Population-Based Study on the Prevalence of Spirometric Obstructive Pattern in Porto, Portugal

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BACKGROUND: The diagnosis of obstructive lung disease (OLD) based on clinical grounds is challenging. There have been no population-based COPD studies that collected pulmonary function data in Portugal, a country in transition between phases 2 and 3 of the smoking epidemic. OBJECTIVE: To estimate the prevalence of obstructive pattern on spirometry in a representative sample of adults from Porto, Portugal. METHODS: We conducted a health survey between 2001 and 2003, and 758 participants ≥ 40 years old had reliable spirometry. We used a structured questionnaire to collect demographic, clinical, social, and behavioral data. Obstructive pattern was defined as FEV_1/FVC < 70%. Logistic regression was performed to quantify the association between socio-demographic and clinical factors and outcome. RESULTS: The participants' mean ± SD age was 58.5 ± 11.5 years, and 62% were women. The prevalence of spirometric obstructive pattern was 10.7%, 95% CI 8.6–13.1%; 13.4% in men, and 9.1% in women (*P* = .08). The age-adjusted odds ratios for cumulative smoking exposure of less than and more than 20 pack years, in comparison with never smokers, were 3.49 (95% CI 1.02–11.92) and 3.91 (95% CI 1.29–11.89) among men, and 1.47 (95% CI 0.53–4.08) and 2.68 (95% CI 1.07–6.68) among women, respectively. Previously diagnosed OLD was reported by 30.9% (95% CI 21.1–42.1%) of the participants with spirometric obstructive pattern. Spirometry confirmed the OLD diagnosis in 20.5% (95% CI 13.7–28.7%) of subjects who self-reported OLD (kappa = 0.14, 95% CI 0.07–0.20). CONCLUSIONS: The prevalence of spirometric obstructive pattern was high. Considering Portugal's position in the smoking epidemic, together with the aging of the population, we can expect an increase in the prevalence of OLD in older people and in women. Our results confirm the limited validity of self-reported OLD in epidemiological studies. *Key words: OLD; prevalence; population; spirometry.*
[Respir Care 2011;56(5):619–625. © 2011 Daedalus Enterprises]

Introduction

COPD is a major and growing cause of morbidity and mortality worldwide,[1,2] accounting for an enormous economic and social burden.[3] Despite the publication of guidelines on COPD prevention and management,[1,4,5] the burden of the disease is increasing as the world population ages.[1] In 2001 COPD was the fifth leading cause of death in the world, and it is predicted to be third by 2020.[2,6] A recent European survey suggested that even young adults

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This research was partly supported by Fundação para a Ciência e a Tecnologia grant POCTI/SAU-ESP/61492/2004.

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DOI: 10.4187/respcare.00698

already suffer from COPD.[7] Cigarette smoking is the most claimed risk factor and remains a widespread habit.[8]

COPD is a heterogeneous process with different phenotypes.[8,9] Several imprecise definitions have been proposed, and various diagnostic criteria have been applied in different studies, which impairs the comparison of prevalence estimates derived from different populations. Depending on the definition, the reported prevalence has differed by more than 15%. Self-reported and symptom-based COPD diagnosis have had the lowest and the highest estimates, respectively.[10] COPD is under-diagnosed, and the prevalence estimates probably underestimate the true burden.[3,10] Spirometry-based classification of air-flow limitation and disease severity according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria is gaining acceptance and is being used in epidemiological studies, because it provides objective measurement of lung function.[1] The GOLD criteria are based on post-bronchodilator measurements. Recently, two multinational investigations conducted to provide more accurate estimates of the overall prevalence of COPD and its risk factors found a higher than previously reported prevalence.[11,12] Despite the use of standardized methods, estimates of COPD prevalence have been highly variable across populations. Several other population-based studies reported pre-bronchodilator spirometry, aiming to quantify airway obstruction.[7,13-15]

In Portugal, the burden of COPD is high. According to the 2002 World Health Organization, the age-standardized death rate for COPD was 13.4 per 100,000 (2,600 deaths).[16] However, reliable data regarding the prevalence of objectively documented obstructive lung disease (OLD) are lacking.

We aimed to measure the prevalence of obstructive pattern on spirometry, defined as an $FEV_1/FVC < 70\%$, by age, sex, and smoking status in a representative sample of non-institutionalized adults ≥ 40 years old, in Porto, Portugal. We also determined the prevalence of self-reported OLD in subjects with and without obstruction.

Methods

This study was performed in the Serviço de Higiene e Epidemiologia, Faculdade de Medicina da Universidade do Porto, Porto, Portugal. The study was approved by our local ethics committee, and all participants provided written informed consent.

This was a population-based health and nutrition survey of adult residents in Porto, Portugal, which is the second largest Portuguese city: the resident population was 216,080 in 2001. It is urban, with few green areas, and large industrial areas in the surroundings. The survey was conducted between 1999 and 2003. Households were selected by random digit dialing. In each household, one eligible subject older than 18 years was randomly selected. Substitution of refusals was not allowed in the same household. The participation rate was 70%.[17]

Among the 2,485 members of the cohort, we evaluated a subsample of 2,003 subjects ≥ 40 years old to measure the prevalence of obstructive pattern. We performed spirometry in 878 subjects recruited from June 2001 to December 2003. Among the remaining participants, we evaluated 1,125 before June 2001, when spirometry was not available, and 106 (5.3%) did not complete the test for reasons that were not registered. Fourteen subjects (1.4%) were excluded from the analysis because the spirometry results were considered unacceptable by the physician who assessed and validated the spirometry.

We used a structured questionnaire, administered by trained interviewers, to collect social, demographic, behavioral, and clinical data. Education was registered as completed years of schooling, and subsequently divided into categories: < 5 years, 5–11 years, and > 11 years. Body weight was measured to the nearest 0.1 kg with a digital scale, and height was measured to the nearest centimeter with a wall stadiometer. We categorized body mass index into the categories defined by the World Health Organization: ≤ 24.9 kg/m^2, 25.0–29.9 kg/m^2, and ≥ 30 kg/m^2.[18]

We asked the subjects about previous diagnoses of any respiratory diseases and use of β_2 agonists (Anatomical Therapeutic Classification codes R03AC and R03AK), and/or anticholinergics (Anatomical Therapeutic Classification code R03BB) during the previous 12 months. We also asked about smoking history, current smoking status, number of cigarettes smoked, and age at smoking initiation. Ex-smokers were also asked about the number of smoking years. Participants were classified as current, never, or ex-smokers. Current smokers included both daily (at least one cigarette per day at the time of the survey) and occasional smokers. Ex-smokers were former smokers who had not smoked for at least 6 months. Lifetime cumulative smoking exposure, expressed in pack years, was defined as the number of cigarettes smoked per day divided by 20 and multiplied by the number of years that the participant smoked.

Spirometry was performed using a portable spirometer (Spirolab II, Medical International Research, Waukesha, Wisconsin), a device approved by the Food and Drug Administration and certified by the American Thoracic Society.[19] The spirometer was regularly calibrated, cleaned, and maintained according to the manufacturer's instructions. The measurement accuracy was ± 3% or 50 mL for volume, and ± 5% or 200 mL/s for flow. Measurements were considered reproducible if repeated observations differed < 5% or < 200 mL for FVC and < 5% or < 100 mL for FEV_1. We used the American Thoracic Society and European Respiratory Society acceptability criteria.[20] We used the European Respiratory Society predicted values as the reference standard.[21] The interviewers who performed the tests were not professionally qualified technicians in the area of respiratory disease; however, all the interviewers had been trained by an experienced respiratory physician (HF) on how to use the spirometer, and provided with selected bibliography support and periodic repeat training. During spirometry, all subjects were standing and had a clip on the nose. We recorded the flow-volume trace in all the spirometries, and each spirometry session had at least 3 attempts to obtain reproducible results, according to the American Thoracic Society and European Respiratory Society criteria.[20] All spirometry results were assessed and validated by an experienced respiratory physician (HF), who selected the best test for analysis. Based on the GOLD spirometry criteria for COPD,[1] we defined an obstructive pattern as a pre-bronchodilator $FEV_1/FVC < 70\%$. Our obstruction severity classification was:

- Mild: $FEV_1 \geq 80\%$ of predicted
- Moderate: FEV_1 50–80% of predicted
- Severe: FEV_1 30–50% of predicted
- Very severe: $FEV_1 < 30\%$ of predicted

Previously diagnosed OLD was self-reported.

Table 1. Baseline Characteristics Relative to Availability of Spirometry Results*

	Spirometry Available (n = 758)	Spirometry Unavailable (n = 1,245)	P
Age (mean ± SD y)	58.5 ± 11.5	58.4 ± 11.5	.92
Men, no. (%)	284 (37.5)	481 (38.6)	.60
Women, no. (%)	474 (62.5)	764 (61.4)	
Education, no. (%)			
≤ 4 y	347 (45.8)	604 (48.5)	.42
5–11 y	227 (29.9)	365 (29.3)	
≥ 12 y	184 (24.3)	276 (22.2)	
Body Mass Index, no. (%)			
< 25.0 kg/m^2	215 (27.5)	396 (32.6)	.12
25.0–29.9 kg/m^2	338 (44.6)	521 (43.0)	
≥ 30 kg/m^2	204 (26.9)	296 (24.4)	
Smoking Status, no. (%)			
Never smoker	434 (58.9)	690 (57.3)	.52
Ex-smoker	171 (23.2)	273 (22.7)	
Current smoker	132 (17.9)	241 (20.0)	
Smoking History, no. (%)			
Never smoker	434 (58.6)	690 (57.2)	.46
0–20 pack years	126 (17.0)	232 (19.2)	
≥ 20 pack years	181 (24.4)	284 (23.5)	

* Counts may not add up to the totals because of missing data.

Statistical Analysis

We analyzed the data with statistics software (SPSS, SPSS, Chicago, Illinois). We present quantitative variables as mean ± SD, and categorical variables as counts and proportions. We used the Student *t* test for normally distributed continuous variables, and chi-square for proportions. A significance level of .05 was used. Logistic regression was used to identify predictors of spirometric obstructive pattern. Variables significantly associated with the outcome in univariate analysis were considered in a multivariate model. Education was excluded because it did not affect outcome or have a confounding effect on other variables. Smoking status and cumulative exposure are highly collinear, so only smoking cumulative exposure was included, as it conveys dose information. We express the associations as odds ratios and 95% CI. We assessed the agreement between spirometric obstructive pattern and self-reported previous diagnosis of OLD with the kappa coefficient and its 95% CI.

Results

Seven-hundred fifty-eight subjects had reliable spirometry results available. The distribution of these subjects by age, sex, education, body mass index, and smoking status/history was similar to that of the 1,245 participants older than 40 years who did not have reliable spirometry results available.(Table 1).

Table 2 shows the baseline characteristics of the subjects who had reliable spirometry results available, relative to sex. Sixty-two percent were women, and the mean ± SD age 58.5 ± 11.5 years. The prevalence of current or former smoking was significantly higher in the men (73.4% versus 21.6%, $P < .001$), among whom 50.2% reported a cumulative smoking exposure of ≥ 20 pack years (see Table 2). Younger age was associated with current or former smoking exposure in women (27.5% vs 12.9% in women younger and older than 60 years, respectively, $P < .001$). Among men, smoking did not correlate significantly with age.

The overall prevalence of spirometric obstructive pattern was 10.7% (95% CI 8.6–13.1), and was similar in men and women (13.4% vs 9.1%, $P = .08$). The majority of participants with obstructive pattern (76 of 81, 93.8%) had at least moderate obstruction (Table 3). Only 5 subjects (all women) had mild obstruction, among whom none self-reported OLD. The prevalence of moderate to very severe obstruction was significantly higher among men (13.4 vs 8.0%, $P = .02$). Among the 31 included participants who were using bronchodilators, 9 met the criteria for spirometric obstructive pattern and 22 did not.

As shown in Table 4, the prevalence of spirometric obstructive pattern increased with age and smoking in both

Table 2. Baseline Characteristics of the Subjects Who Had Reliable Spirometry Results Available, Relative to Sex*

	Men (n = 284)	Women (n = 474)	P
Age, no. (%)			
40–59 y	146 (51.4)	274 (57.8)	.10
≥ 60 y	138 (48.6)	200 (42.2)	
Education, no. (%)			
≤ 4 y	110 (38.7)	237 (50.0)	.009
5–11 y	99 (34.9)	128 (27.0)	
≥ 12 y	75 (26.4)	109 (23.0)	
Body mass index (kg/m^2)	27.0 ± 3.8	28.1 ± 5.0	< .001
Body Mass Index, no. (%)			
< 25 kg/m^2	86 (30.3)	129 (27.3)	.004
25.0–29.9 kg/m^2	141 (49.6)	197 (41.6)	
≥ 30 kg/m^2	57 (20.1)	147 (31.1)	
Smoking Status, no. (%)			
Never smoker	74 (26.6)	360 (78.4)	< .001
Ex-smoker	131 (47.1)	40 (8.7)	
Current Smoker	73 (26.3)	59 (12.9)	
Smoking History, no. (%)			
Never smoker	74 (27.1)	360 (78.8)	< .001
0–20 pack years	62 (22.7)	53 (11.6)	
≥ 20 pack years	137 (50.2)	44 (9.6)	
FEV_1 (L)	2.90 ± 0.85	2.14 ± 0.57	< .001
FVC (L)	3.56 ± 0.92	2.57 ± 0.66	< .001
FEV_1/FVC (%)	81.1 ± 11.2	83.9 ± 10.9	.001

± values are mean ± SD.
* Counts may not add up to the totals because of missing data.

Table 3. Obstruction Severity Relative to Sex

	Men (n = 284) no. (%)	Women (n = 474) no. (%)
Obstruction	38 (13.4)	43 (9.1)
Obstruction Severity		
Mild	0 (0)	5 (1.1)
Moderate	33 (11.6)	31 (6.5)
Severe	3 (1.1)	5 (1.1)
Very severe	2 (0.7)	2 (0.4)

sexes, although these associations were not significant among women. Obstruction decreased with education in men. Among them, the age-adjusted odds ratio was 3.49 (95% CI 1.02–11.92) and 3.91 (95% CI 1.29–11.89) for cumulative smoking exposure less than and more than 20 pack years, respectively, in comparison with never smokers. Among the women those odds ratio were 1.47 (95% CI 0.53–4.08) and 2.68 (95% CI 1.07–6.68), respectively (see Table 4).

Among the 81 subjects who met spirometric criteria for obstruction, only 30.9% (95% CI 21.1–42.1) reported a previous diagnosis of OLD. Spirometry data confirmed the diagnosis of OLD in 20.5% (95% CI 13.7–28.7) of subjects who self-reported the disease. The agreement between spirometric obstructive pattern and self-reported previous diagnosis of OLD was low (kappa 0.14, 95% CI 0.07–0.20). The sensitivity and specificity of self-reported OLD to predict spirometric obstructive pattern were 30.9% (95% CI 21.1–42.1) and 85.7% (95% CI 82.8–88.2), respectively.

Discussion

To our knowledge, this is the first population-based study to quantify the prevalence of physiologically defined OLD in Portugal. 10.7% of adults older than 40 years had spirometric obstructive pattern as defined by a pre-bronchodilator FEV_1/FVC < 70%. We observed a particularly high prevalence of obstruction in older men with smoking history. We also found discrepant results between self-reported previous diagnosis of OLD and objective evidence of lung function impairment, which underlines the impact of OLD definition on prevalence estimates.

The diagnosis of COPD based on clinical grounds can be challenging. Not only are signs and symptoms nonspecific, but patients, especially smokers, frequently underestimate and do not report their symptoms.[13,22] Additionally, air-flow limitation can remain asymptomatic until moderate or even severe obstruction is established, which may hinder patients from seeking medical attention. In the symptomatic patients, complaints, particularly dyspnea and fatigue, are frequently attributable to non-respiratory and non-cardiovascular reasons, but rather to sex, age, deconditioning, and psychological factors.[23] That fact conforms with our finding of poor agreement between objectively measured obstruction and self-report of a previous diagnosis of OLD.

In view of this result, the adequacy of using self-reported OLD diagnosis in epidemiological studies should be questioned. Moreover, relying only on objective spirometry data allows having more reliable criteria, which can also be more easily compared with other populations. For maximum accuracy we adopted a definition based on objective measurements of respiratory function. We found an overall prevalence of spirometric obstructive pattern of 10.7% (13.4% in men and 9.1% in women), which is similar to the COPD prevalence as defined by the GOLD guidelines, reported in multicenter survey in Spain,[24] and in line with other recent studies of COPD prevalence, that used both pre-bronchodilator and post-bronchodilator spirometry.[14,25,26] Notwithstanding, comparisons of our estimates to those of other studies should be made carefully, since differences can be explained by the heterogenity of the case definition, namely, whether or not post-bronchodilator data were used, or whether or not cases were defined by distinct population demography.

Table 4. Odds Ratios for the Associations Between the Measured Variables and Obstruction Relative to Sex*

	Men			Women		
	Obstruction no. (%)	Crude Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)	Obstruction no. (%)	Crude Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)
Age						
40–59 y	11 (7.5)	1	1	20 (7.3)	1	1
≥ 60 y	27 (19.6)	2.98 (1.42–6.29)	3.20 (1.50–6.81)	23 (11.9)	1.64 (0.88–3.08)	1.77 (0.90–3.48)
Education						
≤ 4 y	18 (16.4)	1	NA	24 (10.2)	1	NA
5–11 y	16 (16.2)	0.98 (0.47–2.06)		8 (6.3)	0.59 (0.26–1.35)	
≥ 12 y	4 (5.3)	0.29 (0.09–0.89)		11 (10.1)	0.98 (0.47–2.10)	
Smoking Status						
Never	4 (5.4)	1	NA	27 (7.5)	1	NA
Current/former	34 (16.7)	3.50 (1.20–10.23)		13 (13.3)	1.89 (0.93–3.81)	
Smoking History						
Never	4 (5.4)	1	1	27 (7.5)	1	1
0–20 pack years	10 (16.1)	3.36 (1.00–11.33)	3.49 (1.02–11.92)	5 (9.4)	1.28 (0.47–3.50)	1.47 (0.53–4.08)
≥ 20 pack years	24 (17.5)	3.72 (1.24–11.16)	3.91 (1.29–11.89)	7 (16.3)	2.40 (0.98–5.90)	2.68 (1.07–6.68)

* The final multivariate model included age and cumulative smoking exposure.
NA = not applicable

There are several comorbidities traditionally associated with aging. The International Variation in the Prevalence of COPD (BOLD) study confirmed the importance of age as a powerful contributing factor to COPD.[11] We found similar results; age was an independent predictor of spirometric obstructive pattern in men. This can be explained by the progressive nature of the disease or, alternatively, by inaccurate COPD diagnosis in the elderly. As there is a normal age-related decline of lung function,[27] using a fixed FEV_1/FVC threshold of 70%, although it is a pragmatic approach, may lead to over-diagnosis of COPD in the elderly.[15,28-30] According to some authors, post-bronchodilator GOLD stage II is a practical threshold for identifying clinically relevant disease.[31] Given the fact that, in our sample, the majority of participants had moderate or higher obstruction, it is unlikely that prevalence of obstructive pattern was overestimated due to misclassification of healthy elderly individuals as having obstruction. We restricted our analysis to individuals older than 40 years not only because the expected prevalence was very low in younger people but also because it was the age threshold applied in the BOLD study.[11]

Besides the age distribution of the population, patterns of exposure to known COPD risk factors, namely, smoking,[32] explain much of the difference in COPD prevalence around the world.[11] The smoking epidemic can be described according to 4 stages[33]:

- Stage 1: Smoking is characteristic of the advantaged classes but is an otherwise unusual habit.
- Stage 2: Prevalence increases among men in all social classes, whereas in women smoking is adopted by the upper social classes with a lag of 10–20 years.
- Stage 3: Smoking prevalence peaks in women at the same time as there is a quick decline in men.
- Stage 4: The epidemic declines in both sexes, but smoking becomes more prevalent in the lower social classes.

Contrasting with the decline in smoking habits among men in most European countries,[33] previous studies have placed Portugal at an earlier stage (transition between stage 2 and 3) of the smoking epidemic, the prevalence being higher in men and in more educated women.[34-36] Additionally, there is an increasing body of evidence supporting the existence of sex differences in genetic susceptibility to air-flow obstruction and COPD.[35,36] Albeit the results are controversial, women seem to be more predisposed to early-onset and to non-smoking-related COPD.[35] These facts, taken together with the aging of the Portuguese population, lead us to anticipate an increase in OLD prevalence in older people and in women in the coming years.

As expected, the prevalence of spirometric obstructive pattern was higher among current or former smokers, and there was a dose-response relationship with cumulative lifetime exposure. The strength of this association was similar in men and women, and the small differences in the odds ratios were attributable to lower statistical power among women because of the small number of female smokers in our sample.

Outdoor air pollution is associated with higher morbidity and mortality in COPD patients.[37,38] Its role as a risk factor for the development of COPD remains controversial.[39,40] Pollutants claimed as potentially harmful are particulate matter with aerodynamic diameter $< 10\ \mu m$ (PM_{10}), sulfur dioxide, nitrogen dioxide, carbon monoxide, and ozone. Porto is an urban city with few green areas. According to official reports, the air pollution level, particularly the PM_{10}, is out of proportion to the rest of Portugal.[41,42] We did not investigate the potential association between the prevalence of spirometric obstructive changes and air pollution. Although we cannot exclude the possibility that the air pollution might have contributed to the relatively high OLD prevalence that we found, it was probably not the most important factor. In fact, according to the World Health Organization, urban air pollution causes 1–2% of COPD cases, and the risk attributable to outdoor air pollutants in the development of COPD is small when compared to cigarette smoking and indoor air pollution.[9]

Limitations

A major limitation of our study is that we did not conduct post-bronchodilator spirometry, which COPD guidelines recommend to identify obstruction,[43] as there is evidence that 20–30% of individuals classified as "obstructed" from pre-bronchodilator spirometry meet the criteria for reversibility. Thus, in our sample we cannot guarantee that some of the subjects with obstructive pattern might have had reversible obstruction. Aware of the inadequacy of diagnosing COPD without post-bronchodilator data, and to avoid classifying asthma patients as COPD patients, we only estimated the prevalence of objective pre-bronchodilator obstruction. Also, we cannot be sure that the 22 subjects who were taking bronchodilators and did not demonstrate spirometric obstruction had completely reversible obstruction. However, if we had excluded these subjects, the prevalence of spirometric obstructive pattern would be essentially unchanged.

Considering the decreased reproducibility of spirometry results with increasing severity of lung disease,[44] the exclusion of nonreproducible tests can lead to underestimation of spirometric obstructive pattern prevalence, because subjects who meet the obstruction criteria are more likely to be selectively excluded.[22]

It is unlikely that a selection bias occurred, since only 758 out of the 2,003 participants aged $\geq$ 40 years completed spirometry testing. The subsample used in this analysis was representative of the whole study sample surveyed in the characteristics of interest.

Another potential source of bias could be technical issues in the collection of spirometric data, because the quality of the spirometry can affect the assignment of obstructive pattern. The spirometry in our study was not performed by professionally qualified technicians; however, the spirometry operators were trained, we used strict quality control methods, and the spirometer we used is accurate and its measurements are reproducible. The measurements made by different types of spirometers cannot be used interchangeably.[45] An advantage of our study was that the same portable spirometer was used with all participants.

We did not systematically screen for respiratory tract infection. Nevertheless, given that these infections are in general acute and short-lived, we expect their point prevalence at any time to be low.

Conclusions

There is a high prevalence of spirometric obstructive pattern in Porto, Portugal, and our findings highlight the hazard of relying on patients' self-reported diagnosis of OLD. Smoking was a strong determinant of obstruction, independently of age. In Portugal, if the smoking epidemic keeps on mirroring that of other European countries, we can anticipate an increasing burden of COPD in women. Our results should increase physician awareness of COPD and its risk factors and emphasize the importance of early detection and the search for strategies aimed at stopping COPD progression and reducing its impact on health-related quality of life. Ideally, efforts to implement preventive measures directed at smoking cessation should be continuously addressed.

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