38±29.8 vs 25.6±24.3 pack-years). It should be mentioned that, according to our study, a score of 19 points in the IPAG questionnaire discriminates patients better than a cut-off of 17 points.

The major advantage of FEV_6 is that this manoeuvre is easier and more reproducible than FVC. Several recent studies have shown that FVC_6 can be used as a good surrogate parameter for FVC.[28,29] Kaufmann *et al*.[16] studied the role of PiKo-6® as a simple screening tool in primary care, but they diagnosed COPD in only 18 of 74 patients (24.3%) with a positive PiKo-6® measurement (FEV_1/FVC_6 <80%). We defined FEV_1/FVC_6 <70% after bronchodilation as a positive result and diagnosed 89 cases of COPD out of 139 patients (64%) with a positive PiKo-6® measurement.

New questions arising from the study: Need for a randomised trial in primary care comparing conventional evaluation (history and clinical examination) for COPD diagnosis and treatment decisions with an approach using IPAG plus PiKo-6® and outcomes of the two groups after 1 year follow-up.

Lessons for clinical practice: The IPAG questionnaire (high negative predictive value) and the hand-held PiKo-6® spirometer (high positive predictive value) could be used jointly as simple and cost-effective screening tools for the diagnosis of COPD.

We conclude that underdiagnosis of COPD is an important problem in the primary care setting. The IPAG questionnaire (high negative predictive value) and the hand-held PiKo-6® spirometer (high positive predictive value) could be used jointly as simple and cost-effective screening tools to increase the possibility of early and accurate detection of COPD in primary care.

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Conflicts of interest

None.

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Appendix 1:

Question	Answers	Points
1. How old are you?	40-49 years	0
	50-59 years	4
	60-69 years	8
	≥70 years	10
2. How many cigarettes do you smoke daily (if you are an ex-smoker how many cigarettes used you to smoke daily)? How many years do/did you smoke?	0-14 pack-years	0
	15-24 pack-years	2
	25-49 pack-years	3
	≥50 pack-years	7
3. What is your weight? What is your height? BMI = weight/height^2	BMI <25.4	5
	BMI 25.4-29.7	1
	BMI >29.7	0
4. Is your cough affected by weather?	Yes	3
	No or no cough	0
5. Do you suffer from sputum production in the absence of a cold?	Yes	3
	No	0
6. Do you suffer from sputum production first thing in the morning?	Yes	0
	No	3
7. How often do you have wheezing?	Never	0
	Sometimes or often	4
8. Do you have or used you to have any allergies?	Yes	0
	No	3
Total score ≥17 suggests increased risk of COPD being present	Total score	

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