ORIGINAL ARTICLES

Spirometry Is a Good Method for Detecting and Monitoring Chronic Obstructive Pulmonary Disease in High-Risk Smokers in Primary Health Care

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OBJECTIVE: Chronic obstructive pulmonary disease (COPD) is a common disease, the early diagnosis of which allows effective management and treatment. The aim of the present study is to show the effectiveness of a screening and monitoring plan for COPD in high-risk patients in primary health care.

PATIENTS AND METHODS: The subjects in this prospective observational longitudinal study comprised 164 high-risk smokers aged between 40 and 76 years. Age, sex, weight, height, and smoking habit (pack-years) were recorded and spirometry was performed according to the guidelines of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR). Patients were informed of their results and given brief advice on how to stop smoking. After 3 years, the patients underwent the same evaluation.

RESULTS: In 1999, 22% of the smokers were diagnosed with COPD. Three years later, an additional 16.3% were diagnosed as having COPD, and the disease had worsened in 38.8% of those already diagnosed. Of the patients with a forced expiratory volume in one second (FEV_1) less than 90%, 44.8% developed COPD (relative risk: 10.54). An accelerated decrease in FEV_1 was found in 18.1% of the patients (20.7% with COPD and 9.0% without COPD).

Mean tobacco consumption in 1999 was 28.1 pack-years in subjects without COPD and 31.7 pack-years in those with COPD, whereas in 2002, consumption was 30.6 pack-years in patients with COPD and 31.9 pack-years in those without. In 3 years, 22.8% had stopped smoking (20.5% without COPD and 30.3% with COPD).

CONCLUSIONS: Many smokers managed to give up smoking after learning their spirometric results. FEV_1 can identify smokers at greatest risk of developing COPD. Spirometric screening and monitoring of smokers at high risk in primary health care can identify those most susceptible to developing COPD while the disease is in an early phase. Therefore the most appropriate strategy can be adopted for each patient.

Key words: *Susceptible smokers. Chronic obstructive pulmonary disease. High-risk group. Spirometry.*

La espirometría es un buen método para la detección y el seguimiento de la EPOC en fumadores de alto riesgo en atención primaria

OBJETIVO: La enfermedad pulmonar obstructiva crónica (EPOC) es una patología prevalente, cuyo diagnóstico temprano permite adoptar medidas de control y tratamiento. El objetivo del presente estudio es mostrar la efectividad de un plan de cribado y seguimiento de la EPOC en pacientes de alto riesgo desde atención primaria.

PACIENTES Y MÉTODOS: Se trata de un estudio observacional longitudinal y prospectivo. La población de estudio la componen 164 fumadores de alto riesgo de entre 40 y 76 años de edad. Se estudiaron las variables edad, sexo, peso, altura y hábito tabáquico (paquetes/año) y se realizó una espirometría según la normativa de la Sociedad Española de Neumología y Cirugía Torácica (SEPAR). Se informó de los resultados a los pacientes y se les dio consejo breve para dejar de fumar. A los 3 años se llevó a cabo una reevaluación con los mismos criterios.

RESULTADOS: En 1999 el 22% de los fumadores presentaron criterios de EPOC. Al cabo de 3 años se detectó un 16,3% de casos nuevos y el 38,8% de los ya diagnosticados empeoraron. El 44,8% de los pacientes con volumen espiratorio forzado en el primer segundo inferior al 90% evolucionó a EPOC (riesgo relativo: 10,54). El 18,1% de los pacientes presentó pérdida acelerada del volumen espiratorio forzado en el primer segundo (FEV_1) (el 20,7% sin EPOC y un 9,0% con EPOC).

El consumo de tabaco en 1999 fue de 28,1 paquetes/año de media en individuos sin EPOC y de 31,7 paquetes/año en los pacientes con EPOC. En el año 2002 el consumo fue de 30,6 y 31,9 paquetes/año, respectivamente. En el intervalo de 3 años dejó de fumar el 22,8% de los individuos (el 20,5% sin EPOC y el 30,3% con EPOC).

CONCLUSIONES: Un número considerable de fumadores consigue abandonar el hábito de fumar tras conocer sus resultados espirométricos. El FEV_1 tiene una buena capacidad predictiva para identificar a los fumadores con mayor riesgo de evolucionar a EPOC. El cribado y el seguimiento, mediante espirometría, de fumadores de alto riesgo en atención primaria permite identificar a los más susceptibles de evolucionar a EPOC en una fase temprana y así establecer la estrategia de abordaje más adecuada para cada paciente.

Palabras clave: *Fumadores susceptibles. Enfermedad pulmonar obstructiva crónica. Grupo de alto riesgo. Espirometría.*
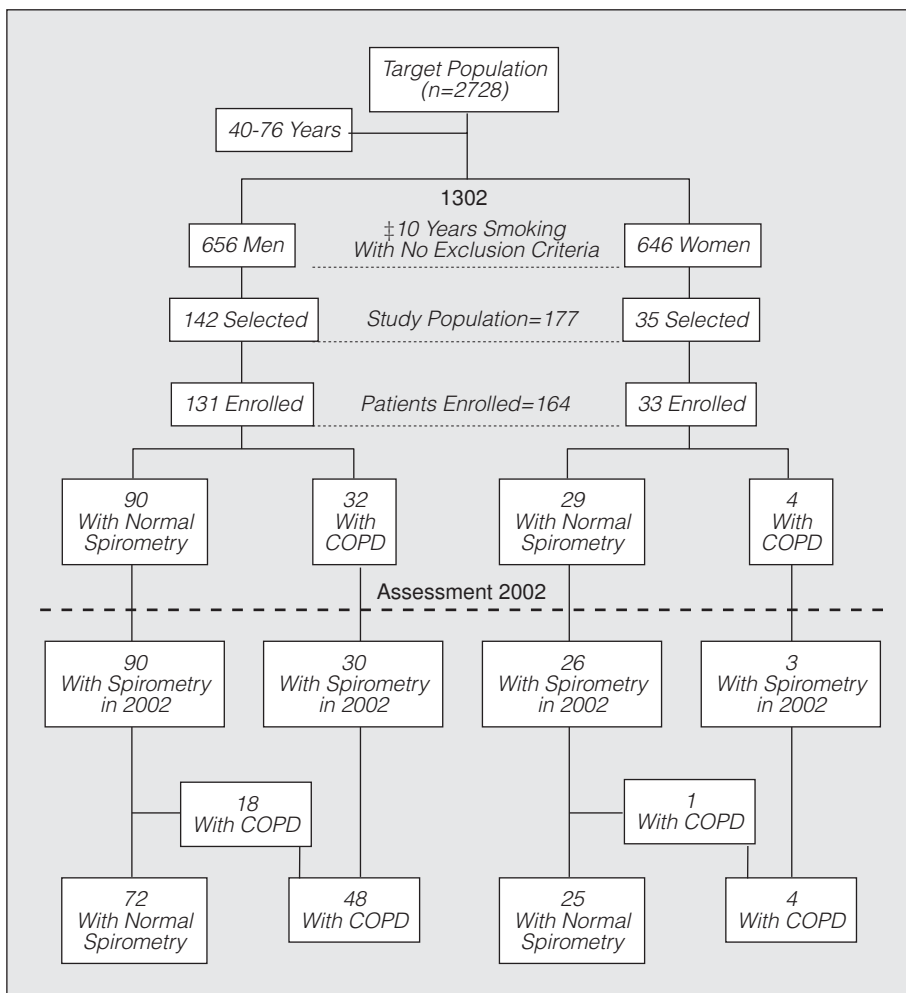
Figure 1. Patient disposition, characteristics, spirometry results, and disease progression during the study period. COPD indicates chronic obstructive pulmonary disease.

Introduction

Chronic obstructive pulmonary disease (COPD) is defined as slow, generally irreversible limitation of airflow. The disease is usually associated with smoking[1] and it is highly prevalent in Spain.[2]

The Lung Health Study showed that COPD could be detected early by spirometry and confirmed that cessation of smoking can have a positive effect on the course of the disease.[3]

Symptoms of COPD are hardly noticeable during the initial phase so few patients take the initiative to visit their physician for spirometric diagnosis.[4] Given that spirometric testing of the entire population has been shown to be inefficient,[5] there is a need to identify high risk groups to improve the yield of testing, both at screening and during follow up.

Important studies have shown that screening of populations at risk for COPD is an effective method for early detection[3,4,6] but few studies have monitored asymptomatic high-risk patients by spirometry, particularly in rural settings.

This study was designed to analyze the effectiveness of a spirometry screening program in early detection and monitoring of the course of COPD in high-risk smokers in a rural primary health care practice over a 3-year period. With this information, we can evaluate the importance and need for extensive use of such screening programs in ordinary clinical practice.

The objectives were to determine the incidence of COPD and its course in patients diagnosed with the disease; to identify the variables associated with the likelihood of progression to COPD; and to determine the effect on how heavily the patients smoke and whether the result from the spirometry test induced them to stop smoking.

Patients and Methods

Patients

In January 1999, we selected patients who had been active smokers for at least 10 years aged 40 to 76 years with no respiratory symptoms or mild ones from a rural village of 2728 inhabitants (Figure 1). Patients with a previous

diagnosis of COPD or asthma, bronchiectasias, cystic fibrosis, tuberculosis or simple chronic bronchitis, restrictive pulmonary diseases (severe kyphoscoliosis, neuromuscular diseases), and patients receiving bronchodilator treatment were excluded from the study.

The total population who met the inclusion criteria comprised 177 subjects (142 men and 35 women). An appointment was made with these patients during the first half of 1999 and 164 were evaluated (131 men and 33 women).

Intervention

The inclusion and exclusion criteria were confirmed, and possible persistent respiratory symptoms such as cough, expectoration, and dyspnea were investigated. Patients with such symptoms were excluded from the study. The age, sex, weight, height, smoking habit, and cigarette consumption in pack-years (number of cigarettes per day×years smoking/20) were recorded. Patients were instructed in the forced spirometry technique. Spirometry parameters were recorded with the DATOSPIR 100 spirometer (Síbelmed, Síbel, S.A., Barcelona) according to the guidelines of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR).[7]

Regardless of the results of spirometry, the intervention consisted of discussing with the patient the spirometric findings with reference to patients of similar characteristics. The natural course of the disease and its possible consequences were inferred from the smoking habit of the patient by means of a modified Fletcher and Peto curve, in which forced expiratory volume in 1 second (FEV_1) is expressed as a percentage of the predicted value. The need to stop smoking was then expressed clearly, emphatically, and concisely (known as minimal intervention).[1] The response of the patient defined his or her attitude to stopping smoking as precontemplation, contemplation, preparation, or action.

COPD was diagnosed according to the most widely accepted criteria, that is, $FEV_1 < 80\%$ of predicted and FEV_1/forced vital capacity <70%.

The severity of COPD was determined according to the criteria of the European Respiratory Society:[8] mild for $FEV_1 \geq 70\%$; moderate for FEV_1 between 50 and 69%; and severe for $FEV_1 < 50\%$.

A new appointment during the first half of 2002 was made with the patients to perform another spirometric test with the same spirometer, the same guidelines, and the same criteria for diagnosis of severity. Age, sex, weight, height, smoking habit, and cigarette consumption (pack-years) were recorded for the 149 subjects who attended. A subject was considered to have stopped smoking if he or she had gone 6 months before the second visit without smoking. A decrease of 12 percentage points or more in FEV_1 with respect to the predicted reference value of FEV_1 in 1999 (equivalent to 150 mL/year) was considered an accelerated loss of capacity.

TABLE
Logistic Regression Model to Determine Variables Predictive of Progression to Chronic Obstructive Pulmonary Disease

Variable	Regression Coefficient	P	RR
Sex	−1.36	.22	0.25
Age, <50/≥50 years	−0.24	.68	0.79
Pack-years in 1999	−0.02	.19	0.98
FEV_1	−0.14	.001	0.86

FEV_1 indicates forced expiratory volume in 1 second; RR, relative risk.
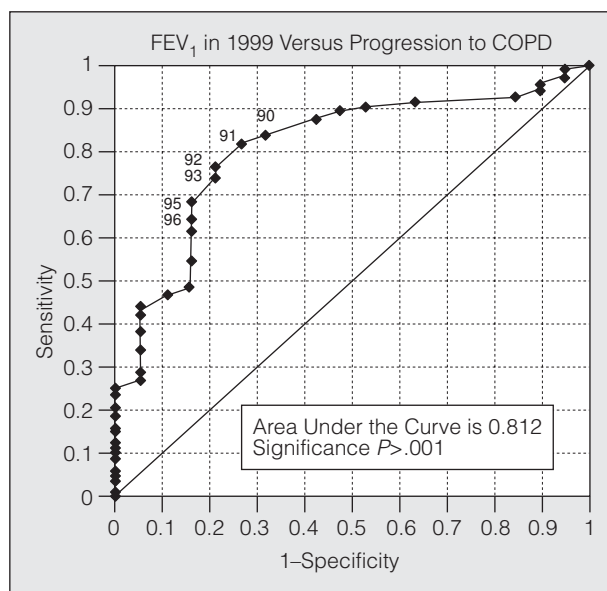

Figure 2. Receiver operating characteristics curve constructed from a multiple logistic regression model to predict risk of progression to chronic obstructive pulmonary disease (COPD). FEV_1 indicates forced expiratory voltme in 1 second.

Statistical Analysis

Age, sex, smoking habit, and spirometry results were presented descriptively. Proportions were compared with the χ^2 and McNemar tests and, when necessary, the Fisher exact test for repeated measurements was applied. Means were compared with the Student t test, the Fisher test for repeated measurements, or the Wilcoxon t test. Multivariate analysis was performed by logistic regression to assess risk of progression to COPD. The receiver operating characteristics (ROC) curves were calculated with this model. Statistical significance was set at .05 for all tests. Data were analyzed with the SPSS statistics package, version 11.0.

Results

Characteristics of the Study Population

Of the 164 subjects evaluated in 1999, 36 (22.0%) had abnormal spirometry.

In 2002, 149 subjects were studied with a mean (SD) age of 54 (9.2) years (men 55 [9.5] years; women 48 [4.4] years).

Thirty-three of the patients (22.1%) with COPD in 1999 were re-evaluated at 3 years. Of these, COPD was considered mild in 18 patients (54.5%), moderate in 13 patients (39.4%), and severe in 2 patients (6.1%).

In 2002, 19 new cases of COPD were identified (16.4%), of which 18 were mild (95.0%). Furthermore, of the 18 patients with mild COPD in 1997, 7 (38.8%) progressed to moderate disease. No patient with moderate COPD progressed to severe disease.

A logistic regression model was developed to predict progression of COPD, with sex, age (<50 or ≥50 years), pack-years, and FEV_1 in 1999 as independent variables.

In this regression analysis, only FEV_1 was independently associated with lower risk of progression of COPD (regression coefficient, –0.143; P=.001; relative risk [RR], 0.866; Table); that is, patients with high FEV_1 in 1999 had a lower risk of progression of COPD after 3 years. A ROC curve constructed with this model encompassed 81.2% of the area under curve (Figure 2). Thus, 44.8% of patients with FEV_1 less than 90% in 1999 progressed to COPD (RR, 10.5), 10% of patients with FEV_1 between 90 and 99% in 1999 did so (RR, 2.3), and 4.2% of the patients with FEV_1 above 99% in 1999 progressed to disease (reference group).

Twenty-seven patients (18.1%) had accelerated loss of FEV_1. In 1999, 24 (20.7%) of these had normal spirometry parameters whereas 3 (9.0%) had already been diagnosed with COPD. The decline was significantly worse in men with FEV_1 above 99% in 1999 (RR, 2.18; P=.017).

Patients with normal spirometry parameters had smoked a mean 28.1 (23.2) pack-years in 1999 and 30.6 (25.5) pack-years in 2002. Patients with impaired spirometry had smoked 31.7 (26.6) pack-years in 1999 and 31.9 (25.0) pack-years in 2002. The number of cigarettes smoked did not differ significantly between patients with normal spirometry and those with impaired spirometry or between the two study periods.

Thirty-four subjects (22.8%) gave up smoking between 1999 and 2002 (31 men [25.8%] and 3 women [10.3%]). Ten of these subjects—all men (33% of male population)—had COPD in 1999 (30.3%). The remaining 24 subjects (20.5%) with normal spirometry in 1999 comprised 21 men (23.2% of all men) and 3 women (11.5% of all women). We found no differences among groups in the proportion of subjects who gave up smoking.

Discussion

COPD is of great clinical importance, though its causes remain unknown. Primary health care clinics should consider early diagnosis as standard practice despite limited availability and operational difficulties of spirometry measurement devices.[2,4]

The study was designed to reflect real conditions in primary health care. The population size was limited to facilitate follow up.

The onset and presentation of COPD in clinical practice is usually undetected because symptoms are either mild or there are no symptoms, therefore we chose asymptomatic patients as our patient population to better emulate the conditions in primary health care.[1]

The proportion of patients with early COPD in 1999—22%—was similar to figures reported by other authors.[4,6] At 3 years, 16% of these were mild new cases, indicating that they had been diagnosed in an early phase. A third of the newly diagnosed patients progressed from mild to moderate disease, in contrast to similar observational studies.[3,5,9] This can be attributed to differences in the study population, the intervention, follow-up period, and the criteria used for assessing severity of COPD.

Forced expiratory volume in 1 second has been shown to be predictive of progression to COPD, such that this parameter can be monitored to identify the population at risk of progression to COPD and increase the yield of subsequent screening. Given that time is limited in primary health care, selective detection of COPD would favor widespread implementation of screening programs, as indicated by other authors.[5,6]

Classification of COPD into different degrees of severity facilitates communication between health professionals, ensures of uniformity of criteria, and helps in therapeutic decision making, but cannot indicate the risk of progression.[7] In contrast, serial measurement of the decrease in FEV_1 by spirometry can detect the rate of progression towards obstruction, whatever the initial condition of the patient.[1,3,9] However, decline in lung function does not occur at the same rate for all smokers. Most show a decrease in FEV_1 of between 45 and 60 mL/year, but some susceptible patients (between 15% and 20%) may show decreases between 50 and 200 mL/year.[1,8]

The decrease in FEV_1 is normally expressed in mL/year, but FEV_1 can also be expressed as percentage of the predicted reference value. The choice of units is empirical and arbitrary, but we expressed FEV_1 as a percentage of the predicted value for practical reasons. To help compare the two scales, for a patient who starts with FEV_1 18% below the predicted value, a decrease in FEV_1 of 12 percentage points would correspond to an absolute loss of approximately 150 mL/year. This implies that some of our smokers had a substantial loss in FEV_1, apparent mainly in those with normal spirometry at the beginning of the study. This may partly be because decrease in FEV_1 is more rapid in the initial phases of COPD, whereas in advanced phases the decrease is slower. Our patients had predominantly normal spirometry and early COPD at the start of the study.

Cigarette consumption varies from patient to patient because of the way we define a smoker, but mean consumption is no different to similar studies.[6] The relationship between smoking habit and COPD is well established,[3] but an actual dose-dependent relationship between the number of cigarettes smoked and development of COPD has not been found.

The present study showed no relationship between the number of pack-years and diagnosis of COPD, though patients who developed COPD had a somewhat higher consumption. The heaviest smokers might already have been diagnosed, in which case they would have been excluded from the study. Alternatively, the susceptibility of progression to COPD may vary among smokers such that the most susceptible subjects progress to COPD whereas the insusceptible subjects would tolerate relatively large numbers of cigarettes without showing any substantial negative effect on spirometry. Overall, cigarette consumption in smokers with and without COPD would therefore be similar.

The National Lung Health Education Program for prevention of COPD in the United States has a slogan which reads, "Test your lungs, know your numbers." The validity of this slogan is supported by studies that show that patients diagnosed with obstruction are more motivated to stop smoking.[5,10] Among our patients, a third of those diagnosed with COPD stopped smoking after 3 years, regardless of age or sex. The proportion of patients with normal spirometry who stopped smoking was slightly higher, though the difference was not statistically significant, perhaps because of the small sample size. These results are probably influenced by how strongly the advice to stop smoking is given to the different groups. Indeed, smokers diagnosed with COPD usually receive more insistent advice to stop smoking. In any case, spirometry results may help not only patients with COPD but smokers in general to stop smoking.

Smokers are usually reluctant to give up smoking, so the substantial number of smokers who quit irrespective of whether they had COPD or normal spirometry contradicts suggestions that normal spirometry results might encourage the smoker to continue smoking.

Our results therefore indicate that screening for COPD is feasible in primary healthy care provided the necessary infrastructure is available such as a spirometer, staff qualified in handling the spirometry apparatus that have time in their work schedules, and a laboratory for performing the measurements. Moreover, FEV_1 is good at predicting smokers at greater risk of progression to COPD and measurement of the decrease in FEV_1 can identify smokers with accelerated progress to greater obstruction, regardless of their initial state.

In view of our results, we suggest the creation of a Spanish working group of primary health care professionals and pneumologists to set standard guidelines for screening and evaluation of COPD. Such a group could be modeled on The Primary Health Care Diabetes Study Group (abbreviated in Spanish as GEDAPS) for type 2 diabetes.

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